California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Board Accreditation of a School of Pharmacy for Purposes of Issuing a California Intern Pharmacist License**

Current regulation, Title 16 CCR 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE).

The University of New England, College of Pharmacy, Portland Maine, was granted pre-candidate status by the ACPE during its June 2009 meeting and the first class of students was admitted in the Fall of 2009. The School of Pharmacy underwent review by the ACPE during *2009/10* Review Period for advancement to candidate accreditation status. The results will be available in late June, about the time of this Licensing Committee Meeting.

Recently, the University of New England School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program, but who may spend some time and work in CA. A copy of the letter from the school requesting recognition by the board is provided in the board materials. Precandidate status is a provisional status awarded to a new school of pharmacy; however it is not "approved" status. Section 1719 provides that:

> **§1719. Recognized Schools of Pharmacy.**
> As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.
> For purposes of issuing a California pharmacist intern license, the school needs to either be accredited by the ACPE or recognized by the board.

Typically pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

Attached is the request from the University of New England College of Pharmacy requesting recognition by the board.

UNE UNIVERSITY OF NEW ENGLAND
College of Pharmacy

RECEIVED BY CALIF. BOARD OF PHARMACY
2010 APR 13 AM 8:43

Office of the Dean

Portland Campus
716 Stevens Avenue
Portland, ME 04103
(207) 221-4500 T
(207) 523-1917 F

April 6, 2010

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Recognition of University of New England College of Pharmacy

Dear Ms. Herold:

I would like to take this opportunity to petition the California State Board of Pharmacy to acknowledge our College of Pharmacy so that our students can be registered as interns in the state of California.

We are a new College of Pharmacy located in Portland, Maine. We were granted Pre-Candidate status by the Accreditation Council for Pharmacy Education (ACPE) at their June 2009 meeting, thus allowing us to enroll our Inaugural Class on September 9, 2009. We have two students that wish to return to California to complete their first Introductory Pharmacy Practice Experience (IPPE) from **May 17 – June 11, 2010.**

Our program is a four year professional program which allows students to complete the Doctorate of Pharmacy degree following the successful completion of two years of pre-pharmacy requirements. This program is comprised of the following pharmacy practice experiences:

Summer following Professional Year One

Introductory Pharmacy Practice Experience - Community: Students will practice as a pharmacy intern for four weeks (160 hours) in a community setting under the supervision of a licensed pharmacist. They will learn the distribution of a drug from the prescription received to the safe administration of the drug to the correct patient. Students will also learn operational aspects with all its related issues during the experiences.

Summer following Professional Year Two

Introductory Pharmacy Practice Experience - Institutional: Students will practice as a pharmacy intern for four weeks (160 hours) in an institutional setting under the supervision of a licensed pharmacist. They will learn the distribution of a drug from the order received to the safe administration of the drug to the correct patient. Students will also learn operational and clinical aspects with all its related issues during the experiences.

Printed on 100% Post Consumer Waste

Professional Year Four

Advanced Pharmacy Practice Experiences: Starting at the completion of year three, the students will complete six rotations, each for six weeks. The required experiences will include Inpatient Acute Care, Ambulatory Care, Community and Institutional Pharmacy plus two APPE electives. Students will have the skills to integrate and apply their knowledge to real patient situations, as well as function as members of the healthcare team.

Listed below you will find the ACPE Detailed Accreditation History for the College, which was taken directly from their website (http://www.acpe-accredit.org/deans/schools.asp). As you can see, we are in the midst of the 2009-2010 Review Period for advancement to Candidate accreditation status. The ACPE site visit team will be on campus April 27, 28 and 29, 2010. The Board will announce their decision at the conclusion of their meeting in late June 2010. You may contact ACPE directly at (312) 664-3575 if further information is required.

Detailed Accreditation History

University of New England College of Pharmacy
716 Stevens Avenue
Portland, ME 40103
Douglas Kay, PhD
Dean
Tel: 207-221-4141
FAX: 207-221-1917
E-Mail: dkay@une.edu
Web Site: www.une.edu/pharmacy

Review Period	Review Type	Board Action	Status
2009-2010	Comprehensive - Advancement to candidate		
2008-2009	Comprehensive - Precandidate status	Granted	Precandidate
2008-2009	Initial Application		

We thank you and the Board of Pharmacy for your consideration of our time sensitive petition. Should you need further information or have any questions, please do not hesitate to contact my office at 207- 221-4141 or by email (dkay@une.edu).

With best regards,

Douglas H. Kay

Douglas Kay, PhD
Dean
College of Pharmacy
University of New England

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 8, 2010**

To: **Licensing Committee**

Subject: **Intern Hour Requirements**

Over the last few years, the Licensing Committee has considered proposals to amend the intern hour requirements. The committee has also discussed major changes to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. These new requirements added hours to the educational requirements students need as part of their intern training and are required as a condition for a school to maintain its accreditation status with the ACPE. Each time the committee has decided not to recommend changes to the board.

Under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California.

Additionally, board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. The remaining 600 hours must be earned under the supervision of a pharmacist and must be substantially related to the practice of pharmacy, but are not required to be earned specifically within a pharmacy. California pharmacy students typically earn these 600 "discretionary" hours for school-related experiential training (such as a clinical clerkship).

Recently, board staff received a new proposal to modify the intern hour requirements. The proposal requests that the board change the current requirements specify a minimum of 600 hours of pharmacy experience earned under the supervision of a pharmacist in a pharmacy, and to allow that the remaining 900 intern hours be accrued within a school of pharmacy. The proposal states that UCSF's current curriculum includes more than 1,000 hours of advanced pharmacy practice.

Should the committee recommend this proposal and the board vote to approve the recommendation, a regulation change would be necessary.

Following this memo are several items:

1. Proposal
2. Current regulation language
3. Overview of prior discussions related to intern hours

Modification of Intern Hours Proposal

Current Law: The California State Board of Pharmacy requires a total of 1500 Intern hours to be eligible for licensure. Of these, 600 can be in a setting that is "substantially related to the practice of pharmacy"; the remaining 900 hours must be in a pharmacy under the supervision of a pharmacist. The 600 hours is accepted as a part of the usual curriculum within a school or pharmacy (in California).

An affidavit is submitted by the Intern to the Board of Pharmacy, signed by an applicant, attesting to the fact that they have completed the required 1500 hours. While the Board may pursue an occasional audit, it is safe to say that the Board does not investigate the veracity of these affidavits.

Rationale for intern hour modification:

According to some students and faculty, there are two main reasons for exploring regulatory options:

1) Students are finding it more difficult to obtain the 900 required hours in a pharmacy. This may be due to budgetary constraints in chain or hospital practice and/or competition for intern sites (due to the addition of new pharmacy schools in California.
2) The practice of pharmacy has continued to expand beyond the four walls of a licensed pharmacy. While there should continue to be a requirement for intern experience within a licensed pharmacy, there is a need to recognize experiences in other established pharmacy practice environments.

UCSF Curriculum:

The UCSF Curriculum currently includes more than 1000 hours of advanced pharmacy practice experience that would meet the Board's criteria for hours that are "substantially related to the practice of Pharmacy". Under current law however, the students can only make use of 600 of these for licensure purposes. We assume the other California Schools of Pharmacy also meet of exceed this 1000 threshold.

Proposal:

We are proposing that the language dealing with intern hours be revised to allow 900 hours to be accrued within a school of pharmacy curriculum and a 600 hour requirement "in a pharmacy under the supervision of a pharmacist."

This modification would:

1) Diminish the student pharmacist's burden of finding licensed pharmacy sites for internship experiences.

2) Allow the schools greater flexibility in determining appropriate experiential requirements that are in line with contemporary practice; and

3) Retain a requirement for practice experience in a licensed pharmacy.

This proposal would have no impact on the Board of Pharmacy itself.

California Code of Regulations
1728. Requirements for Examination.
(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
(C) Experience in both community pharmacy and institutional pharmacy practice settings.
(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
(4) A signed copy of the examination security acknowledgment.
(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.
(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code. Reference: Sections 144, 851, and 4200, Business and Professions Code.

Intern Hours Chronology

March 2006
Licensing Committee heard a presentation from pharmacy students requesting that the board amend the intern hour requirement to increase the number of pharmacy-related experience earned outside a pharmacy to 1,000 hours. Under this proposal, an intern would have only 500 hours of experience in a pharmacy. The committee expressed concern that a minimum of 500 hours in the pharmacy setting is not sufficient to ensure adequate public safety and the experience necessary to perform the duties of a pharmacist.

December 2006
Licensing Committee heard a second presentation from pharmacy students which highlighted the additional pharmacy-related areas an intern could pursue if the intern hours experience requirement were more flexible. The committee concluded that it was premature to move forward with this proposal at that time.

During the same meeting, the committee was advised on a project initiated by the California Schools of Pharmacy to review basic intern experience earned by students. This project would assess the competencies that should be achieved by the end of the introductory pharmacy experience, referred to as IPPEs. The committee recommended that the board participate in this project. Board Member Ravnan was the designated board representative for the project.

March 2007
Licensing committee was provided with the competencies developed by schools of pharmacy along with a request that the board affirm its agreement with the document.

October 2007
Through a written statement to California schools of pharmacy the board recognized the competencies developed by the schools. "The California Board of Pharmacy recognizes these competencies as appropriate competencies for a California licensed pharmacists to possess, and the board strongly supports the need for interns to develop and expand their competency in these areas as among the core responsibilities of pharmacists."

June 2008
Licensing Committee revisited the request to alter the intern hour requirements in light of the completion and recognition by the board of the competency statements developed by the schools of pharmacy. After much discussion and deliberation the committee tabled the discussion.

December 2008
Licensing Committee discussed a written request from a Loma Linda student suggesting that the intern hours requirement allow more flexibility in practice sites in which intern hours can be earned, such as ambulatory care. After discussion and public comment, the committee did not take action on this item.

June 2009
Licensing Committee discussed how the board would confirm compliance of intern hours worked – the committee did not discuss changing the current intern hour requirements specified in law. However, following a subsequent discussion with counsel, it was determined that the solution offered by the committee did not comply with legal requirements detailed in pharmacy law.

December 2009

Licensing Committee discussed intern hours reporting requirements to clarify the requirements detailed in pharmacy law. The board released a statement to all schools of pharmacy, and placed the information on the board's Web site.

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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Continuing Education Audits of Pharmacists**

Pharmacists are required to complete 30 hours of continuing education as a condition of license renewal. These CE hours must be earned within the two years their license was last renewed. At the time of renewal, every pharmacist must certify under penalty of perjury that he or she has completed the 30 units.

The exact language a pharmacist is asked to certify is:

> I certify that I have completed _____ hours of continuing education during my last renewal period. I declare under penalty of perjury under the laws of the state of California that the foregoing is true and correct.
>
> _____ _____
> Signature Date

The board periodically audits a few pharmacists each month to determine their compliance with this requirement. If they are unable to provide 30 hours of CE for the renewal period, they are directed to immediately provide proof of completion of additional CE now (earned outside the renewal period, but to bring them into compliance) and then are cited and fined.

If the pharmacist does not come into compliance, Business and Professions Code section 4231 allows the board to convert the renewal to an inactive license -- which means the individual cannot work as a pharmacist in California.

> **4231. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee**
> (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.
> (b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.
> (c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by

paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.
(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

The results of recent board audits indicates that 16 percent of those audited could not provide proof of completion of continuing education credits earned during the last renewal period. Of these 5 (2 percent) ended up having their licenses converted to inactive status. The month by month audit results appear on the next page.

Continuing Education Audit Monthly Statistics
September 2009- May 2010
FY 09/10

September 2009

	#	%
RPhs Audited	25	
Cite & Fine	1	4%
Inactive Status	0	0%
Passed	24	96%
Failed	1	4%

Reason(s): Failed to respond 1

October 2009

	#	%
RPhs Audited	24	
Cite & Fine	3	13%
Inactive Status	0	0%
Passed	21	88%
Failed	3	12%

Reason(s): Short CE- not compliant still 2
Failed to respond 1

November 2009

	#	%
RPhs Audited	27	
Cite & Fine	4	15%
Inactive Status	1	4%
Passed	23	85%
Failed	4	15%

Reason(s): Short CE- now compliant 3
Failed to respond 1

December 2009

	#	%
RPhs Audited	24	
Cite & Fine	2	8%
Inactive Status	1	4%
Passed	21	88%
Failed	3	12%

Reason(s): Short CE- now compliant 2
Failed to respond 1

January 2010

	#	%
RPhs Audited	27	
Cite & Fine	3	11%
Inactive Status	2	7%
Passed	24	89%
Failed	3	11%

Reason(s): Short CE- now compliant 1
Failed to respond 2

February 2010

	#	%
RPhs Audited	23	
Cite & Fine	3	13%
Inactive Status	0	0%
Passed	20	87%
Failed	3	13%

Reason(s): Short CE- now compliant 2
Short CE- not compliant still 1

March 2010 & April 2010

	#	%
RPhs Audited	50	
Cite & Fine	13	26%
Inactive Status	1	2%
Passed	37	74%
Failed	13	26%

Reason(s):	Short CE- now compliant	10
	Short CE- not compliant still	2
	Failed to respond	1

May 2010

	#	%
RPhs Audited	26	
Cite & Fine	6	23%
Inactive Status	0	0%
Passed	19	73%
Failed	7	27%

Reason(s):	Short CE- now compliant	2
	Pending	5

June 2010

	#	%
RPhs Audited		
Cite & Fine		
Inactive Status		
Passed		
Failed		

TBD

Reason(s):

Continuing Education Audit Final Statistics
September 2009- May 2010
FY 09/10

Final Statistics

	#	%
Total RPhs Audited	226	
Cite & Fine	35	15%
Inactive Status	5	2%
Total Passed	189	84%
Total Failed	37	16%

Fail Explanations

	#	%
Short CE- now compliant	20	54%
Short CE- not compliant still	5	14%
Failed to respond	7	19%
Pending	5	14%
Total:	37	100%

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include "Self-Query" Reports from the Healthcare Integrity and Protections Data Bank (HIPDB)**

The Board currently reports information regarding its licensees who have been disciplined or otherwise had an adverse action to the Healthcare Integrity and Protection Data Bank (HIPDB) as required by law. In addition to our reporting, all adverse actions taken by federal or state agencies, exclusions of health care practitioners in federal or state programs, criminal convictions, and civil judgments are also required to be reported to the HIPDB. HIPDB serves as the repository of data for all such actions takend against healthcare practioners..

It is not unusual for a pharmacist applicant or intern to also be licensed in other jurisdictions. As part of the application process for both the intern and pharmacist exam application, applicants are required to self-disclose several items. The itnern application includes several questions surroudning prior disciplinary action has ever been taken in this state or any other.
The pharmacist exam application includes several of the same types of questions as well as information about licensure in other states. This information is all self-certified by the applicant. In addition, the board requires license verification, where identified by the pharmacist applicant.

Board staff proposes a change to the application requirements to also include a "self-query" report be required as part of the application process. Requiring such a search will ensure that the board has all relevant information when making a licensing decision and does not inadvertently issue a pharmacist or intern license to an individual that has been disciplined in another state unless, after review of the information, it determines that such an issuance is consistent with the board's consumer proteection mandate.

Following this memo is a fact sheet from HIPDB on the self-query process as well as a list of the professional licenses that are contained within the databank. A review of other jurisdictions indicates that several other states are integrating the "self-query" into their licensing requirements for varing health care providers.

National Practitioner Data Bank
Healthcare Integrity and Protection Data Bank

FACT SHEET ON SELF-QUERYING

Practitioner, Provider, and Supplier Self-Query

A self-query is a request by a practitioner, provider, or supplier for information about himself, herself, or his or her organization contained in the National Practitioner Data Bank (NPDB) and/or the Healthcare Integrity and Protection Data Bank (HIPDB).

Practitioners, providers, and suppliers may self-query the Data Banks at any time. To initiate a self-query, go to the Data Banks Web site, at *www.npdb-hipdb.hrsa.gov*. **All self-query applications must be submitted through the NPDB-HIPDB Web site. After initiating the self-query on-line, the practitioner must print and sign the form in the presence of a Notary Public and then mail the signed, notarized form to the Data Banks.** Self-queriers who do not have access to the Internet may call the NPDB-HIPDB Customer Service Center for assistance at 1-800-767-6732 (TDD 703-802-9395).

Subject Report Information in the Data Banks

The NPDB and the HIPDB are committed to maintaining accurate information and ensuring that health care practitioners, providers, and suppliers are informed when medical malpractice payments, adverse actions, and judgments or convictions are reported concerning them. When the Data Banks receive a report, the information is processed by the NPDB-HIPDB exactly as submitted by the reporting entity. Reporting entities are responsible for the accuracy of the information they report to the Data Banks.

When the Data Banks process a report, a *Report Verification Document* is sent to the reporting entity, and a *Notification of a Report in the Data Bank(s)* is sent to the subject. The subject should review the report for accuracy, including such information as current address and place of employment.

Subjects may not submit changes to reports. If report information is inaccurate, the subject must contact the reporting entity to request that it file a Correction, Revision to Action, or Void. The Data Banks are prohibited by law from modifying information submitted in reports. For information on submitting a statement or a dispute to a report, see the *Fact Sheet on the Dispute Process*.

Self-Querying on the Internet

The NPDB-HIPDB employs the latest technology, along with various implementation measures, to provide a secure environment for querying, reporting, data storage, and retrieval. Security features include firewall protection from unauthorized access and encryption of transmitted data to prevent unauthorized use.

Self-queriers complete and transmit their self-queries to the NPDB-HIPDB on-line; however, a self-query is not officially submitted until a signed and notarized paper copy is received by the Data Banks. A formatted copy of the self-query is generated immediately after electronic transmission. To complete the self-query process, self-queriers must print the formatted copy, sign and date it in the presence of a notary public, and mail the notarized self-query to the address specified. After processing the self-query, the Data Banks send an e-mail alerting the practitioner that the self-query response is available for on-line viewing. In addition to the electronic response, you will receive a paper copy (or copies), if you have elected to do so.

Self-Query Fees

Individual and organization self-query requests are automatically sent to both the NPDB and the HIPDB for a total charge of $16.00. The fee consists of an NPDB charge of $8.00 per self-query and a HIPDB charge of $8.00 per self-query. **Note:** One mailed copy is included in the self-query processing fee. Each additional paper copy of your self-query response will be assessed a fee by each Data Bank under which the self-query is processed.

All self-query fees must be paid by credit card (VISA, MasterCard, Discover, or American Express). Personal checks and cash are not accepted. Credit card information may be provided either on-line or written on the formatted copy that is printed for notarization. The credit card will not be charged until the NPDB-HIPDB receives and processes the notarized self-query. A notarized self-query lacking credit card information will be rejected.

Self-Query Mailed Responses

The NPDB-HIPDB does not accept stamped, photocopied, or faxed signatures, and faxed self-queries cannot be accepted. Previously processed self-queries are also not accepted. You may reduce transit time by submitting self-queries via U.S. Postal Service Express mail to the address at the top of this fact sheet, or by returning your self-query through another overnight delivery carrier to the following street address:

NPDB-HIPDB
4094 Majestic Lane, PMB-332
Fairfax, Virginia 22033

Please do not enclose pre-paid, self-addressed envelopes for overnight return mail delivery with your formatted self-query application.

Self-query notification is sent to practitioners via an e-mail alerting them that their self-query results are available for viewing and printing on-line. During the self-query process, practitioners create a personal response password enabling them to log in to the Self-Query Service and view the self-query response.

In addition to the electronic response, practitioners will still receive one paper copy by mail for the $16.00 self-query processing fee (unless they elect not to receive a mailed copy). Practitioners and organizations can also request additional sealed copies of their self-query response. Each additional copy has a separate processing fee of $16.00. Self-query responses are mailed separately to the address specified in the self-query submission.

Self-Query Notarization

All self-queries must be notarized, and all fields in the notarization section must be completed. The NPDB-HIPDB will reject any self-query received without notarization or with an incomplete notarization. The NPDB-HIPDB requires notarization of the formatted copy of the self-query to protect the privacy of sensitive and confidential information requested by practitioners, providers, and suppliers. By appearing before a notary and having the notary sign and date the form, the NPDB-HIPDB is reasonably assured that the individual submitting the self-query has requested the information on behalf of himself, herself, or his or her organization.

To successfully process a self-query, both the self-querier and the notary public must sign and date the form. The notary must also provide the date that his or her commission expires and affix his or her seal. If the notary public does not have a stamp or seal, he or she must provide other proof of office (e.g., a copy of a notary certificate). The only lawful date on a notarial certificate is the date the signer actually appeared, according to *12 Steps to a Flawless Notarization* published by the National Notary Association.

Self-Query Status

On the *Self-Query Service Sign-In* screen, enter the Self-Query Tracking #/DCN and then click **Continue**. Self-queriers enter a password to check the status of a self-query, following the on-screen instructions. The *Self-Query Status* screen will display status information for the indicated self-query.

NPDB-HIPDB Assistance

For additional information, visit the NPDB-HIPDB Web site at *www.npdb-hipdb.hrsa.gov*. If you need assistance, contact the NPDB-HIPDB Customer Service Center by e-mail at *help@npdb-hipdb.hrsa.gov* or by phone at 1-800-767-6732 (TDD 703-802-9395). Information Specialists are available to speak with you weekdays from 8:30 a.m. to 6:00 p.m. (5:30 p.m. on Fridays) Eastern Time. The NPDB-HIPDB Customer Service Center is closed on all Federal holidays.

OCCUPATION/FIELD OF LICENSURE

National Practitioner Data Bank
Healthcare Integrity and Protection Data Bank

Entity: CALIFORNIA STATE BOARD OF PHARMACY (SACRAMENTO, CA)

Please select the code that best describes the subject's occupational activities or licensure category associated with the adverse action being reported.

- ○ **Physician**
- ○ **Nurse - Advanced, Registered, Vocational or Practical**
- ○ **Nurse Aide, Home Health Aide And Other Aide**
- ○ **Dental Service Practitioner**
- ○ **Chiropractor**
- ○ **Counselor**
- ○ **Dietician/Nutritionist**
- ○ **Emergency Medical Technician (EMT)**
- ○ **Eye and Vision Service Practitioner**
- ◉ **Pharmacy Service Practitioner**
  - ○ Pharmacist (050)
  - ○ Pharmacy Intern (055)
  - ○ Pharmacist, Nuclear (060)
  - ○ Pharmacy Assistant (070)
  - ○ Pharmacy Technician (075)
- ○ **Physician Assistant**
- ○ **Podiatric Service Practitioner**
- ○ **Psychologist/Psychological Assistant**
- ○ **Rehabilitative, Respiratory and Restorative Service Practitioner**
- ○ **Social Worker**
- ○ **Speech, Language and Hearing Service Practitioner**
- ○ **Technologist/Technician**
- ○ **Other Health Care Practitioner**
- ○ **Health Care Facility Administrator**
- ○ **Other Occupation**

Continue

Return to Options | Log Out

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 9, 2010

To: Licensing Committee

Subject: Emergency and Disaster Response Planning Update

In 2007, the board developed and released an emergency response policy, pursuant to California Business and Professions Code section 4062 to waive statutory requirements to benefit public safety in response to a declared emergency or disaster. In 2009, the section was amended to add subdivision (c) to provide for use of temporary facilities during declared emergencies. Section 4062 reads as follows:

> **4062. Furnishing Dangerous Drugs During Emergency; Mobile Pharmacy**
> (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
> (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.
> (c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:
> (1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.
> (2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).
> (3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.
> (4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
> (5) The mobile pharmacy is located within the declared emergency area or affected areas.
> (6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

A copy of the board's Emergency Response policy follows this memorandum.

At the October 2009 Board Meeting, the board voted that in situations following a declared emergency where the board cannot convene a meeting timely, that the board delegates its authority to waive statutory requirements to benefit public safety in response to a declared emergency or disaster to a committee of three board members via teleconference.

MOTION: In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., e-mail), or by other means of communication to exercise the powers delegated to full board pursuant to Business and Professions Code section 4062.

At this Meeting:

The executive officer was recently asked by the California Department of Public Health how will the board know when to rescind its emergency suspension of requirements under the emergency provisions once the emergency has ended. What is the trigger for the emergency to be dissipated and have licensees return to practices? Who initiates and when does it go into place?

Below is the response of the executive officer, who initially discussed this topic with staff of the Department of Public Health.

A: There is not a definitive answer. Often there is a point where either the Governor or the Office of Emergency Services makes a statement that the emergency is over. The California Department of Public Health, I would suspect, would also be a likely agency to note when the emergency has dissipated. At some point, business and patients return to normal. This is the point when the board would advise entities to return normal business practices. In the limited instances where the board used its emergency policy (several years ago during CA's wildfires), we did not need to issue notice about the end of the emergency. Things returned to normal on their own.

The board may wish to discuss and amplify this response, and develop its policy about criteria for ending the emergency authorization.

Disaster Response Policy Statement

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at *www.medicalvolunteer.ca.gov* (California) and *www.medicalreservecorps.gov* (federal).

The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

[1]Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

[2]See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 9, 2010

To: Licensing Committee

Subject: Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

The board instituted a quality assurance review of the CPJE effective April 1, 2010. This process is done periodically to ensure the reliability of the examination. As of the date of this report, approximately half of the candidates required to complete the quality assurance review have taken the CPJE. The board intended to complete this review and release examination results in June 2010. As soon as the required numbers of candidates have taken the CPJE, the board will release the results.

Job Analysis and Content Outline for the CPJE

Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the CPJE examination. To complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. The information learned from this survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California.

Under the leadership of the board's psychometric consultant, the Competency Committee has worked on revising its content outline and the completed work was presented to the board at the April 2010 board meeting. During this meeting, the board reviewed and approved the new content outline. The Competency Committee will begin working with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Competency Committee Meetings

Competency Committee Workgroups have met three times during 2010 to develop the CPJE. Both Workgroups will meet together at their annual meeting in August to continue examination development as well as incorporate the new content outline and ensure implementation for examinations administered after April 1, 2011.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Review and Possible Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies**

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

Currently the board has 243 such licensed facilities in California, and 93 nonresident pharmacies with such permits.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health AND
- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Currently there are two accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc (ACHC), and 2. Community Health Accreditation Program (CHAP). At the April 2010 Board Meeting, the board extended the accreditation of these two agencies for one year while the board prepares a detailed review.

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. Recently the board modified its regulations for pharmacies that compound medication. Included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. These regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, will take effect July 6, 2010. (The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.)

Since 2003 when both agencies were approved by the board, board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of

accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Both agencies were last reviewed by the board in 2006.

1. **Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

<u>At this meeting</u>:

At the April Board Meeting board staff were directed to (1) review and assess the three accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding pharmacies, (2) bring staff's report to a future Licensing Committee Meeting (the next meeting is scheduled for June 16, 2010), and (3) bring the committee's recommendations to the board for action at a future meeting.

Staff believes that a meaningful review of the two agencies and a third accreditation agency seeking board approval involves the agencies' incorporation of the new sterile injectable compounding requirements and ability to accredit against these standards into their accreditation inspections. However, at the current time, the board has not initiated this review of the accreditation standards (although all three agencies have been advised of the modified requirements).

The committee will hear an assessment by Supervising Inspector Janice Dang in her review of each agency to assess a pharmacy's ability to meet the board's requirements for sterile injectable compounding pharmacies. Both the current requirements and the new requirements will be assessed for each agency.

A detailed response of each of the three agencies against the 8 criteria above follows on the next pages. The following three agencies are requesting board approval as accrediting agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)
2. Community Health Accreditation Program (CHAP).
3. New -- Det Norske Veritas (DNV)

Representatives of DNV will appear at the meeting to respond to questions of the committee.

Accreditation Commission for Health Care, Inc (ACHC)

ISO 9001:2008 Certified
CMS Approved

March 30, 2010

Debbie Anderson
Site Licensing Manager
California Board of Pharmacy
1625 N. Market Blvd.
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The Accreditation Commission for Health Care, Inc. (ACHC) would like to request the California Board of Pharmacy to accept ACHC for re-approval as an accrediting organization for pharmacies that compound injectable sterile products. Please consider the following information and attached documents in your decision process:

1. Periodic Inspection – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years:
   I. ACHC accreditation is valid for three years. Each provider must re-apply prior to the expiration of their three year accreditation. Re-accreditation requires a full site survey. Please see attached copy of ACHC policies and procedures, and reference specific section below that addresses re-accreditation requirements:

      C. Accreditation Status Criteria
      Approval of Accreditation
      Full accreditation is awarded to an organization when the overall score and each section score are within a range of 90% or above. Submission of a plan of correction will be required for any standard not fully met. Accreditation is good for 3 years. Effective accreditation dates for new and renewal organizations are determined as follows:
      New organization:
      1. First day following the survey, if the organization passes survey on the first review.
      2. First day after receipt of plan of correction once the plan of correction is approved from deferral status.
      3. First day after the focus survey, if the deferral is cleared upon review.
      Renewal organization:
      1. First day following current accreditation expiration date if the organization passes survey on the first review.
      2. First day following current accreditation expiration once the plan of correction is approved from deferral status.

2. Documented accreditation standards – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations:
   a. ACHC grants accreditation based on many components of the survey. The clinical manager for pharmacy services reviews each summary of findings, the scoring grid and the surveyor's comments after each survey. A decision is made based on all three criteria. Accreditation is granted for

scores of 90% and above; the deferral range is 80% to 89% and denial is determined for scores below 80%.

b. Standard 107A as stated below reflects any state specific criteria that is met or not met by a provider during the survey.

> *Standard 107, Criterion A: There are written policies and procedures established and implemented by the organization regarding compliance with all applicable federal, state, and local laws and regulations. The organization also complies with accepted professional standards and practices.*
>
> *Note: Failure to meet this criterion will result in automatic deferral.*

c. Please see attached standards for accreditation for pharmacies.

3. Evaluation of surveyor's qualifications – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditations:

ACHC surveyors for pharmacies are required to meet the following criteria:

a. Maintain a current pharmacist license in one of the 50 states or territories of the United States. Surveyor is required to have a minimum of 5 years managerial experience in the homecare and/or pharmacy market. A PharmD is preferred.
b. Surveyor must complete the initial two day surveyor training and a minimum of two preceptorships, prior to conducting their initial survey.
c. Surveyors must attend an annual full day training session.
d. Surveyors must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards.
e. All surveyors are evaluated annually for their ability to perform surveys in accordance with ACHC policies and procedures.

4. Acceptance by major California payors – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS)

   I. ACHC is recognized by most major payors; example of these payors in California are: Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.

5. Unannounced inspection of California accredited sites – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.

   I. ACHC welcomes feedback from the California Board of Pharmacy on any ACHC accredited organization that is licensed by the Board.

6. Board access to accreditor's report on individual pharmacies.

   I. ACHC will make available to California Board of Pharmacy any provider's Summary of Findings as requested. In addition the Board can access current accredited provider by visiting our website.

7. Length of time accrediting agency has been in operation.
   I. ACHC is an independent, private, not-for-profit corporation established in 1986.

8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.
   I. ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the United States.

Thank you for considering ACHC for re-approval as an accrediting organization for the California Board of Pharmacy in regard to pharmacies that compound injectable sterile drug products. If you have any questions or require additional information please call me at 919-785-1214.

ACHC

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INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

DMEPOS AND PHARMACY CORE: SECTIONS 100 - 600

SECTION 100: Business Operations and Administration

Standard 101. The organization is an established entity with legal authority to operate.

Standard 101, Criterion A: There is appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: Legal authority is granted to one individual, members of a limited liability corporation, a board of directors, or a board of health; usually referred to as the governing body, and as allowed in state statutes for the appropriate type and structure of the organization. Whether private or public entity, the individual, or organization will have a copy of the appropriate authorization(s) to conduct business. All required license(s) and or permit(s) must be current and posted in a prominent location accessible to public view in all locations/branches and/or in accordance with appropriate regulations or law.

Evidence: Copy of Articles of Incorporation/Bylaws and all applicable amendments
Copy of all current applicable license(s)/permit(s) for each premise

Standard 101, Criterion B: The organization's written policy and procedure defines action requirements for request for information and changes in authority, ownership, or management.

Interpretation: The organization's written policy and procedure describe the required action and timeframes if a request for information is received from a regulatory or accrediting body, or there is a change in ownership, governing body, or management.

Evidence: Written Policies and Procedures
Response to Interviews

Standard 102. The organization's leadership assumes full legal authority and responsibility for the operation of the organization. Examples of leadership positions may include the owners, governing body, chief executive officer, and other individuals responsible for managing services provided by the organization.

Standard 102, Criterion A: Governing body duties and accountabilities must be clearly defined.

Interpretation: A governing body assumes full legal authority and responsibility for the operation of the organization consistent with acceptable standards of practice. Activities of the governing body may include but are not limited to the following: decision making, appoints a qualified administrator, arranges for professional advice, reviews the annual program evaluation, adopts and periodically reviews written bylaws or equivalent, establishes or approves written policies governing operations, human resource management, quality improvement, community needs planning and oversight of the management and fiscal affairs of the organization.

Policies must be reviewed and revised on an ongoing basis as needed and reviewed/revised as part of the annual evaluation.

Although many governing bodies delegate authority for some of these functions to individual staff members or to an advisory committee, the ultimate responsibility continues to rest with the governing body. In situations where the board of directors serves as the governing body for a large, multi-service organization, board activities will address the overall organization; however, oversight of the organization's program must be evidenced in some manner such as reports to the board documented in minutes of board meetings.

Evidence: Written Policies and Procedures
Minutes of Board of Directors Meetings
For privately owned organizations whose owners serve as leader/executive, records of organizational decisions including dates and participants
Response to Interviews

Standard 103. The organization has a written policy and procedure which defines conflict of interest and the procedure for disclosure.

Standard 103, Criterion A: The organization's written policy defines conflict of interest.

Interpretation: The organization's policy defines conflict of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and clients/patients. The policy must include the required conduct of any affiliate or representative of the governing body and/or employee having an outside interest in an entity providing services to the organization and/or other client/patient relationships.

In the event of proceedings that require input, voting, or decisions, the individual(s) with a conflict of interest must be excluded from the activity.

Evidence: Written Policies and Procedures
Written Minutes of Meetings

Standard 103, Criterion B: The written policy and procedure for conflict of interest disclosure will be shared and understood.

Interpretation: The conflict of interest disclosure policy and procedure must be shared with and understood by the governing body, staff members, and organization representatives.

Evidence: Response to Interviews
Board Meeting Minutes
Orientation Records
Signed Conflict of Interest Disclosure Statements

Standard 104. There is a designated individual, accountable to the governing body/owner, who is responsible for the overall operations and services of the organization.

Standard 104, Criterion A: There is an individual who is designated as responsible for the overall operation and services of the organization.

Interpretation: The leader/executive *is responsible for all programs* and services and must be accountable to the governing body. There will be written policies and procedures that specify the responsibilities and authority of this individual.

The administrator organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. The resume and/or application of the current leader/executive verify that the individual who holds this position meets the minimum education and experience requirements as defined by the organization and any applicable state and federal laws and regulations. The organization must also provide information regarding changes in the administrator position to ACHC and other required agencies.

Evidence: Written Policies and Procedures
Leader/Executive Resume/Application

Standard 104, Criterion B: An individual is appointed to assume the role of the leader/executive during temporary absences and/or vacancies.

Interpretation: There must be a person or designated position appointed to assume the role of the leader/executive for temporary absences and/or vacancies. This appointment must be written into operations policy and must be included in the job description of the position intended to perform this responsibility. The duties that the individual assumes during the absence of the leader/executive must be written into operations policy and into the orientation of this individual.

Evidence: Written Policies and Procedures

Standard 105: Service personnel can accurately describe the chain of command.

Interpretation: Personnel must be able to provide a description of the organization's chain of command that is consistent with the organization chart.

Evidence: Response to Interviews

Standard 106: There is a written organization mission and philosophy statement that directs the services and goals of the organization.

Interpretation: There is a written organization mission and philosophy statement that directs the goals and service/care delivery activities of the organization. The organization regularly reviews the mission and philosophy statements. The mission and philosophy are communicated to all staff.

Evidence: Written Mission and Philosophy Statement
Response to Interviews

Standard 107. The organization complies with all federal, state, and local laws and regulations

and reports compliance outcomes.

Standard 107, Criterion A: There are written policies and procedures established and implemented by the organization regarding compliance with all applicable federal, state, and local laws and regulations. The organization also complies with accepted professional standards and practices.

Note: Failure to meet this criterion will result in automatic deferral.

Interpretation: This standard requires compliance with all laws and regulations such as local and state licensure, professional licensure/certification, practice standards, the Americans with Disabilities Act, Equal Employment Opportunities Act, Fair Labor Standards Act, Title VI of the Civil Rights Act of 1963, Occupational Safety and Health Standards, Medicare regulations, Medicaid regulations, Omnibus Budget Reconciliation Act 1987, Balanced Budget Act of 1997, occupational licensure laws, Public Health regulations relating to infectious diseases, HIPAA regulations and other laws and regulations as applicable to the service/care provided by the organization.

Compliance with Civil Rights and Equal Employment Opportunity Acts is required for organizations receiving State or Federal funds (Medicare, Medicaid, Title III, Title XX, etc.).

Compliance with OSHA, FDA, DEA, Dept. of Transportation, State Dept. of Agriculture, all appropriate occupational licensing boards, and all required business licenses for city, county, and state are required for all organizations as applicable to the service/care provided.

Accepted standards of practice and occupational licensure acts are utilized by the organization to guide the provision of service/care.

The supplier shall have a physical location and display all licenses, certificates, and permits to operate. The licenses and certificates must be displayed in an area accessible to customers and patients. The supplier shall provide copies upon request, to government officials or their authorized agents
The supplier shall provide only durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other items that meet applicable Food and Drug Administration (FDA) regulations and medical device effectiveness and safety standards. The supplier shall obtain from the manufacturer copies of the features, warranties, and instructions for each type of non-custom-fabricated item.

Evidence:
- Written Policies and Procedures
- Copies of Appropriate Licenses
- Copies of all Applicable Occupational Licensure Acts, Rules, and Standards of Practice
- Copies of Required Posters in a prominent location
- Observation

Standard 107. Criterion B: The organization will inform the accrediting body and Board of Directors of any negative outcomes from review/audits.

Interpretation: Negative outcomes affecting accreditation or licensure will be reported to the governing body/owner and to ACHC within 30 days. All responses and actions to the outcomes will be included in the report.

Outcomes that must be reported to ACHC include, but are not limited to: license suspension(s); license probation; conditions/restrictions to license(s); and civil penalties of ten thousand dollars ($10,000.00) or more.

Evidence: Board Meeting Minutes
Response to Interviews
Reports to ACHC
Federal Agency and State Licensure Agency Report(s) and/or Inspections from authorized regulatory and accrediting bodies

Standard 108. Descriptions of specific service/care provided by the organization are available to all staff, clients/patients, and the community.

Interpretation: Marketing materials and/or handouts must include: (1) types of service/care available; (2) service/care limitations; (3) charges or client/patient responsibility for service/care and/or products before or at time of delivery (or indication that charges are available upon request); (4) eligibility criteria; (5) hours of operation, including on call availability (if applicable); and (6) contact information and referral procedures.

Written descriptions of service/care with detailed information must be available to staff members. Marketing and instructional materials must use lay language and provide a more general description of services offered.

Descriptions must include each service/care provided to the client/patient. The contact information and referral procedures must provide instructions for telephoning the organization or an answering service and procedures to make a referral for services. Hours of operation must be included.

Evidence: Written Policies and Procedures
Written Description of Services
Marketing Materials to include Electronic Media
Documents that include Service Descriptions

Standard 109. A written Client/Patient Bill of Rights is reviewed with and distributed to each recipient of in-home service/care. The agency protects and promotes the exercise of these rights.

Standard 109, Criterion A: There are written policies and procedures established and implemented by the organization regarding the rights and responsibilities of clients/patients.

Interpretation: Written policies and procedures outline the client/patient rights and responsibilities. The policy shall require that the organization provide the client/patient with a written copy of their rights before initiation of service/care. The policy must state that if a client/patient cannot read the statement of rights, it shall be read to the client/patient in a language the client/patient understands. For a minor or a client/patient needing assistance in understanding these rights, both the client/patient and the parent, legal guardian, or other responsible person must be fully informed of these rights. An agency that provides advance directives information must provide written information concerning its policies on advance directives, prior to care being provided.

The Client/Patient Bill of Rights must include, but not be limited to the right to:

- Be fully informed in advance about service/care to be provided, including the disciplines that furnish care and the frequency of visits as well as any modifications to the service/care plan.

- Participate in the development and periodic revision of the plan of service/care.
- Informed consent and refusal of service/care or treatment after the consequences of refusing service/care or treatment are fully presented.
- Be informed, both orally and in writing, in advance of service/care being provided, of the charges, including payment for service/care expected from third parties and any charges for which the client/patient will be responsible.
- Have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality.
- Be able to identify visiting staff members through proper identification.
- Voice grievances/complaints regarding treatment or care, lack of respect of property or recommend changes in policy, staff, or service/care without restraint, interference, coercion, discrimination, or reprisal.
- Have grievances/complaints regarding treatment or care that is (or fails to be) furnished, or lack of respect of property investigated.
- Choose a health care provider.
- Confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information.
- Be advised on agency's policies and procedures regarding the disclosure of clinical records
- Receive appropriate service/care without discrimination in accordance with physician orders.
- Be informed of any financial benefits when referred to an organization.
- Be fully informed of one's responsibilities.
- Be informed of provider service/care limitations.

When state or federal regulations exist regarding client/patient Bill of Rights, the organization's Bill of Rights statement must include those components. The client/patient has the right to be informed of his or her rights. The organization must protect and promote the exercise of these rights.

Evidence: Written Policies and Procedures
Client/Patient Bill of Rights
Response to Interviews

Standard 109, Criterion B: All staff members are provided training during orientation and at least annually thereafter concerning the organization's client/patient Bill of Rights.

Interpretation: All staff must receive training regarding client/patient Bill of Rights upon hire and annually.
Evidence: Orientation and In-Service Records
Response to Interviews

Standard 109, Criterion C: The written client/patient Bill of Rights and Responsibility statement will be discussed and distributed to the client/patient at the time of the admission.

Interpretation: The Client/Patient Bill of Rights and Responsibility statement must be reviewed with the client/patient or responsible party. Documentation of receipt and understanding of the information must be placed in the client/patient record. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient record that the Client/Patient Bill of Rights was reviewed and understood by the client/patient/responsible party. A copy of the Bill of Rights and Responsibilities is made available to others in the community upon request.

Evidence: Client/Patient Records

Response to Interviews

Standard 109, Criterion D: DMEPOS Supplier Standards are distributed to and reviewed with each Medicare recipient of service/care.

Interpretation: A copy of the DMEPOS Supplier Standards must be distributed to the client/patient/responsible party with documentation of receipt and understanding of the information. This evidence may be provided either by obtaining signatures of the client/patient/responsible party or by noting in the client/patient/responsible party record that the DMEPOS Supplier Standards were reviewed and understood by the client/patient/responsible party.

Evidence: Client/Patient Records
Response to Interviews

Standard 110. The organization will maintain and follow their written grievance, complaint, and concern policy and procedure.

Standard 110, Criterion A: The organization written policies and procedures require that the client/patient be informed at the initiation of service/care how to report grievances, complaints, or concerns and explain how they will be investigated and resolved.

Interpretation: The organization must have a written procedure that describes how client/patient grievances, complaints, and concerns will be investigated and resolved. Policy and procedure will describe at a minimum: (1) the appropriate person to be notified of the grievance/complaint/concern; (2) time frames for investigation activities, to include after hours; (3) reporting of information; (4) review and evaluation of the collected information; (5) effective action taken and outcome; (6) communication with the client/patient/caregiver/family; and (7) documentation of all activities involved with the grievance/complaint/concern, investigation, analysis and resolution. The organization will investigate and attempt to resolve all client/patient grievance/complaint/concern and document the results within a described time frame as defined in policy.

Evidence: Written Policies and Procedures

Standard 110, Criterion B: All personnel are knowledgeable of the policy and procedure for handling a grievance/complaint/concern during any contact with clients/patients.

Interpretation: Personnel will be oriented and familiar with the client/patient grievance/complaint/concern policy and procedure. Staff will assist in implementing the resolution process as needed.

Evidence: Personnel Orientation Checklist
Response to Interviews

Standard 110, Criterion C: Within five (5) calendar days of receiving a beneficiary's complaint, a supplier shall notify the beneficiary, using either oral, telephone, e-mail, fax, or letter format, that it has received the complaint and that it is investigating. Within 14 days, the supplier shall provide written notification to the beneficiary of the results of its investigation and response. The supplier shall maintain documentation of all complaints that it receives copies of the investigations, and responses to beneficiaries.

Interpretation: The organization will maintain records of grievances/complaints and their outcomes, and include this information in the annual program service/care review/evaluation. A summary of the grievances/complaints will be reported quarterly in the performance management plan.

Evidence: Grievance/Complaint Records and/or Files
Response to Interviews

Standard 110, Criterion D: The organization must provide the client with written information concerning how to contact the organization, appropriate state agencies, and ACHC concerning grievances/complaints at time of admission.

The organization must provide all client/patient with written information listing a telephone number, contact person, and the organization's process for receiving, investigating and resolving grievances/complaints about its service/care.

The agency must advise the patient in writing of the telephone number of the appropriate state regulatory body's hot-line telephone number(s), the hours of operations and the purpose of the hotline. This may be a separate information sheet given to the client/patient or incorporated with the Client/Patient Bill of Rights information. ACHC's telephone number must be provided. ***Note: The ACHC phone number requirement is not applicable to organizations if this is their first ACHC survey.***

Evidence: Client/Patient Records

Standard 111. There are written policies and procedures regarding confidentiality and privacy of client /patient information.

Standard 111, Criterion A: There are written policies and procedures for securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

Interpretation: Confidentiality policies address, at a minimum, the following: (1) a definition of protected health and confidential information, the types of information that are covered by the policy, including electronic, and computerized information, telephone and cell phone communications, and verbal and faxed information; and (2) persons/positions authorized to release PHI/EPHI and confidential information and person's to whom it may be released; (3) conditions which warrant its release; (4) persons to whom it may be released; (5) signature of the client/patient or someone legally authorized to act on the client/patient's behalf; (6) a description of what information the client/patient is authorizing the organization to disclose; (7) securing client/patient records and identifying who has authority to review or access clinical records; (8) when records may be released to legal authorities pursuant to subpoenas with appropriate documentation; (9) the storage and access of records to prevent loss, destruction or tampering of information; and (10) the use of confidentiality/privacy statements and who is required to sign a confidentiality/privacy statement. The organization has clearly established written policies and procedures that address the areas listed above which are clearly communicated to staff.

Evidence: Written Policies and Procedures

Standard 111, Criterion B: Personnel, governing body/owner are knowledgeable about and consistently follow confidentiality and privacy policies and procedures.

Interpretation: There is evidence that personnel and governing body/owner have been trained and practice confidentiality policies. The organization must designate an individual to be responsible for seeing that the confidentiality and privacy procedures are adopted and followed.

Evidence: Signed Confidentiality Agreements
Orientation Checklists
Job Descriptions
Response to Interviews

Standard 111, Criterion C: The client/patient and/or responsible party receive and understand information related to the confidentiality policy prior to the receipt of services/care.

Interpretation: The individual visiting the client/patient/responsible party for the first time will provide written information and will discuss confidentiality/privacy of client/patient-specific information as included in the client/patient rights and responsibilities. Client/patient records must contain signed release of information statements/forms when the organization bills a third party payer or shares information with others outside the organization as required by HIPAA and other applicable law and regulations.

Evidence: Client/Patient Records
Response to Interviews

Standard 111, Criterion D: The organization has Business Associate Contracts for all Business Associates that may have access to Protected Health Information as required by HIPAA and other applicable law and regulations.

Interpretation: A copy of all Business Associate Contracts will be on file at the organization.

Evidence: Business Associate Contracts

Standard 112: Written policies and procedures describe resuscitative guidelines and the responsibilities of staff.

Interpretation: The organization has written policies and procedures for staff responsibilities regarding client/patient resuscitation and the response in the event of a medical emergency. The policies must identify which staff, if any, may perform resuscitative measures, response to medical emergencies and utilization of "911" services (EMS) for emergencies. Successful completion of appropriate training, such as CPR course(s) must be defined in the policies and procedures. Clients/patients and families are provided information about the organization's policies for resuscitation, medical emergencies and accessing "911" services (EMS).

Evidence: Written Policies and Procedures
Response to Interviews
Patient Education Materials

Standard 113. The organization has written policies and procedures for the reporting of suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children in accordance with state law.

Standard 113, Criterion A: The written policies and procedures define and outline the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Written policies and procedures incorporate state law in relation to reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Written Policies and Procedures

Standard 113, Criterion B: All staff members are knowledgeable of the policy and procedure for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Interpretation: Personnel will be oriented and familiar with the process for reporting suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children.

Evidence: Employee Orientation Checklist
Response to Interviews

Standard 113, Criterion C: The organization will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the appropriate authorities.

Interpretation: All staff members are knowledgeable of and will report suspected abuse, neglect, or exploitation of clients/patients and suspected abuse or neglect of children to the designated organization staff member who is responsible for reporting to the appropriate authorities.

Evidence: Incident Reports
Response to Interviews

Standard 114. The organization has mechanisms in place to investigate and make recommendations on specific ethical concerns and issues related to client/patient service/care.

Standard 114, Criterion A: The organization has written policies and procedures that address identification, evaluation, and discussion of ethical issues.

Interpretation: The organization provides service/care within an ethical framework that is consistent with applicable professional and regulatory bodies. Written policies and procedures must address the mechanisms utilized to identify, address, and evaluate ethical issues in the organization.

Evidence: Written Policies and Procedures

Standard 114, Criterion B: All personnel are knowledgeable of the policy and procedure for reporting ethical concerns to the organization's management.

Interpretation: Orientation and annual training of personnel must include a list of potential ethical issues and the process to follow when an ethical issue is identified.
Personnel are trained regarding professional relationships, conflict of interest, and professional boundaries.

Evidence: Personnel Orientation Checklist
In-Service Records
Response to Interviews

Standard 115. The organization has mechanisms in place to provide service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Standard 115, Criterion A: The organization has written policies and procedures that address the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Written policies and procedures describe the mechanism the organization will utilize to communicate to clients/patient and families of different nationalities. The policies and procedures will also describe any actions expected for staff members providing service/care to clients/patients who have different cultural backgrounds and beliefs.

Evidence: Written Policies and Procedures

Standard 115, Criterion B: All personnel are knowledgeable of the written policy and procedure for the provision of service/care to clients/patients and families from various cultural backgrounds, beliefs, and languages.

Interpretation: Different cultural backgrounds and beliefs impact the client's/patient's lifestyles, habits, view of health, healing, terminal illness, and dying. Organization staff must identify differences in their own beliefs and the client's/patient's beliefs and find ways to support the client/patient. Staff members must make efforts to understand how the client/patient and family's cultural beliefs impact their perception of his illness approach to health and home care. If applicable, staff also considers the impact on end of life service/care issues, loss, and bereavement.

All staff members are provided with annual education and resources to increase their cultural awareness of the clients/patients/families they serve.

Evidence: Personnel Orientation Checklist
In-Service Training Records
Response to Interviews

Standard 116. The organization has a Compliance Program to prevent violations of the fraud and abuse laws.

Standard 116, Criterion A: There is an established Compliance Program and designates one or more individuals in leadership positions to address compliance issues.

Interpretation: The organization will have an established Compliance Program that provides both general and specific guidance as to various internal anti-fraud and abuse controls. The Compliance Program identifies and discusses numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program must detail actions the organizations must take to prevent violations of the fraud and abuse laws. The guidelines include the following: (1) implementation of written policies, procedures, and standards of conduct; (2) designation of a compliance officer and compliance committee; (3) conducting effective training and education programs; (4) development of open lines of communication between the compliance officer or compliance committee and organization employees for receiving complaints and protecting callers from retaliation; (5) performance of internal audits to monitor compliance; (6) establishing and publicizing disciplinary guidelines for failing to comply with organization standards and policies and applicable statutes and regulations; and (7) prompt response to detected offenses through corrective action.

Evidence:
- Written Policies and Procedures
- Compliance Plan
- Internal Audits
- Quality Improvement Activities
- Orientation and In-Service Education Records
- Response to Interviews

SECTION 200: FINANCIAL MANAGEMENT

Standard 201. There is an annual budget that includes all projected revenue and expenses for the organization's programs.

Standard 201, Criterion A: The organization has written policies and procedures that address the budgeting process. The organization's annual budget is developed by the governing body/owner.

Interpretation: The organization has a budget that includes projected revenue and expenses for all programs and service/care it provides. The budget is reflective of the organization's service/care, strategic plan, and programs.

The organization's leaders and the individuals in charge of the day-to-day program operations must be involved in developing the budget and in planning and review of periodic comparisons of actual and projected expenses and revenues for the service/care.

Evidence: Written Policies and Procedures
Copy of Current Annual Budget

Standard 201, Criterion B: The budget is reviewed and updated at least annually by the governing body and leadership staff of the organization.

Evidence: Copy of Annual Budget(s)
Response to Interviews

Standard 202. Fiscal policies and procedures describe activities to ensure sound business practices for program service/care operations.

Standard 202, Criterion A: There are written policies and procedures, which ensure sound business practices.

Interpretation: There must be written policies and procedures that address each of the following: (1) receipt and tracking of revenue; (2) billing of clients/patients/transmission to third party payers; (3) notification to the client/patient/family of changes in reimbursement from third party payers; (4) collection of accounts/reconciliation of accounts; (5) extension of credit; (6) consequences of non-payment, if applicable; (7) acceptance of gifts and/or restricted funds, if applicable; (8) process for receiving, recording and acknowledging mailed contributions, if applicable; and (9) assignment of revenue to the appropriate program. An organization which does not extend credit must state that there is no extension of credit and specify procedures for dealing with non-payment and partial payment situations.

Evidence: Written Policies and Procedures

Standard 202, Criterion B: There is an accounting system that tracks all revenue and expenses and reconciled charges to beneficiaries for equipment, supplies, and services with invoices, receipts, and deposits.

Interpretation: Organizations must have an accounting system or process that tracks all revenue and expenses.

A large, multi-faceted organization is not required to maintain a separate accounting system for the service/care program(s) being accredited.

Evidence: Accounting System

Standard 202, Criterion C: Financial hardship forms are completed if client/patient is unable to pay.

Interpretation: Appropriate documentation is completed if a client/patient is unable to pay.

Evidence: Client/Patient Records

Standard 203. The organization establishes the necessary time frames for keeping financial records.

Standard 203, Criterion A: All financial records are kept for the time frames described in financial record management policies and procedures and in compliance with regulatory standards.

Interpretation: Written policies and procedures reflect applicable statutes, IRS regulations, and/or Medicare/Medicaid program service/care requirements of maintaining financial records for at least five years after the last audited cost report.

Evidence: Written Policies and Procedures

Standard 204. There are written policies and procedures that require established rates for all program service/care and define methods for providing full reimbursement disclosure to the client/patient or other interested parties.

Standard 204, Criterion A: Written policies and procedures require established service/care rates and describe the method(s) for conveying charges to the public, consumers, and referral sources.

Interpretation: There are written policies and procedures for establishing and conveying the charges for the products and services/care provided to clients/patients. Written charges for services/care are available upon request.

Evidence: Written Policies and Procedures
A list of Services/Care with Corresponding Charges

Standard 204, Criterion B: All staff members responsible for conveying charges are knowledgeable of the policy and procedure.

Interpretation: Current charges for services/care are available in writing for reference by employees when conveying information to the client/patient, public, consumers, and referral sources.

All staff members responsible for conveying charges are oriented and provided with education concerning the conveying of charges.

Evidence: Orientation Checklist
Response to Interviews

Standard 204, Criterion C: The client/patient and/or responsible party is advised orally and in writing of the charges for service/care at or prior to the receipt of services. The client/patient also has the right to be informed of changes in payment information no later than 30 days after the agency becomes aware of the change. Patients that are Medicare eligible are informed when Medicare assignment is accepted.

Interpretation: The client/patient/responsible party will be provided written information concerning the charges for service/care at or prior to the receipt of service/care. Client/patient records contain written documentation that the client/patient was informed of the charges, the expected reimbursement for third party payers, and the financial responsibility of the client/patient.

Evidence: Client/Patient Records
Response to Interviews

Standard 204, Criterion D: There are criteria for the use of sliding fee scale.

Note: This criterion is required for organizations that utilize a sliding scale fee.

Interpretation: If the organization utilizes a sliding scale fee, there must be written criteria for determining eligibility for adjusted rates and methods used to determine the rate the client/patient would be expected to pay for service/care.

Evidence: Written Criteria for utilizing the Sliding Fee Scale

SECTION 300: HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Direct service/care personnel include anyone who has direct responsibility for client/patient/family service/care, including, but not limited to: contract personnel, delivery technicians, respiratory care practitioners, pharmacists, clinical supervisors, fitters, rehab tech supplies, and case managers.

Standard 301. There are written personnel policies and procedures describing the activities related to personnel management.

Standard 301, Criterion A: There are written policies and procedures that describe personnel policy management and the review of personnel policies.

Interpretation: Personnel policies must address: (1) wages; (2) benefits; (3) grievances; (4) recruitment, hiring and retention of personnel; (5) disciplinary action/termination of employment; (6) staff conflict of interest; and (7) performance expectations and evaluations. Personnel policies are reviewed at least annually and updated as needed and are in accordance with applicable law and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

It is preferred that wage information be available in the form of salary scales, with information about beginning salaries for each position classification, salary ranges, overtime, on-call and holiday pay.

An explanation of benefits must be shared with all benefit eligible employees. Organizations, which provide no benefits to some categories of employees, must communicate this fact in writing to affected employees. For example, the contract/agreement with home care staff who is utilized on an "as needed" basis may address that benefits are not available to persons employed in that classification.

Written grievance information must address options available to employees who have work-related complaints, including steps involved in the grievance procedure.

Disciplinary action and termination of employment policies must clearly define time frames for probationary actions, conditions warranting termination, steps in the termination process, and appeal procedures.

Evidence: Written Policies and Procedures and/or Employee Handbook
Response to Interviews

Standard 301, Criterion B: Personnel policies are accessible to employees.

Interpretation: Each employee must receive a copy of the company employee handbook or copies of all personnel policies. Any employee handbook and all personnel policies are reviewed at least annually and updated as needed.

Evidence: Employee Handbook and/or Personnel Policies
Personnel Files
Response to Interviews

Standard 302. There is a job description for each position within the organization.

Standard 302, Criterion A: There is a job description for each position within the organization which is consistent with the organization chart with respect to function and reporting responsibilities.

Interpretation: The job description lists: (1) job duties; (2) reporting responsibilities; (3) minimum job qualifications, experience requirements, education, and training; (4) requirements for the job; and (5) physical and environmental requirements with or without reasonable accommodation. If the owner is not involved in day to day operations, then that individual does not need a job description.

Written job descriptions are reviewed at least annually and updated as needed.

The organization's job descriptions are consistent with the organization chart with respect to function and reporting responsibilities.

Evidence: Job Descriptions
Organization Chart

Standard 302, Criterion B: Each employee reviews and/or receives a copy of their current job description upon hire and whenever the job description changes.

Interpretation: Receipt and/or review of the job description with the employee is a necessary part of the orientation process and must be repeated during the annual performance evaluation and whenever the job description changes. The organization will verify the receipt and review by giving each employee a copy of the job description and requiring the employee to sign a copy of the job description and placing it in the employee's personnel file.

Evidence: Personnel Files
Response to Interviews

Standard 303. Employees are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the organization.

Standard 303, Criterion A: Written policies and procedures describe the activities required to verify education, training, and experience when selecting a new employee.

Interpretation: Persons hired for specific positions within the organization must meet the minimum qualifications for those positions in accordance with applicable laws or regulations, as well as the organization's policies and the job description.

Prior education, training, and experience will be verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, licenses, certificates, and workshop attendance records.

Evidence: Written Policies and Procedures
Personnel Files
Job Descriptions

Standard 303, Criterion B: All new employee qualifications will be reviewed through previous employer reference checks.

Interpretation: At least two references will be obtained prior to hire. All employer references will address position held, dates of employment and eligibility for rehire if the reference is allowed to disclose this information. In the case of an applicant with no previous work experience, educational or personal references may be accepted. In the case of an applicant who was a prior employee of the organization, the applicant's previous employment history may serve as their reference.

While written reference checks are preferred, documentation of telephone references is acceptable.

Evidence: Personnel Files

Standard 303, Criterion C: Personnel credentialing activities are conducted at the time of hiring and annually to verify qualifications of all credentialed/licensed staff in the positions they hold.

Interpretation: The personnel file or other employee records will contain validation that credentialing information is obtained on an annual basis. Credentialing information includes a procedure for the review of professional occupational licensure, certification, registration or other training as required by state boards and/or professional associations for continued credentialing.

Evidence: Personnel Files

Standard 304. Employees will have appropriate TB screening, Hepatitis B vaccination or declination, a valid driver's license, and a criminal background check.

Standard 304, Criterion A: TB screening or verification that the employee is free of symptoms will be mandatory for direct care employees.

Interpretation: Tuberculin skin testing (PPD) must be performed on all direct care staff as recommended by CDC and OSHA guidelines based upon community and company TB incidence and prevalence rates. The organization's written policy and procedure must describe this process. Direct Care employees are employees that deliver equipment or provide care or service inside the home or face to face in a facility.

Evidence: Written Policies and Procedures
Personnel Files or other Confidential Employee Records

Standard 304, Criterion B: All direct care personnel will have access to Hepatitis B vaccine as each job classification indicates and as described in federal CDC and OSHA standards.

Interpretation: Hepatitis B vaccination program and post-vaccination antibody titer must be performed in accordance with CDC and OSHA guidelines. Employees must sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.

The following are circumstances under which an employer is exempted from making the vaccination available: (a) the complete Hepatitis B vaccination series was previously received; (b) antibody testing shows the employee to be immune; or (c) the vaccine cannot be given to the individual for medical reasons or the individual cannot receive antibody testing.

Evidence: Personnel Files or other Confidential Employee Records

Standard 304, Criterion C: All personnel, who are required to operate a motor vehicle in the course of their duties, are required to have a valid state driver's license appropriate to the type of vehicle being operated in compliance with state laws and the organization's policies.

Interpretation: Evidence of valid drivers' licenses must be kept in personnel files, along with record of all inquiries made on individual driving records (MVR) through the State Department of Motor Vehicles. The organization must conduct a MVR check on each staff member who is required to operate a motor vehicle in the course of his/her duties at the time of hire. It is preferred that the organization recheck the MVR at least every 3 years to insure the driving records of the staff member are clear of violations that may be of concern to the organization. Copies of valid Commercial Drivers License (CDL), HAZMAT Endorsement and valid DOT physicals must be kept on file for employees that require CDL's.

Evidence: Personnel Files

Standard 304, Criterion D: The organization must carry an appropriate amount of vehicle insurance when required to operate a motor vehicle in the course of their duties and in compliance with state laws and the organization's policies.

Interpretation: The organization must carry an appropriate amount of insurance on all company vehicles. The organization's insurance carrier will instruct the company on what is an appropriate amount of insurance based on risk assessments.

Evidence: Written Policy and Procedures
Personnel Files
Company Vehicle Insurance Documents

Standard 304, Criterion E: All personnel providing direct client/patient service/care will have a criminal record background check.

Interpretation: The organization must perform a criminal background check and a national sex offender registry check, at the time of hire, for each employee providing direct client/patient's service/care.

The organization must have a policy regarding special circumstances, if any, for hire of a person convicted of a crime. The policy may include, but not be limited to: documentation of special considerations, restrictions, or additional supervision.

Evidence: Written Policies and Procedures
Personnel Files

Standard 305. The organization maintains a personnel file for each employee.

Standard 305, Criterion A: Written policies and procedures describe the procedures to be used in the management of personnel files and confidential records for each employee.

Interpretation: Written policies and procedures will describe: (1) employee positions having access to the personnel file; (2) proper storage; (3) the required contents; (4) review requirements; and (5) time frames for retention of personnel files.

The organization maintains a personnel file for each employee that will contain, at a minimum, an application, dated, and signed withholding statements, verification of citizenship status, and all other items noted in the standards/criterions.

The organization is required to have complete personnel records available for inspection by federal, state regulatory agencies and accreditation agencies.

Evidence: Written Policies and Procedures
Personnel Files

Standard 306. The organization assures that all employees receive orientation.

Standard 306, Criterion A: The organization has a written orientation plan for all new employees.

Interpretation: The written orientation plan must include the following, at a minimum: (1) review of the individual's job description and duties to be performed and their role in the organization; (2) organization chart/supervision; (3) mission/philosophy; (4) record keeping and reporting; (5) confidentiality and privacy of protected health information; (6) client/patient's rights; (7) conflict of interest; (8) written policies and procedures; (9) training specific to job requirements; (10) additional training for special populations (i.e.: nursing homes, pediatrics, disease processes with specialized care); (11) cultural diversity; (12) ethical issues; (13) professional boundaries; (14) quality improvement plan; and (15) OSHA requirements, safety and infection control.

The organization must have a checklist or other method to verify that the topics have been discussed with individual workers; and written policies and procedures describing the orientation process.

Evidence: Written Policies and Procedures
Orientation Checklist/Orientation Plan

Standard 306, Criterion B: The organization will designate trained personnel responsible for conducting orientation activities.

Interpretation: The orientation process includes a description of position(s)/qualifications representing trained personnel responsible for conducting orientation activities.

Evidence: Written Policies and Procedures and/or Job Description

Standard 306, Criterion C: All staff members participate in an orientation program appropriate to the classification of the employee and the service/care he/she will provide prior to assuming client/patient responsibilities.

Interpretation: Orientation is conducted with all staff and volunteers prior to their assuming client/patient service/care responsibilities. Staff members are oriented to their specific client/patient assignments.

The orientation is documented in the personnel files for all staff members and volunteers.

Evidence: Orientation Checklist or other Documentation of Attendance
Personnel Files

Response to Interviews

Standard 307. The organization assures that all employees receive training and/or demonstrate competence appropriate to job requirements.

Knowledge and skills can be acquired through a variety of methods such as classroom instruction, on-the-job observation and demonstration, self-instruction, internships, etc. The focus and type of training is directly related to the goals of the employee and/or the organization.

Standard 307, Criterion A: The organization assures that all staff members have received training and/or education and can competently perform the required client/patient service/care activities prior to being assigned to work independently.

Interpretation: The organization's written policies must define the minimum education and training, licensure, certification, experience, and the minimum competencies, required for each service/care offered, as well as the method for documenting that personnel have received the required training (i.e. certificates, diplomas, etc).

The organization designs and implements a competency assessment program based on the service/care provided. Competency assessment must be an ongoing process and focus on the primary service/care, and/or therapies being provided. Competency assessment is conducted initially during orientation and annually thereafter. Validation of skills is specific to the staff member's job responsibilities.

Procedures for determining that staff are competent to provide quality service/care must be in place and may be accomplished through observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment. All competency assessments and training must be sufficiently documented. A self-assessment tool alone is not acceptable. Peer review of clinical staff competency by like disciplines will be acceptable if defined by the organization. There must be a plan in place for addressing performance and education of staff when staff does not meet competency requirements.

Evidence: Written Policies and Procedures
Evidence of Competency Assessment
Response to Interviews

Standard 307, Criterion B: Staff members are trained and/or have demonstrated competence to perform any new tasks/procedures prior to performing those tasks independently. Direct care staff are not allowed to perform any task for which they have been evaluated as unsatisfactory.

Interpretation: The organization has a process that assures that each direct service staff member has demonstrated competency in any new task before being assigned to that task. The organization also has a process to ensure that staff have been proven competent to perform task(s) after re-training has been provided.

Evidence: Written Policies and Procedures
Evidence of Competency Assessment for New Tasks/Procedures
Response to Interviews

Standard 308. The organization implements an education plan for all personnel.

Standard 308, Criterion A: The organization has an in-service education plan that provides ongoing in-service education for all staff members.

Interpretation: In-service education refers to ongoing training provided by the employer to develop and maintain skills necessary for all staff members to perform their current job responsibilities. Organizations may provide this training directly or arrange for staff to attend sessions offered by outside sources. The in-service education plan is a written document that may outline program topics to be offered or designate how program topics will be identified for personnel throughout the year. The plan must be based on reliable and valid assessment of needs relevant to individual job responsibilities. Ongoing education activities include methods for obtaining information about staff learning needs, outcome data from competency assessments, and staff input about the effectiveness of the in-services provided. Education activities also include a variety of methods for providing staff with current relevant information to assist with their learning needs. These methods include provision of journals, reference materials, books, internet learning, in house lectures and demonstrations, and access to external learning opportunities.

All staff are required to have continuing education hours. The organization must have a written policy defining the number of hours of in-service or continuing education required for each classification of personnel. It is preferred that organizations encourage supervisors to attend in-service education programs to improve their supervisory skills. The organization must comply with all professional or occupational licensure laws for continuing education requirements and organization policy requirements regarding continuing education.

There is written documentation confirming attendance at in-service and/or continuing education programs.

As applicable, education programs must be designed to assist staff with work related issues of grief, loss and change, and pain and symptom management.

Evidence: Written Policies and Procedures
Documentation of In-service Education Programs and Attendance
Documentation of Staff Attendance at Continuing Education Programs
Response to Interviews

Standard 309. Qualified personnel evaluate all staff members.

Standard 309, Criterion A: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at least annually and in accordance with state or federal regulations. All patient care is provided in compliance with professional standards and principals.

Interpretation: Qualified personnel observe and evaluate each direct service/care staff performing their job duties at frequencies required by state or federal regulations. Industry principles and professional standards also used to determine appropriate staffing and care. If no regulation exists the evaluation must be performed at least once annually to assess that quality service/care are being provided. This activity may be performed as part of a supervisory visit. Written policies and procedures must define assessment items/standards. The evaluation(s) shall become part of the personnel record.

Evidence: Written Policies and Procedures
Personnel Files

Standard 309, Criterion B: Written annual performance evaluations are completed for all personnel based on specific job descriptions.

Interpretation: The organization has written policies and procedures addressing individual performance evaluations for all staff and/or volunteers. These policies describe how performance evaluations are conducted, who conducts them, and when they are to be conducted. The policy must also identify any deviations to their policy, i.e. if the organization's annual evaluation serves as the performance evaluation for the leader(s)/executive(s) of the organization. Evaluations involve both the supervisor and the individual in rating work performance based on performance criteria for their specific job description.

Annual performance evaluations are required for part-time staff members that have worked for six months or longer in a year.

Evidence: Written Policies and Procedures
Personnel Files

Standard 309, Criterion C: The results of annual performance evaluations are shared with personnel.

Interpretation: A copy of the performance evaluation must be reviewed by the employee and signed by the individual performing the evaluation and the employee. Performance evaluation results must be shared with the employee by a face-to-face conference with the supervisor.

Evidence: Personnel Files
Response to Interviews

Standard 309, Criterion D: Action is taken when negative client/patient outcomes are directly related to staff performance.

Interpretation: An assessment is completed to determine the best course of action when negative client/patient outcomes are experienced due to staff performance. Based on this assessment, actions may include remedial training of the staff, reassignment of the staff, or limitation of the staff's involvement in client/patient service/care or other appropriate actions. The actions taken must be documented in personnel records, variance reports or other appropriate documents.

Evidence: Organization Documentation
Personnel Files
Response to Interviews

Standard 310. Written contracts and/or agreements govern the components of services/care that are purchased from another entity resulting in shared responsibility for service/care delivery.

Note: This criterion is applicable to organizations that have contracts/agreements for shared responsibility components.

Standard 310, Criterion A: Written contracts/agreements are on file within the organization.

Interpretation: A contract or agreement is required whenever the organization sells or purchases services, personnel, training, or supervision from another organization/individual for direct or indirect client/patient service/care on an on-going or individual client/patient basis.

Evidence: Written Contracts and/or Agreements

Standard 310, Criterion B: Service/care contracts/agreements are reviewed and renewed as required in the contract.

Interpretation: The organization has an established process to review and renew contract/agreements as required in the contract. A mechanism to indicate that the review and or renewal have been accomplished may be evidenced by either a notation of the review dates on the initial contract/agreement or development of an updated contract/agreement.

Evidence: Written Contracts and/or Agreements

Standard 310, Criterion C: There are copies of professional liability insurance certificates of coverage on file for any personnel providing direct service/care and/or organizations providing shared responsibility service/care.

Interpretation: The organization maintains current copies of professional liability insurance certificates of coverage for all personnel providing direct service/care and/or organizations providing shared responsibility service/care. The certificates should be maintained with the respective contract.

Evidence: Copies of current Insurance Certificates confirming liability coverage

Standard 310, Criterion D: Contracts/agreements contain the required items.

Interpretation: The following items must be included in the contract/agreement: (1) Name and type of service/care to be provided; (2) duration of contract/agreement; (3) responsibilities of each organization; (4) the manner in which service/care will be controlled; coordinated, and evaluated by the primary organization; (5) the amount and procedures for payment for service/care furnished under the contract; (6) compliance with all organization policies including applicable personnel policies; (7) requirements to meet Medicare Conditions of Participation; if applicable, (8) overall responsibility for supervision of staff, if applicable and (9) other applicable law and regulations.

Evidence: Written Contracts and/or Agreements

SECTION 400: CONSUMER SERVICES/RECORDS

Standard 401. An accurate record is maintained for each client/patient.

Standard 401, Criterion A: The organization has written policies and procedures relating to the required contents of client/patient records.

Interpretation: The organization's written policies and procedures must define the required contents of the client/patient records the organization maintains. The contents must include, but are not limited to the following: (1) identification data; (2) emergency contact; (3) name of primary caregiver(s); (4) source of referral; (5) name of physician responsible for care; (6) diagnosis; (7) physician's orders; (8) signed release of information and other documents for protected health information; (9) admission and informed consent documents; (10) assessment of the home, if applicable; (11) initial assessments, if applicable (12) ongoing assessments, if applicable. A separate record must be kept for each client.

For programs providing clinical service/care (i.e.: Clinical Respiratory Care), the client/patient record must also include: (13) advance directives; (14) names of power of attorney and/or healthcare power of attorney; (15) evidence of coordination of service/care provided by the organization with others who may be providing service/care; (16) physician orders that include medications and dietary, treatment and activity orders; (17) signed and dated clinical and progress notes; (18) copies of summary reports sent to physicians; (19) client/patient/family response to service/care provided; and (20) a discharge summary, if applicable.

Evidence: Written Policies and Procedures

Standard 401, Criterion B: Written policies and procedures address access, storage, removal, and retention of client/patient records and information.

Interpretation: Organizational policies must be consistent with HIPAA standards. Policies must define who can have access to client/patient records, including persons authorized to enter information and review the records. Original copies of all active client/patient records must be kept in a secure location on the organization's premises. Current electronic client/patient records must be stored in an appropriate secure manner as to maintain the integrity of the client/patient data through routine backups on or off site. The organization's policies specify any circumstances and the procedure to be followed to remove client/patient records from the premises or designated electronic storage areas. Policies describe the protection and access of computerized records and information, including back-up procedures, electronic transmission procedures, storage of back-up disks and tapes and methods to replace information if necessary.

Clinical record information is safeguarded against loss of unauthorized use. An organization must have written consent from the patient to release information not authorized by law. Written procedures govern use and removal of records and the conditions for release of information.

All client/patient records must be maintained in accordance with all applicable state and federal laws and rules.

Portions of client/patient records may be copied and removed from the licensed premises to ensure that appropriate service/care staff will have information readily accessible to them to enable them to provide the appropriate level of service/care.

Evidence: Written Policies and Procedures

Standard 401, Criterion C: Client/patient records contain documentation of all service/care provided with entries dated and signed.

Interpretation: The client/patient record must contain documentation of all service/care provided, directly or by contract, with entries dated and signed by the appropriate staff member. Each home visit, treatment, or service/care must be documented in the record and signed by the individual who provided the service/care. Signatures must be legible, legal and include the proper designation of any credentials.

Evidence: Client/Patient Records

Standard 402. There is a process for client/patient referral and acceptance.

Standard 402, Criterion A: There are written policies and procedures, which describe the referral process.

Interpretation: Written policies and procedures describe the referral process including the required referral information. Written policies and procedures designate the positions in the organization that may receive referrals.

Referrals containing verbal orders must be given by the referring physician, by others approved by law to prescribe, or the individual directly designated to convey orders and will be referred to a designated staff member(s) for verification and documentation of verbal orders.

Evidence: Written Policies and Procedures

Standard 402, Criterion B: There are written policies and procedures for service/care guidelines, which define eligibility for all service/care and programs.

Interpretation: There are written policies and procedures that designates the staff member(s) that are assigned to assess the level and type of service/care required by clients/patients referred to the organization, and determine whether the client/patient is eligible for admission based on the organization's criteria and availability of service/care to meet the client/patient's needs.

Eligibility guidelines must identify the following: (1) target population(s); (2) geographic area served; (3) service/care limitations; and (4) method of payment. Eligibility guidelines may vary for different service/care programs. Eligibility criteria are periodically reviewed for appropriateness and continued accessibility to the organization's programs. Specialized populations may be defined generally as anyone needing the service/care, or in some cases, may be defined by special funding sources, specific ages (elderly, infants, children, etc.), special service/care needs (medical care, homemaking, personal care, etc.), or specific diseases/disabilities (Alzheimer's, arthritis, etc.). The organization shall identify the geographic area served.

Service/care may have limitations such as client/patient-related restrictions (provided only to ambulatory patients, provided only when client/patient cannot perform personal care tasks independently, limited life expectancy, availability of a responsible caregiver, safety restrictions etc.), or organization-related restrictions (ability of staff, hours of operation, etc.). Policies describe eligibility guidelines and procedures to follow for clients/patients who have no ability to pay for service/care.

Evidence: Written Policies and Procedures

Standard 402, Criterion C: There are written policies and procedures that address the organization's compliance with federal, state, and local anti-discrimination laws in the acceptance of clients/patients.

Interpretation: There must written policies and procedures verifying the organization's intent to abide by anti-discrimination legislation which must include, but not be limited to the following: age, race, nationality, creed, sex, sexual orientation, diagnosis/infectious disease, disability, ability to pay, and DNR status.

Evidence: Written Policies and Procedures

Standard 402, Criterion D: Client/patient records and other sources provide verification that the clients/patients receiving service/care meet eligibility requirements.

Interpretation: Client/patient records and other sources provide verification that clients/patients receiving service/care meet eligibility requirements.

Evidence: Client/Patient Records

Standard 402, Criterion E: Client/patient is provided with information regarding expected time frames for delivery of equipment.

Interpretation: Clients/patient's notified at time of referral when equipment/supplies will be delivered.

Evidence: Client/Patient Record

Standard 403. The organization coordinates planning and service/care delivery efforts with other community agencies.

Standard 403, Criterion A: There are written policies and procedures for addressing client/patient needs, which cannot be met by the organization. Clients/patients are referred to other agencies when appropriate. The prescribing physician and/or referral source is notified within 3 days if the equipment or services ordered cannot be provided.

Interpretation: Service/care needs which cannot be met by the organization will be addressed by referring the client/patient to other organizations when appropriate. Client/patient records or referral or intake forms must indicate a referral was made to another organization or communication was provided to the physician or referral source when client/patient needs could not be met.

Evidence: Written Policies and Procedures
Client/Patient Records or Referral Log or Intake Form

Standard 403, Criterion B: All staff members are knowledgeable about other service/care available in the community.

Interpretation: All staff members are aware of other community service/care and make an effort to work cooperatively with these organizations to promote a full range of home and community based service/care options in the communities served. Service/care needs, either identified by staff, referring physicians, or requested by clients/patients/families/responsible party, which cannot be met by the organization will be addressed by referring the client/patient/family to other community agencies.

Evidence: Client/Patient Records
Response to Interviews

SECTION 500: QI/Performance Management

Standard 501. There is organizational participation and involvement in quality improvement activities by all staff members.

Standard 501, Criterion A: The organization ensures the implementation of a quality outcome/improvement plan by the designation of a person or persons responsible for quality improvement coordination activities.

Interpretation: Duties and responsibilities relative to QI coordination include: assisting with the overall development and implementation of the QI plan; assisting in the identification of goals and related client/patient outcomes; and coordinating, participating, and reporting of activities and outcomes results.

The individual(s) responsible for quality improvement coordination activities may also be the owner, manager, supervisor, or other organization employee.

Evidence: Job Description

Standard 501, Criterion B: There is evidence of involvement of the governing body/owner.

Interpretation: The governing body and leaders are ultimately responsible for all actions and activities of the organization; therefore, their role in the evaluation process and the responsibilities delegated to staff must be clearly documented. There must be evidence that the results of quality improvement activities are communicated to the governing body and organizational leaders.

The organization's leaders allocate resources for implementation of the quality improvement program. Resources may include but are not limited to training and education programs regarding quality improvement, staff time, information management systems, and computer programs.

Evidence: Response to Interviews
Meeting Minutes

Standard 501, Criterion C: There is evidence of staff involvement in the quality improvement process.

Interpretation: Personnel will receive training related to quality improvement activities and their involvement. Training may include, but not be limited to, the purpose of quality improvement activities, person(s) responsible for coordinating quality improvement activities, the staff's individual role in quality improvement, and performance improvement outcomes resulting from previous activities.

The staff must be involved in the evaluation process through carrying out quality assessment activities, evaluating findings, recommending action plans, and/or receiving reports of findings. Staff must be informed of results of quality improvement activities that directly impact or reflect the service/care they provide.

Evidence: Minutes of Staff Meetings
Response to Interviews

Standard 502. There is a quality improvement program that includes all quality aspects of the program and service/care provided.

Standard 502, Criterion A: Quality improvement activities must include an annual evaluation of the program service/care.

Interpretation: An annual evaluation is a process that measures the organization's performance in relation to its mission, philosophy, goals and objectives and in meeting the needs of the clients/patients and communities served. As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote quality patient care. The annual evaluation is summarized in a written report which includes: (1) the effectiveness of the quality improvement program; (2) the effectiveness, quality and appropriateness of service/care provided to the clients/patients, service/care areas and community served, including culturally diverse populations; (3) effectiveness of the overall administrative and fiscal operations; (4) effectiveness of all programs including service/care provided under contractual arrangements; (5) utilization of staff; and (6) review and revision of policies and procedures, and forms used by the organization.

Evidence: Annual Program Evaluation

Standard 502, Criterion B: The organization investigates all adverse events.

Interpretation: The organization investigates all adverse events and develops a plan of correction to prevent the same or similar events from occurring again.

Adverse events include but are not limited to: (1) unexpected death, including suicide of client/patient/caregiver; (2) any act of violence, including rape of staff and/or client/patient/caregiver; (3) a serious injury (specifically includes loss of limb or function); (4) inadequate or malfunctioning equipment; (5) adverse effect to patient/client as a result of untimely delivery

Evidence: Adverse Event Reports and Action Plans

Standard 502, Criterion C: Quality improvement activities must include ongoing monitoring of at least one important aspect related to the service/care provided.

Interpretation: The organization must conduct monitoring of at least one important aspect of the service/care provided by the organization. An important aspect of service/care reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of clients/patients), high risk (causes a risk of serious consequences if the service/care is not provided correctly), or problem-prone (has tended to cause problems for staff or clients/patients in the past.)

Examples of activities may include, but not be limited to: delivery of service/care (timeliness, incorrect product deliveries, etc.), medication administration, and clinical procedures.

Evidence: Quality Improvement Reports

Standard 502, Criterion D: Quality improvement activities must include ongoing monitoring of billing and coding errors.

Interpretation: The organization tracks the number of billing inconsistencies found through chart reviews as well as errors found through Medicare claims denied.

Evidence: Quality Improvement Reports

Standard 502, Criterion E: Quality improvement activities must include satisfaction surveys.

Interpretation: The QI plan identifies the process for conducting client/patient satisfaction surveys. The QI plan also identifies the process for conducting staff, physician, and referral source satisfaction surveys.

Evidence: Quality Improvement Reports

Standard 502, Criterion F: The quality improvement plan includes a review of the client/patient record.

Interpretation: The client/patient record review is conducted by all disciplines or members of the client/patient service/care team. An adequate sampling of open and closed records is selected to determine the completeness of documentation.

Evidence: Quality Improvement Reports

Standard 502, Criterion G: QI activities include ongoing monitoring of patient complaints about products and/or services.

Interpretation: QI activities include ongoing monitoring of patient complaints and the action(s) needed to resolve complaints and improve client/patient service/care.

Evidence: Quality Improvement Reports
Complaint logs

Standard 503. The organization uses appropriate methods to collect data and monitor performance.

Standard 503, Criterion A: Each quality improvement activity or study contains the required items.

Interpretation: Each quality improvement activity/study must include the following items: (1) a description of indicator(s)/activities to be conducted; (2) frequency of activities; (3) designation of who is responsible for conducting the activities; (4) methods of data collection; (5) acceptable limits for findings; (6) who will receive the reports; and (7) plans to re-evaluate if findings fail to meet acceptable limits in addition to any other activities required under state or federal laws or regulations.

Evidence: Quality Improvement Activities/Studies

Standard 504. Information gained from the quality improvement activities and evaluation is

utilized by the organization.

Standard 504, Criterion A: There is a written plan of correction developed in response to any quality improvement findings that do not meet an acceptable threshold.

Interpretation: A written plan of correction is developed in response to any quality improvement activity that does not meet an acceptable threshold. The plan of correction may identify changes in policy, procedure, or processes that will improve performance.

The plan of correction may require governing body action or approval or may be within the scope of authority already delegated to organization staff.

Evidence: Written Corrective Action Plans

Standard 504, Criterion B: Plans of correction indicates changes or revisions in the service/care, policies, and/or procedures.

Interpretation: A written summary describes changes made as part of a corrective action plan. This summary may be found as a separate document, as part of the minutes of governing body meetings, or as part of quality assessment reports.

Evidence: Quality Improvement Reports
Minutes of Governing Body Meetings

SECTION 600: PRODUCT SAFETY

Standard 601. The organization has a program designed to identify, prevent, and control infections.

Standard 601, Criterion A: The organization has written policies and procedures that address infection control and the compliance with regulatory standards.

Interpretation: Written policies and procedures, in accordance with CDC, Health Department, APIC (Association for Professionals in Infection Control Epidemiology) and OSHA standards, address education of staff, volunteers, clients/patients and caregivers about: (1) general infection control measures appropriate for service/care provided; (2) hand washing; (3) use of universal precautions and personal protective equipment; (4) needle-stick prevention and safety plan; if applicable (5) appropriate cleaning/disinfecting procedures; (6) infection surveillance, monitoring and reporting of employees and clients/patients; (7) disposal and transportation of regulated waste, if applicable; (8) precautions to protect immune-compromised clients/patients; (9) employee health conditions limiting their activities; and (10) assessment and utilization of data obtained about infections and the infection control program.

The organization has written policies and procedures that detail OSHA Blood borne Pathogen and TB Exposure Control Plan training for all direct care staff. The exposure control plans must be reviewed annually and updated to reflect significant modification in tasks or procedures that may result in occupational exposure. The Exposure Control Plan must include engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent, i.e. use of safer medical devices, and appropriate respiratory protection devices. A copy of the plans must be made available to the employee at the workplace during the work shift.

The TB Exposure Control plan must include a current organization assessment indicating the community and company TB incidence and prevalence rates as recommended by CDC guidelines.

Written policies and procedures identify the staff member who has the responsibility for the implementation of the infection control activities, and staff education.

Written policies and procedures describe the conditions limiting the employee's assignments to office or home. Examples may be impetigo, communicable disease, fevers, respiratory diseases, etc.

Evidence: Written Policies and Procedures
Observation
Home Visits

Standard 601, Criterion B: All staff members, clients/patients, and caregivers are knowledgeable of the policies and procedures for infection control.

Interpretation: The organization must ensure staff members, volunteers, clients/patients and caregivers receive instruction about basic and high-risk infection control procedures as appropriate to the services/care provided. Training is consistent with OSHA and CDC recommendations: Clinical staff must provide infection control instructions to the client/patient/family and caregivers.

Evidence: Orientation Records
In-Service Education Records
Personnel Files
Response to Interviews

Standard 601, Criterion C: All staff members and volunteers must consistently follow infection control procedures in the provision of service/care to the organization's clients/patients.

Interpretation: All staff members and volunteers demonstrate infection control procedures in the process of providing service/care to clients/patients as described in OSHA and CDC standards and as adopted into program service/care policies and procedures.

Evidence: Observation

Standard 602. The organization has a system designed to identify, prevent, and control safety hazards related to the service/care provided to the client/patient.

Standard 602, Criterion A: The organization has written policies and procedures that address safety issues relating to service/care provision and education of staff members concerning safety.
Interpretation: Written policies and procedures must include types of safety training as well as the frequency of training. Safety training is included at orientation and ongoing training. Safety training activities may include but not be limited to: (1) body mechanics; (2) workplace fire safety management and evacuation plan; (3) workplace or office security; (4) personal safety techniques; (5) common environmental hazards, (i.e. icy parking areas and walkways, blocked exits, cluttered stairways, etc.); (6) office equipment safety; and (7) safety and compliance monitoring measures relating to the client/patient's medication, when applicable.

For programs providing in-home service/care, the safety training activities may also include: (1) personal safety techniques relating to in home service/care; (2) safety measures relating to oxygen use, if applicable; (3) client/patient medical equipment safety; if applicable (4) basic home safety measures (i.e., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits, bathroom safety, electrical safety, etc.); and (5) use of restraints, if applicable.

Evidence: Written Policies and Procedures

Standard 602, Criterion B: The organization educates all personnel about safety issues relating to service/care provision.

Interpretation: The organization has a process in place to educate personnel about home and work place safety measures. Safety measures address building safety and security, staff safety and security, equipment safety, client/patient/family safety and security and home safety.

Evidence: Orientation Records
In-service Records
Response to Interviews

Standard 603. The organization has a plan to meet client/patient needs in a disaster or crisis situation.

Standard 603, Criterion A: The organization has written policies and procedures that outline the process for meeting client/patient needs in a disaster or crisis situation.

Interpretation: The written policies and procedures describe a process to organize and mobilize staff adequate to secure resources needed to meet client/patient needs in the event of a disaster or crisis. The process includes a system to identify alternative methods for contacting staff and mobilizing resources to meet critical client/patient needs. The process includes alternative methods, resources, and travel options for the provision of service/care and safety of staff and identified time frames for initiation of the plan. The supplier shall have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster.

The process includes specific measures for anticipated emergencies typical or appropriate for the geographical area served (i.e., hurricanes, tornadoes, floods, earthquakes, chemical spills, and inclement weather). The organization must have, at a minimum, an annual practice drill to evaluate the adequacy of their plan.

The emergency plan also describes access of 911 services in the event of needed emergency services/care for clients/patients, personnel, and visitors.

The program also has a method to identify and prioritize clients/patients based upon their need so that service/care is ensured for clients/patients who would otherwise be at risk of threat to their health or safety.

Evidence: Written Policies and Procedures

Standard 603, Criterion B: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation.

Interpretation: The organization educates all staff members about the process to meet client/patient needs in a disaster or crisis situation. The staff education requirements must include at a minimum; (1) orientation to the emergency plan; and (2) annual review of the emergency plan.

Evidence: Orientation Records
In-Service Records
Response to Interviews

Standard 604. Services/care is provided in a safe and secure environment.

Standard 604, Criterion A: The organization has written policies and procedures that address the organization's fire safety and emergency power systems.

Interpretation: The written policies and procedures or fire safety plan address fire safety and management for all client/patient service/care areas, office and worksite environments. The written policies and procedures include the organization's policies for providing emergency power to critical areas.

Evidence: Written Policies and Procedures
Observation

Standard 604, Criterion B: The organization implements its fire safety and emergency power system plan.

Interpretation: Smoke detectors, fire alarms, and extinguishers are present and placed in secure areas to meet NFPA and LSC Code, (National Fire Protection Agency and Life Safety Code). These items are inspected, maintained and tested on a regular basis and as recommended by the manufacturer. Fire drills are conducted at least annually. The organization evaluates their response to the fire drill and communicates these results to personnel.

Evidence: Observation
Inspection/Maintenance Logs

Standard 605. The organization has a procedure for the safe transportation and labeling of hazardous chemicals and/or materials used in the provision of service/care.

Standard 605, Criterion A: The organization has written policies and procedures for the acceptance, transportation, and pick-up of hazardous chemicals and/or materials used in the provision of client/patient service/care.

Interpretation: Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal, and pick-up of hazardous wastes and hazardous chemicals and/or materials used in the home and organization. The organization must follow state and federal guidelines.

Evidence: Written Policies and Procedures

Standard 605, Criterion B: The organization has written policies and procedures following OSHA's Hazard Communication Standard that describe appropriate labeling of hazardous chemicals and/or materials, instructions for use, storage and disposal requirements.

Interpretation: The organization has written policies and procedures following OSHA's Hazard Communication Standard detailing: (1) the labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings; (2) the use of current Material Safety Data Sheet (MSDS) which must be maintained on file for each chemical used at the facility; and (3) the proper use, storage, and disposal of hazardous chemicals and/or materials, and (4) the use of appropriate personal protective equipment (PPE).

Evidence: Written Policies and Procedures
Review of MSDS Log

Standard 606. The organization has a system for identifying, monitoring, reporting, investigating, and documenting all variances.

Standard 606, Criterion A: The organization has written policies and procedures for identifying, monitoring, reporting, investigating, and documenting all incidents, accidents, variances, or unusual occurrences.

Interpretation: Written policies and procedures describe the process for reporting, monitoring, and investigating and documenting a variance. Procedures must describe: (1) action to notify the supervisor or after hours' personnel; (2) time frame for verbal and written notification; (3) appropriate

documentation and routing of information; (4) guidelines for notifying the physician; and (5) follow-up reporting to the administration/board.

There will be written policies and procedures for the organization to comply with the OSHA guidelines to include recording of information about every work-related injury or illness that involves loss of consciousness, restricted work activity, or job transfer, days away from work, or medical treatment beyond first aid.

There will be written policies and procedures for the organization to comply with the FDA's Medical Device Tracking program and to facilitate any recall notices submitted by the manufacturer, if applicable.

Written policy identifies the person(s) responsible for collecting incident data and monitoring for patterns or trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

The organization defines incidents to be reported, including but not limited to: (1) Adverse client/patient service/care outcomes; (2) Personnel injury or endangerment; (3) Client/Patient/family injury, including falls; (4) Motor vehicle accidents when conducting agency business; (5) Environmental safety hazards, malfunctions or failures, including equipment; (6) Unusual occurrences.

There is an incident report form and identification of the types of situations that must be reported and documented. These would include but not be limited to personnel or client/patient injury during service provision, and adverse events.

Evidence: Written Policies and Procedures
Incident Report Form

Standard 606, Criterion B: Personnel demonstrate knowledge of the procedure for reporting and documenting variances involving self or client/patient.

Interpretation: The organization educates all personnel about examples of incidents/variances that may occur and the organizations policies and procedures for documenting and reporting incidents/variances.

Evidence: Orientation Records
In-Service Records
Response to Interviews

Standard 606, Criterion C: The supplier shall investigate any incident or injury in which DMEPOS may have contributed to the injury or incident, when the supplier becomes aware.

Interpretation: The investigation should be initiated within 24 hours after a supplier becomes aware of an injury or incident resulting in a beneficiary's hospitalization or death. For other occurrences, the supplier shall investigate within 72 hours after being made aware of the incident or injury. The investigation includes all necessary information, pertinent conclusions about what happened, and whether changes in systems or processes are needed. The supplier should consider possible links between the items and services furnished and the adverse event.

Evidence: Incident Reports

INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

SECTION 1700: PHARMACY SCOPE OF SERVICES

These standards are applicable to all the Pharmacy Scopes of Practice including Infusion Pharmacy, Ambulatory Infusion Center, Specialty Pharmacy and Respiratory Nebulizer Medication Pharmacy, except where noted.

Infusion Pharmacy *is defined as a pharmacy that provides parenteral medications for patients in alternate settings. The service includes clinical monitoring by the pharmacy, and may include nursing services as well.*

Ambulatory Infusion Center *is defined as a centralized location where a patient can receive infusion therapy. The facility will be staffed by a nurse(s) and in some cases, a pharmacist. Services provided are ordered by an appropriate licensed provider (physician, nurse practitioner, physician assistant) as defined by state law.*

Specialty Pharmacy *is defined as a pharmacy that dispenses medications (typically self injectable drugs) to a patient's home, physician's office, or clinics specializing in certain chronic disease states. These medications benefit a targeted patient population with a chronic and sometimes life-threatening disease.*

Respiratory Nebulizer Medication Pharmacy *is defined as a pharmacy that dispenses aerosolized single patient dose respiratory medications. The medications may be prepackaged or compounded by the pharmacy. The medications are delivered directly to the patient's home by either the organization or by the use of outside delivery services such as UPS, FedEx or US Mail. The medications benefit a targeted patient population with chronic diseases such as Emphysema, Chronic Bronchitis or Asthma. Examples of Respiratory Medications include Beta Adrenergic Bronchodilators, Anticholinergic Bronchodilators, Cortico Steroids (Anti-inflammatory Agents), Cromolyn Sodium, Mucolytics, and Antibiotics.*

Standard 1701. All Pharmacy Services will be provided by qualified pharmacists in accordance with state laws, regulations and recognized professional practice standards.

Standard 1701, Criterion A: All Pharmacy Services will be provided by qualified personnel and administered in accordance with the organization's policies and job descriptions, federal, state and local laws and established regulatory guidelines as dictated by the Board(s) of Pharmacy of the state(s) into which medications are dispensed.

Interpretation: Pharmacists and pharmacy technicians will function in accordance with the organization's job description, accepted ethical and professional practice standards and in accordance with all applicable federal, state and local laws and guidelines set by the Board of Pharmacy.

If Pharmacy Services are dispensed in other states, a pharmacy license or permit for states serviced will be obtained if required by that state (many states require a nonresident license). Current copies of applicable rules and regulations are available to appropriate organization staff.

Evidence: State Board of Pharmacy Regulations (for all states licensed)
USP General Chapter <797>
Pharmacist(s) Licenses
Pharmacy Technician(s) Licenses/Certificates, where required
Job Descriptions
Personnel Record Review

Standard 1701, Criterion B: All required licenses and/or permits for the physical facility are current and placed on display in an appropriate public area.

Interpretation: The organization will display all licenses and/or permits required in the operation of the pharmacy services in an area of public view.

Evidence: Resident State Board of Pharmacy Permit/License
Non-resident Board of Pharmacy Permit/License as required
DEA Registration
State Controlled Substance License (when required)
Pharmacist(s) Licenses
Pharmacy Technician(s) Licenses/Certificates, where required
Device Dispensing Permit (if required)
CLIA Certificate (if applicable)
State Board of Pharmacy License or contract with a locally licensed pharmacy (contract will be available for review during survey)
Biohazard generator permit or appropriate contract as required

Standard 1702. There are written policies and procedures relating to pharmacy services.

Standard 1702, Criterion A: There are written policies and procedures describing the scope of services offered by the pharmacy program.

Interpretation: The pharmacy program has written and implemented policies and procedures addressing the scope of services offered by the organization. These services should include, but not be limited to, types of services provided, target patient populations and goals of the program.

Evidence: Written Policies and Procedures

Standard 1702, Criterion B: Pharmacy Services are provided according to the patient's plan of care with access to a Registered Pharmacist available 24 hours a day, 7 days a week

Interpretation: The organization provides Pharmacy Services 24 hours a day, 7 days a week to meet patient needs. An on-call coverage system may be used to provide this coverage during evenings, nights, weekends and holidays. Written policy should define the on-call system used, back-up plan, and regular testing procedures. For organizations that have multiple employees on-call concurrently, written policy should define the sequence and method of notification to reach each discipline / employee on-call.

Evidence: On-Call Schedule/Log
Written Policies and Procedures

Standard 1703. Qualified personnel supervise the pharmacy services.

Standard 1703, Criterion A: All Pharmacy Services are provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.

Interpretation: All Pharmacy Services must be provided under the direction of a registered pharmacist with sufficient education and experience in the scope of services offered. The policies and procedures identify the method and frequency for assessing pharmacist practice to ensure that services are provided appropriately.
Individual state boards of pharmacy and/or USP Chapter <797> list requirements for pharmacist training.

Evidence: Personnel Record Review
Pharmacist(s) Licenses
Written Policies and Procedures
Response to Interviews

Standard 1703, Criterion B: A Registered Pharmacist supervises Pharmacy Technicians in accordance with organizational policy and the state Board of Pharmacy.

Interpretation: The pharmacy follows their state Board of Pharmacy regulations and organizational policies and procedures that demonstrate supervision of services provided by pharmacy technicians. The policies and procedures identify the method and frequency for assessing pharmacy technician practice to ensure that services are provided appropriately.

Evidence: Written Policies and Procedures
Documentation of Supervision Activities - Patient Record and/or Personnel Record Review
Response to Interviews

Standard 1703, Criterion C: Verification of license/certification of the referring physician or others approved by law to prescribe medical services, treatments, and/or pharmaceuticals will be conducted prior to providing service/care.

Interpretation: Written policies and procedures describe the process for verification of physician credentials. Ongoing periodic assessments of current physician license/other license/certification may be obtained from the state Licensing Board of Medicine or other Licensing/Certification Boards, or verification of physician privileges at the local or regional accredited hospital. The organization must have a mechanism to ensure that orders are only accepted from currently licensed physicians.

Evidence: Written Policies and Procedures
Approved Physician List
Response to Interviews

Standard 1704. Patients will have an assessment of need and plan of care.

Standard 1704, Criterion A: Written policies and procedures describe the process for assessment and the plan of care.

Interpretation: The Pharmacy Services program has written policies and procedures that describe the process for a patient assessment, the development of the plan of care and the frequency and the process for the plan of care review. The plan of care should be appropriate for the type of treatment/care that is provided. Care planning is directed toward driving positive patient outcomes.

Evidence: Written Policies and Procedures

Standard 1704, Criterion B: All patients referred for Pharmacy Services will have an assessment appropriate of therapy provided.

Interpretation: An assessment will be performed and information documented in the patient's record for patients referred for pharmacy services. The assessment will focus on appropriateness for therapy in the home, appropriateness of medication to include dosing and frequency of dose, safety in the home, and method administering the drug to the patient.

Evidence: Patient Record Reviews

Standard 1704, Criterion C: There is a written plan of care for each patient accepted for services and based upon assessment data.

Interpretation: The plan of care will include at a minimum: (1) problems; (2) goals; (3) interventions; (4) monitoring parameters; and (5) patient outcomes.

Physician orders are needed to provide any services requiring the administration of medication, treatment(s), ongoing assessments or other activities as governed by state law. Physician orders may also be required under certain program requirements (i.e., Medicare, Medicaid, Managed Care, and other third party payers). The organization has a responsibility to obtain physician orders as applicable.

Evidence: Patient Record Reviews

Standard 1704, Criterion D: The organization will show evidence of the patient/caregiver participation in the plan of care.

Interpretation: The patient/responsible parties have a right to be involved in the development of the plan of care and any changes in that plan. However, the degree of involvement may vary depending on the ability of the patient to participate in the plan of care. At a minimum, the patient or responsible party must agree to the plan of care prior to the beginning of services and as subsequent changes occur.

The patient record must show involvement of the patient/family/caregiver in the development or at least agreement to the plan of care and any revisions made to the plan. The following are suggestions as to how organizations may document this information: (1) the plan of care may be signed by the patient/responsible party; (2) a notation may be made in the patient record that the patient/responsible party participated in the development of the plan of care; (3) there may be documentation in the patient

record that the plan of care was reviewed and accepted by the patient/responsible party; or (4) there is evidence that the plan of care was provided to the patient for review and change.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1704, Criterion E: Pharmacy services are delivered in accordance with the written plan of care.

Interpretation: The patient record reflects that pharmacy services are delivered in accordance with the plan of care and directed at achievement of established goals.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1704, Criterion F: There is evidence that the plan of care is reviewed.

Interpretation: There is documentation in the patient record that reflects the plan of care is reviewed for: (1) appropriateness (care being provided is still needed); (2) effectiveness (patient outcomes/response to care); and (3) to determine if all needed services are being provided. Included in this review is a discussion with the patient/responsible party to determine the level of satisfaction with the care that has been provided. Notation of a review may be made in the patient record, in minutes of meetings, such as team meetings, or case conferences.

The organization follows program policies and any applicable laws and rules for the frequency of plan of care review. The plan of care should be reviewed: (1) at a minimum of every 60 days; (2) when there are changes in patient's response to therapy; (3) when physician orders change; (3) at the request of the patient; and (4) as defined in the pharmacy's policy and procedure;. The plan of care review would occur more frequently based on the patient's need for changes.

Evidence: Patient Record Reviews
Responses to Interviews

Standard 1704, Criterion G: There is evidence of changes in the plan of care based on reassessment data.

Interpretation: Changes are noted on the plan of care and/or in the progress notes based on patient requests, patient's condition, patient's response to therapy, and when physician orders indicate changes.

There is evidence of communication to the physician regarding the patient's condition. If new or revised patient or treatment goals are indicated, they must be reflected in a revised plan of care. Revised plans of care shall be approved by the patient's physician.

Evidence: Patient Record Reviews

Standard 1705. Patient and/or caregiver education focus on goal and outcome achievement.

Standard 1705, Criterion A: Written policies and procedures describe the process for patient and/or caregiver education.

Interpretation: The Pharmacy services program has written policies and procedures that describe patient and/or caregiver education. The policies and procedures must include: (1) treatment and disease management education; (2) proper use, safety hazards, and infection control issues related to the use and maintenance of any equipment provided; (3) plan of care; (4) how to notify the company of problems, concerns and complaints; and (5) emergency preparedness information.

Evidence: Written Policies and Procedures

Standard 1705, Criterion B: Patient and/or caregiver education must focus on goal and outcome achievement as established in the plan of care.

Interpretation: Patient education is an integral part of pharmacy services. Assessment of the patient and/or caregiver's knowledge deficits and learning abilities are evaluated during the initiation of services. Knowledge deficits and learning abilities are documented on the care plan or in the progress notes. Patient education/instruction will proceed in accordance with the patient's willingness and ability to learn.

Education must be coordinated with the patient/caregivers and the health care team and must focus on goal and outcome achievement as established in the plan of care. Elements of patient education may include, but not be limited to: (1) ongoing assessment of patient and caregiver's learning needs; (2) communication of needs to other health care team members; and (3) incorporating patient needs into the plan of care. The patient records will include documentation of all teaching, patient's response to teaching, and the patient's level of progress/achievement of goals/outcomes. Written instruction will be provided to the patient as appropriate.

Evidence: Patient Record Reviews
Response to Interviews

Standard 1706. Pharmacy Services discharge patients as appropriate and in accordance with established policies and procedures.

Standard 1706, Criterion A: Pharmacy Services follow discharge policies and procedures.

Interpretation: The organization has a process, which assesses the patient's ongoing appropriateness for therapy/services. The written discharge policy will define the activities that represent patient discharge.

The patient record should reflect discharge planning activities, the patient's response and understanding to these activities, patient care instructions and a reasonable notice prior to discharge whenever possible.

There is a discharge summary report or notation in the progress notes or a software section dedicated to discharge that includes: (1) a summary of the services provided; (2) patient's response to therapy, i.e. progress toward clinical goals; (3) the date and reason for the discharge; (4) a brief description of ongoing needs that could not be met; (5) any instructions or referral information given to the patient/responsible party. A copy of the discharge summary is made available to the physician and a copy is placed in the patient record.

Evidence: Written Policies and Procedures
Patient Record Reviews

Standard 1707. All pharmaceuticals, supplies, and equipment are dispensed/delivered/administered in accordance with applicable laws/regulations and organization policies and procedures.

Standard 1707, Criterion A: A Registered Pharmacist must review all patient medications and consult with other health care professionals caring for the patient, including the physician. All OBRA counseling is completed as specified by law.

Interpretation: A licensed pharmacist must review all prescription and non-prescription medications that a patient is currently taking prior to dispensing medications.

A medication profile is established at the start of therapy. This profile is updated and kept current minimally every 30 days, whenever there are changes in the patient's medication therapy, or as designated by the pharmacy policy and procedures. If patient is transferred to another healthcare facility, a copy of the medication profile is offered to the new facility or agency.
A licensed pharmacist is specifically responsible for recognizing the following as they pertain to infusion related diagnosis and infusion drugs: (1) side effects; (2) toxic effects; (3) allergic reactions; (4) desired effects; (5) unusual and unexpected effects; (6) drug interactions; (7) appropriateness of the drug for the patient's diagnosis; (8) appropriateness of the dose; (9) changes in the patient's condition that contraindicate continued use of the drug. The pharmacist, in conjunction with other health care professionals caring for the patient, must be able to anticipate those effects which may rapidly endanger a patient's life or well being, and instruct the patient, family member and/or caregiver, as necessary, in following the prescribed regimen.

Evidence: Patient Record Reviews
Written Policies and Procedures
Response to Interviews

Standard 1707, Criterion B: Medications and supplies are accurately labeled and dispensed to the patient for whom they are ordered. Labels of Compounded Sterile Preparations (CSPs) will include: (1) names and amounts or concentrations of ingredients; (2) total volume; (3) the Beyond Use Date (BUD); (4) route of administration; (5) storage conditions; (6) instructions for use; and (7) any additional requirements specified by the individual state Board of Pharmacy for labeling.

Interpretation: Medications dispensed to patients are appropriately labeled according to applicable law and regulation and standards of practice. In the absence of sterility testing, Beyond Use Dating follows *USP General Chapter <797>* requirements.

Evidence: Pharmacy Logs
Prescription Labels
Delivery Tickets or Logs

Standard 1707, Criterion C: There are written policies and procedures relating to special education, experience, or certification requirements for pharmacy staff to prepare compounded sterile preparations.

Interpretation: The organization must have written guidelines defining any special education, experience or certificates necessary for pharmacy staff to prepare sterile compounded preparation. Qualifications may vary based upon classifications of drugs as well as State Board of Pharmacy requirements, and requirements defined by *USP General Chapter <797>*.

For organizations that prepare compounded sterile preparations (CSPs), compounding personnel training is documented initially during orientation and at a minimum annually. Initial training and review may include multi-media instructional sources and professional publications. Training must address: (1) the principals and practical skills of aseptic technique; (2) hand hygiene and garbing procedures; and (3) maintenance of the controlled air environment(s). Compounding personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially and at least annually or semi-annually thereafter as dictated by risk level of compounded sterile preparations.

Evidence: Written Policies and Procedures
Personnel Record Review

Standard 1707, Criterion D: There are written policies and procedures that address response to adverse drug reactions.

Interpretation: The organization has written policies and procedures that address the steps taken if an adverse drug reaction occurs.

Policies and procedures should address the standard protocol for managing and reporting Adverse Drug Reactions (ADR) internally and to outside state agencies as required by law. This may include standing orders to treat anaphylaxis and recommended dosages of drug per age group.

Evidence: Written Policies and Procedures
Response to Interviews
ADR Record Book
MedWatch Records (for more information see www.fda.gov/medwatch)

Standard 1707, Criterion E: There are written policies and procedures to ensure that the right patient receives the right treatment.

Interpretation: There is a process to verify the identity of the patient and the treatment the patient is to receive.

Evidence: Written Policies and Procedures
Response to Interviews
Patient Records

Standard 1708. The pharmacy has a system for the recall of medications and products.

Standard 1708, Criterion A: The organization has written policies and procedures for medication and product recall.

Interpretation: There are written policies and procedures for tracking medications and products dispensed to patients. There are written procedures for external reporting of medication or product defects. There are written procedures for the safe disposition of recalled medications or products dispensed to patients.

Evidence: Written Policies and Procedures
MedWatch Records (for more information see www.fda.gov/medwatch)

Standard 1708, Criterion B: Records are maintained to identify each patient who is receiving or has received recalled medications or products.

Interpretation: Documentation will include, but not be limited to, the manufacturer of each patient's medication, lot numbers and expiration dates. Serial numbers will be used to track equipment.

Evidence: Dispensing/Recall Records
Equipment tracking logs
Patient Record Reviews
Response to Interviews

Standard 1708, Criterion C: Staff implements organization's policies and procedures for the safe disposition of recalled medications or products and external reporting.

Interpretation: Staff implements the organization's written policies and procedures for the safe disposition of recalled medications or products stocked and dispensed to patients.

Staff implements the organization's written policies and procedures for external reporting of medication or product defects. Patient's physicians are notified when medications or products are recalled.

Evidence: Dispensing/Recall Records
Patient Record Reviews
Response to Interviews
MedWatch records

Standard 1709. All compounded sterile preparations are prepared by qualified personnel in a suitable environment using appropriate aseptic technique.

This standard and criterions only apply if the organization performs sterile compounding.

Standard 1709, Criterion A: The organization has written policies and procedures for compounded sterile products, and must minimally comply with all requirements set forth by *USP General Chapter <797>* and the requirements set forth by individual state boards of pharmacy.

Interpretation: The written policies and procedures for compounded sterile products defines quality control procedures for monitoring aseptic technique and the compounding environment to comply with established standards by the individual Board of Pharmacy regulations and Federal law. The written

policies and procedures define processes for preparing/compounding sterile products and include: (1) environmental considerations of security, temperature, and ventilation; (2) introduction of medications and supplies into the controlled air environments (3) appropriate hand hygiene and garbing procedures; (4) proper aseptic technique and manipulations within the ISO Class 5 environment to include: (A) procedure for media-fill process validation; (B) preparation of parenteral drugs for administration in various delivery devices, i.e., elastomerics, ambulatory pump reservoirs, minibags, LVP, etc; (C) procedure for use, calibration, maintenance, and accuracy testing of automated compounding devices (ACD); (D) preparation of sterile drugs from non-sterile products, if applicable; (E) procedure for pyrogen and endotoxin testing, if applicable; and (F) procedure for hazardous drug preparation, if applicable.

Evidence: Written Policies and Procedures
Observation of compounding processes
Media Fill Logs
Pyrogen/Endotoxin testing logs
Compounding equipment calibration testing and accuracy testing logs

Standard 1709, Criterion B: The organization has written policies and procedures for cleaning and disinfecting of the controlled air environment(s).

Interpretations: Cleaning and disinfection procedures will follow requirements set forth by *USP General Chapter <797>* and the individual state Boards of Pharmacy. Written policies and procedures for cleaning of the controlled air environments, i.e., ISO Class 5 area(s), ISO Class 7 or better clean room, and ISO Class 8 or better anteroom, to reduce the risk of particulate matter in the work area and contamination of the compounding environment include: (1) process and frequency for cleaning work surfaces, equipment, and work areas, i.e., floors, walls, ceilings, counters, etc; (2) using dedicated cleaning tools specific to the area, including the use of non-shedding wipers, sponges, and mops; (3) use of appropriate disinfectant solutions; and (4) documentation of the cleaning process.

Evidence: Written Policies and Procedures
Quality Control Records

Standard 1709, Criterion C: Qualified personnel comply with aseptic technique when compounding sterile preparations.

Interpretation: Personnel demonstrate knowledge and understanding of contamination control and aseptic techniques in accordance with written policies and procedures, *USP General Chapter <797>*, state specific Board of Pharmacy regulations and Federal law. Personnel qualifications include initial and follow-up training for periodic evaluation of performance.

Evidence: Observation
Quality Control Records
Personnel Record Review
Response to Interviews

Standard 1709, Criterion D: Non-hazardous compounded sterile preparations are compounded in an ISO Class 5 or better primary engineering control, such as an ISO Class 5 or better room, ISO Class 5 or better countertop area; ISO Class 5 or better laminar airflow workbench (LAFW), ISO Class 5 or better Biological Safety Cabinet (BSC) or an ISO Class 5 or better Compounding Aseptic Isolator (CAI). The ISO Class 5 or better primary engineering control is located within an

ISO Class 7 or better room. For clean rooms providing a physical separation from the anteroom, a minimum positive pressure differential of 0.02-0.05 – inch water column is required. The only exception would be an ISO Class 5 or better CAI with documentation from the manufacturer that the CAI does not need to be used within an ISO Class 7 or better environment.

Interpretation: The ISO Class 5 and ISO Class 7 environment are certified every 6 months or in accordance with ISO 14644 standards, NSF 49, state Board of Pharmacy regulations, *USP General Chapter <797>* and/or Federal law. A qualified independent contractor performs certification according to accepted standards for operational efficiency to include but not limited to: viable and non-viable particle levels, air changes per hour (ACH), and pressure differential monitoring. Procedures are maintained for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines.

Evidence: Observation
Engineering Control Certification Reports and Certification Certificates
Quality Control Records
Response to Interviews

Standard 1709, Criterion E: Hazardous compounded sterile preparations are compounded in an ISO Class 5 or better Biologic Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI). The ISO Class 5 or better BSC or CACI is placed in an ISO Class 7 or better area that is physically separated and has not less than 0.01- inch water column negative pressure to the adjacent ISO Class 7 or better anteroom. In facilities that prepare a low volume of hazardous drugs, a negative pressure room is not required.

Interpretation: The ISO Class 5 BCS/CACI and ISO Class 7 environment are certified every 6 months or in accordance with ISO 14644 standards, NSF 49, state Board of Pharmacy regulations, *USP General Chapter <797>* and/or Federal law. A qualified independent contractor performs certification according to accepted standards for operational efficiency to include but not limited to: viable and non-viable particle levels, air changes per hour (ACH), and pressure differential monitoring. Procedures are maintained for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines.

Evidence: Observation
Engineering Control Certification Reports and Certification Certificates
Quality Control Records
Response to Interviews

Standard 1710. The pharmacy assures pharmaceuticals are stored under appropriate conditions.

Standard 1710, Criterion A: There are written policies and procedures relating to pharmaceutical storage.

Interpretation: The written policies and procedures must include, but are not limited to: (1) Storage of pharmaceuticals (separated from food items or other sources of contamination); (2) monitoring of storage room, refrigerator, and freezer temperatures; (3) accessibility of legend drugs; (4) storage during delivery; (5) cleaning and disinfecting of any reusable containers (i.e. delivery coolers); and (6) pharmaceutical labeling as to the appropriate storage

Evidence: Written Policies and Procedures
Temperature logs
Cleaning logs
Observation

Standard 1710, Criterion B: The pharmacy stores pharmaceuticals under appropriate conditions of security, sanitation, light and temperature.

Interpretation: Pharmaceuticals are stored in accordance with manufacturer or USP requirements. Temperatures are monitored wherever pharmaceuticals are stored to assure the requirements are met. Prescription and legend drugs are stored in the licensed pharmacy, which is accessible only under the supervision of licensed pharmacist(s).

Evidence: Observation
Temperature logs

Standard 1710, Criterion C: The pharmacy uses delivery containers that assure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

Interpretation: The pharmacy assures pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperatures in the course of deliveries. Where appropriate, the pharmacy uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with manufacturer and USP <797> requirements.

The policies and procedures for the cleaning and disinfecting of any reusable containers are implemented. Shipping methods are tested periodically to ensure that containers stay within specified temperature requirements.

Evidence: Observation
Shipping Records

Standard 1710, Criterion D: The pharmacy ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light and temperature in the patient's home.

Interpretation: The pharmacy has and acts upon information affecting the maintenance of appropriate conditions of sanitation, light and temperature.in the patient's home. Where necessary, the pharmacist intervenes appropriately to ensure that appropriate conditions are achieved or maintained. Pharmaceuticals dispensed to the patient are clearly labeled as to the appropriate storage.

Evidence: Prescription Labeling
Response to Interviews

Standard 1711. Nutritional products are stored and provided in accordance with organization policies and procedures and applicable law and regulations.

This standard does not apply to organizations that either does not provide enteral nutritional products or products are provided through the DME service model.

Standard 1711, Criterion A: The Pharmacy has written policies and procedures for the provision of enteral nutritional products.

Interpretation: The pharmacy has written policies and procedures for the provision of enteral nutritional products. The written policies and procedures must include, but are not limited to: (1) storage of products; (2) rotation of products; (3) labeling of products; (4) tracking of lot number and expiration dates; (5) disposal/return of expired products; and (6) written instructions the patient will receive.

Evidence: Written Policies and Procedures

Standard 1711, Criterion B: Enteral nutritional products are stored in accordance with policies and procedure and manufacturer guidelines.

Interpretation: The pharmacy ensures that enteral products are stored in an appropriate environment. The storage room temperature is monitored to verify compliance with manufacturer guidelines for storage.

Evidence: Written Policies and Procedures
Temperature Logs
Response to Interviews

Standard 1712. The pharmacy maintains medical equipment.

Standard 1712, Criterion A: The pharmacy has policies and procedures relating to the maintenance and repair of medical equipment.

Interpretation: The written polices and procedures must include, but are not limited to: (1) cleaning, storage, and transportation of patient-ready equipment; (2) separation of dirty and clean equipment; (3) warehousing and tagging equipment; (4) use of cleaning and disinfecting agents and process of contaminated or soiled home medical equipment, including curbside disinfection; (5) maintenance and repair of equipment; (6) separation of inoperative equipment; (7) tracking of equipment; (8) manufacturer recalls; and (9) back-up systems for equipment or power failure. Written polices and procedures will clearly define training, qualifications, and skill validation required by personnel to perform routine maintenance and repair of all equipment. Written policies and procedures clearly define the use of outside repair sources.

Evidence: Written Policies and Procedures

Standard 1712, Criterion B: Pharmacy staff is trained to perform routine cleaning and maintenance of equipment.

Interpretation: Staff responsible for delivery; set-up; pick-up and maintenance of equipment are trained and competent in the use of all equipment.

Evidence: Personnel training records

Standard 1712, Criterion C: Pharmacy staff implements the organization's written policies and procedures for the delivery, set-up, environmental requirements, and electrical safety of equipment dispensed to a patient.

Interpretation: Pharmacy staff will perform environmental assessments, set-up, and provide appropriate information regarding safe and proper use of all equipment according to manufacturer's guidelines.

Prior to or at time of delivery, personnel will address at a minimum the following: (1) safety and adequacy of electrical outlets (if applicable); (2) safe use of extension cords and outlet adapters (if applicable); (3) location and function of all equipment controls; and (4) expected results/outcomes of proper use.

Training provided to the patient will be documented in the patient record according to the company's written policy and procedure.

Equipment used in patient care is properly cleaned and maintained. Routine maintenance, preventive maintenance, and repairs will be performed according to manufacturer's guidelines. Equipment requiring calibration will be calibrated according to manufacturer's guidelines. Inoperative equipment must be separated from other equipment and tagged for repair.

Evidence: Maintenance logs
Manufacturer's service manuals/set-up guidelines
Patient Records-including documentation of pump setting verification
Response to Interviews

Standard 1713. The pharmacy will have access to a reference library appropriate to the level of the services provided.

Standard 1713, Criterion A: The Pharmacy staff will have access to a reference library appropriate to the level of services provided.

Interpretation: The pharmacy staff will have access to a reference library appropriate to the level of services provided. The pharmacy has available reference books, journals, Internet access, etc. appropriate for the patient population served. The library will contain, at a minimum: (1) drug compatibility and stability; (2) drug interactions; (3) general clinical references; (4) <797> Pharmaceutical Compounding – Sterile Preparations and (5) pharmacy regulations for any state into which medications are dispensed.

Evidence: Observation
Response to Interviews

INTERPRETIVE GUIDE
STANDARDS FOR ACCREDITATION

SECTION 1800: AMBULATORY INFUSION CENTER SCOPE OF SERVICES

In addition to all 1700 pharmacy standards, the following standard(s) and criteria apply to Ambulatory Infusion Center Programs.

Standard 1801. The facility housing the Ambulatory Infusion Center will be staffed by qualified health care providers in accordance with state laws, regulations and recognized professional practice standards.

Standard 1801, Criterion A: The Ambulatory Infusion Center services will be provided by qualified personnel and administered in accordance with the organization's policies and procedures, federal, state and local laws and established regulatory guidelines. The Ambulatory Infusion Center will meet laws/regulations for facilities that provide services/care to patients on site.

Interpretation: The Ambulatory Infusion Center will meet all guidelines specified by law or regulation relating to the facility, pharmacy and nursing, including but not limited to: (1) OSHA; (2) Federal, State, and local laws: (3) Fire department regulations; (4) Americans with Disabilities Act and (5) National Fire Protection Agency and Life Safety Code

Evidence: Observation
Inspection Reports
Response to Interviews

Standard 1801, Criterion B: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required in the facility and its use.

Interpretation: The Ambulatory Infusion Center has written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The resuscitation equipment/supplies required shall include but not be limited to: (1) resuscitation bag and mask, (2) medications for adverse reaction and/or resuscitation with protocols for use and (3) current CPR posters.

Evidence: Written Policies and Procedures
Medication Protocols

Standard 1801, Criterion C: The Ambulatory Infusion Center implements its policies and procedures for resuscitation equipment/supplies.

Interpretation: The Ambulatory Infusion Center implements the written policies and procedures that describe the resuscitation equipment/supplies required by the facility. The facility educates the professional staff members in the use of resuscitative equipment/supplies on at least an annual basis. The cart(s) and/or box(s) that store the resuscitative equipment/supplies are inventoried on a regular basis at least every 30 days to insure correct inventory and non-expired products.

Evidence: Observation
In-service Education Files/Logs
Inspection Logs
Response to Interviews

Standard 1801, Criterion D: The Ambulatory Infusion Center has written policies and procedures that describe patient monitoring during infusion.

Interpretation: The Ambulatory Infusion Center has written policies and procedures that describe the monitoring of patients during infusion by either a pharmacist or nurse or both. The written policies and procedures describe the equipment required for monitoring. The monitoring equipment must be visual and audio to warn staff when no one is in the room with the patient.

Evidence: Written Policies and Procedures

Standard 1801, Criterion E: The Ambulatory Infusion Center implements its policies and procedures for patient monitoring during infusion.

Interpretation: The Ambulatory Infusion Center implements the written policies and procedures that describe the monitoring of patients during infusion. The facility educates the professional staff members in the use of monitoring equipment on at least an annual basis. The monitoring equipment is calibrated and preventative maintenance is performed per manufacture guidelines.

Evidence: Observation
In-service Education Files/Logs
Inspection/Calibration/Maintenance Logs
Response to Interviews

Standard 1801, Criterion F: The Ambulatory Infusion Center has adequate space and climate controls for treating patients on site.

Interpretation: The site has adequate space for supplies, equipment, waiting area and treatment areas. The facility has separate treatment areas. Ventilation is adequate to maintain comfortable temperature and humidity levels.

Evidence: Observation
Response to Interviews

ACCREDITATION
POLICIES & PROCEDURES

Accreditation Policies & Procedures

I. Introduction

The Accreditation Commission for Health Care, Inc. (ACHC) is an independent, 501(c)3 non-profit accrediting organization, which is certified to ISO 9001:2008 standards. ACHC is governed by a voluntary Board of Commissioners (Board), which is composed of health care professionals and consumers. The Board is responsible for leadership, governance and oversight of the quality of all services provided by the organization. The Board focuses on the development and maintenance of services that promote excellent outcomes through national health care standards. The Board accepts the ongoing duty to monitor the mission and philosophy of the organization and establish the future direction of ACHC in keeping with its mission. In addition to the expert Board members, the organization solicits the support and input from leadership committees such as the Standards and Review Committee, as well as clinical advisors.

The policies and procedures contained in this section pertain to all applicant organizations, whether they are applying for the first time, renewing, or adding or eliminating branches or services. All applicant organizations must follow these accreditation policies and procedures to achieve ACHC accreditation and maintain compliance. Submission of a signed application and contract for survey by an applicant organization constitutes intent to adhere to the policies and procedures in effect on the date on which the application is received by ACHC.

II. Eligibility

Applicant organizations which provide health care services and/or products may apply for accreditation if all of the following eligibility criteria are met:

A. Must be currently operating within the United States and/or its territories;
B. Must have served a minimum of ten (10) clients/patients and have (7) active clients/patients at the time of the survey;
C. Is licensed according to applicable state and federal laws and regulations and maintains all current legal authorization to operate;
D. The building in which services are provided/coordinated is identified, constructed, and equipped to support such services;
E. Clearly defines the services it provides under contract or directly;
F. Must be willing to complete and sign attestation to never falsify or misrepresent accredited programs;
G. Must submit all required documents and fees to ACHC within specified time frames;
H. Medicare providers must meet all criteria for participation with Medicare.

Deemed Status Eligibility

Currently, deemed status accreditation is available to home health and DMEPOS applicant organizations. In addition to the above eligibility criteria, applicant organizations applying for deemed status must meet the following requirements:

A. Meet the intent of the definition set forth by Medicare.
B. Meet the intent of the regulations set forth by state and/or federal regulations for certification;
C. Application must clearly denote and/or include:

- the intent to seek deemed status
- copy of CMS-855 approval letter (new providers/organizations only)
- evidence of successfully completed OASIS transmission (Home Health only)

ACHC Programs

ACHC provides programs with designated services for accreditation. The applicant is required to accredit all services provided within that corporate structure. If the applicant organization offers services under another corporate name/structure and the services are covered under an additional ACHC program, the organization has the option to add additional services for accreditation.

(1) **Private Duty Aide**: Aide services encompass all levels of care provided by a nursing assistant or sitter including Personal Care Services, chore, companion sitters and homemakers.

(2) **Private Duty Nursing**: PDN services are usually provided either hourly or by shift and are covered by various payers, but not Medicare. Services can be provided by an RN or LPN.

(3) **Home Health**: Home Health services are skilled services that are usually provided on a visit basis, as opposed to hourly, for a short duration of time. These services are usually provided by a licensed and /or Medicare certified agency. Home Health services are provided by skilled professionals including nursing; physical, occupational and speech therapy; medical social work and home health aide.

(4) **Home/Durable Medical Equipment**: HME/DME services are the selection, delivery, set-up and maintenance of medical equipment and/or oxygen as well as patient education regarding the use of this equipment. Assessment and hands-on care of patients, including performance of any tests, is considered clinical services and will be accredited using the Clinical Respiratory Standards. This includes pulse oximetry measurements.

(5) **Clinical Respiratory Care**: This service is provided by a licensed respiratory care practitioner or respiratory therapist. The care includes the skilled assessment, treatment and education of patients.

(6) **Hospice**: Hospice is the care of patients with life limiting illnesses in the home or hospice inpatient facility. End of life care involves a multidisciplinary approach to medical care, pain management and emotional/spiritual care. This team approach will be used in the survey process. ACHC surveys are conducted by a hospice nurse surveyor as well as a clinical support surveyor, such as a medical social worker. An agency that provides inpatient services must adhere to the inpatient standards as well as the primary hospice standards.

(7) **Infusion Nursing**: This service is the administration of parenteral medications via various accesses and ports by an RN specifically trained in these specialized services. This service can be provided in a variety of settings.

(8) **Medical Supply Provider**: The storage and delivery of medical supplies designed to meet the needs of a client/patient requiring the product for their medical management in the home care setting. A physician generally prescribes these services. The items sold are usually disposable or semi-durable in nature. The supplies are normally delivered by mail.

(9) **Pharmacy Services**: The infusion therapy continuum of care includes IV drug mixture preparation, IV administration, therapy monitoring, client/patient counseling and education. It is the administration of medications using intravenous, subcutaneous and epidural routes. The IV therapies include IV antibiotics, prescribed primarily for diagnoses such as steomyelitis, sepsis, cellulites, total parenteral nutrition, pneumonia, sexually transmitted diseases and others. ACHC scope of service includes: home infusion pharmacy, specialty pharmacy, first

dose services, ambulatory infusion centers and respiratory nebulizer medications.

(10) **Complex Rehab and Assistive Technology Supplier:** Rehabilitation Technology Supplier Services are defined as the application of enabling technology systems designed to meet the needs of a specific person experiencing any permanent or long-term loss or abnormality of physical or anatomical structure or function. These services, prescribed by a physician, primarily address wheeled mobility, seating and alternative positioning, ambulation support and equipment, environmental control, augmented communication and other equipment and services that assist the person in performing their activities of daily living.

(11) **Fitter Services:** These services include prosthetic fitting of a variety of products such as diabetic shoes and post-mastectomy breast prosthesis.

(12) **Sleep Lab:** A Sleep Lab is a facility that provides testing for sleeping disorders either in an Independent Diagnostic Testing Facility (IDTF), as defined by CMS, or in hospital based testing facilities. Sleep testing can also be conducted in the home.

III. Purpose or Principles Governing the Accreditation Survey

A. Compliance

Throughout the survey process, ACHC determines whether the organization is meeting the intent of the accreditation standards. Proof of compliance is based upon such things as review of client records, personnel records, policies and procedures, as well as onsite observations and interviews and other activities as necessary.

Standard Revision Compliance

It is the organization's responsibility to ensure compliance with ACHC standards at all times during the accreditation period. Upon revision of standards, ACHC will establish timeframes for the organization to come into compliance. Timeframes for compliance are determined in part by mandatory timeframes required by state/federal regulations, HIPAA, etc. Compliance with revised standards will be 120 days after notification of the revision by ACHC.

B. Education

While the organization is preparing for its onsite survey, ACHC is available to provide assistance in interpretation of standards. A list of independent consultants is available for organizations that need more extensive assistance with preparation for accreditation. These consultants are not employees of ACHC and use of any consultant does not guarantee successfully becoming accredited. ACHC does not endorse any consultant(s). During the onsite survey, surveyors will provide education in areas where standards are not fully met, in addition to "best practice" suggestions to help the organization achieve optimum performance.

C. Frequency of Surveys

Accreditation surveys are conducted upon receipt of a new accreditation application and, after receipt of accreditation status, on a triennial basis (upon receipt of a renewal application). All surveys are unannounced. Organizations are allowed to choose up to 10 black out days on which ACHC will not schedule a survey. ACHC does not conduct surveys on major holidays including New Years Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the day after Thanksgiving, Christmas Eve, and Christmas Day.

Intermittent unannounced surveys are conducted based upon original survey results, random selection of a percentage of accredited organizations, number of branch additions during an accreditation period, or if a grievance/complaint has been received against an accredited organization.

D. Types of Surveys

1. **Initial Survey**: Organizations which apply for ACHC accreditation for the first time will have an initial survey. Applicant organizations must have served at least ten (10) active clients/patients prior to application submission and have seven (7) clients/patients on service at the time of survey.

2. **Renewal Survey**: Organizations that are accredited by ACHC will receive notification regarding renewal of their accreditation 12 to 15 months prior to their expiration date. Renewal surveys are processed in the same format as an initial survey; however, during the site survey the surveyor also reviews previous deficiencies for compliance.

3. **Deferral Focus Survey**: Organizations that receive a deferral decision may require a focus survey at the applicant organization's expense. A deferral decision requires a plan of correction and evidence demonstrating compliance with the standard(s) in question. A focus survey will be scheduled if a review of personnel or client/patient files, or site observations are required to verify results of the plan of correction.

4. **Interim Survey**: ACHC reserves the right to randomly visit any ACHC accredited organization during the three-year cycle to determine ongoing and continuing compliance with standards. These interim surveys are random and unannounced. If significant non-compliance with standards is found that requires further action from ACHC, the costs of the survey will be billed to the organization.

5. **Service Addition Survey**: Organizations adding a service(s) within their accredited program during their three-year accreditation period must notify ACHC of the addition within 30 days and complete a Service Addition Application. Service addition applications follow the same process and survey procedures as Initial and Renewal applications. All service additions require an onsite survey to ensure compliance of added service scope standards. Organizations requesting a deemed status survey must have all documentation regarding licensure and certification from CMS/State Agency before ACHC can conduct a survey. (See Section VI. D. Service Addition and Section VII. A. Advertising)

6. **Branch Addition Survey**: Organizations adding branches that meet ACHC's branch definition must notify ACHC at least 30 days prior to the opening of that branch, complete a Branch Addition Application for each branch added, and submit required information and applicable branch fees. To qualify as a branch addition, the branch must provide the same services under the organization's current accreditation. Branch additions may require an onsite survey based on the number of sites seen during the initial accreditation survey. Organizations requesting deemed status must have all documentation regarding licensure/certification from CMS/State Agency before ACHC can conduct an onsite survey. ACHC branch surveys consist of a desk review of submitted documentation and photos, and, when necessary, onsite surveys. (See Section VI. C. Branch Office Addition and Section VII. A Advertising)

IV. Accreditation/Survey Process

A. Interpretive Guide

Prospective applicant organizations can receive an ACHC Interpretive Guide by registering the organization on the ACHC website and downloading a free copy of the Interpretive Guide. ACHC, working with the applicant organization, determines which accreditation manual is most appropriate for services provided. (See Section II. ACHC Programs for guidelines regarding selection of programs and services). Once the manual is ordered, the company will be assigned an Account Manager that will be available to assist them with any questions. Also a username and password will be assigned and the customer will have access to our customer central website. Customer central is a private website that will contain all the information to get started on **your** accreditation. It will have the application, interpretive guide (standards) and PER specific to the services the customer provides.

B. Organizational Structure and Governance

Based on governance, complexity of corporate structure, tax reporting, and other factors, ACHC will determine the number of applications and number of surveys required. Organizations are required to submit statistical data forms for all locations and an organizational chart with the application to assist in the determination of corporate structure.

C. What is Required to Submit to ACHC to Start the Accreditation Process

Application:

Applications are located on customer central which is an aspect of the ACHC accreditation manual. All information submitted and/or reviewed by ACHC is regarded as confidential and in compliance with HIPAA regulations.

Applications must be filled our correctly and completely in order to proceed with the accreditation process. Statistical data forms are located in the application and must be filled out for the corporate location and all branches (if necessary). Please direct any questions about filling out your application with your account manager. All tax ID; NPI, MCR provider #'s and/or NSC #'s **must** be included on the application.

Upon receipt of an application, ACHC will assign an application number.

Once application process is complete and validated by ACHC, the onsite survey will be completed within 9 months. If an onsite survey is not completed within 9 months of the application receipt date, by fault of the applicant organization, the application expires and ACHC will require a new application and accreditation fees if the applicant organization wishes to continue the accreditation process.

Deposit:

A deposit of $1500.00 is required to be sent in with your application and PER. Deposits are non-refundable and are applied to your accreditation fees.

D. Preliminary Evidence Report (PER)

The PER is included on customer central as part of the accreditation manual and must be returned with the completed application and deposit. ACHC staff will be available to answer questions during the PER completion process. PER's can be completed electronically or by paper (Electronically is preferred). Organizations with 10 or more locations must submit their PER in electronic format. After ACHC receives the customer's PER(s), accreditation staff prepares and mails a complete PER package to each member of the survey team.

*****Note: If one of the three items (application, deposit, PER) is not submitted to your account manager, a contract for survey will not be generated until we have everything in its entirety. Once all three items are submitted to ACHC, this is indication that your organization is ready for an ACHC survey.**

E. Accreditation Fees

As part of the application review process, a quote for accreditation fees is prepared. Fees, number of surveyors/type of surveyors and number of survey days are based upon statistics from the organization's last completed fiscal year prior to application for those program(s)/service(s) indicated on the Application and Statistical Data Form. Relevant statistics include but may not be limited to: (a) number and type of services; (b) number of employees; (c) volume of clients/patients served; and (d) number of branches. Applicant organizations which have not completed at least one fiscal year prior to application must submit year to date statistics.

Full accreditation fees are not refundable. Requests for partial refunds must be made in writing, detailing the reason for the request. The partial refund amount is determined on an individual basis and is dependent on the stage in the accreditation process where the organization has withdrawn it's application.

The applicant organization is held accountable for accurate and timely information. ACHC reserves the right to review and/or adjust accreditation fees based on new or validated information obtained during the survey process which may affect the number of survey days or surveyors required. Continuation of the survey process is contingent upon receipt of total fees prior to the survey. If a surveyor arrives at an organization for survey and discovers the organization is providing services that were not indicated on its' application, the surveyor will notify ACHC and the organization will be responsible for any additional survey fees.

Accreditation fee structures are reviewed periodically. ACHC reserves the right to adjust accreditation fees and establish the effective date of change based upon the review.

F. Contract for Survey

Once fees and payment schedules are confirmed with the applicant organization, a Contract for Survey is issued. The Contract for Accreditation Survey identifies, but is not limited to: (1) payment schedule for accreditation fees; (2) rescheduling provisions; (3) contract execution timeframe; and (4) notification time frames for organizational changes in ownership/governance, facilities, services, etc.

The organization must review the contract in its entirety and sign and return the entire contract to ACHC within seven (7) calendar days to ensure continuation of the accreditation process. Failure to meet any of the contract terms may result in cancellation of the survey with rescheduling/cancellation fees assessed.

G. Scheduling

Upon execution of the contract, the survey is scheduled. Surveyors are chosen based on their qualifications in a specific area. The number of surveyors for a survey is determined by the size of the organization and the number of services provided. A minimum of one surveyor will be scheduled for all programs. A minimum of two surveyors, one nursing and one non-nursing surveyor (MSW or Clergy) will be scheduled for hospice program surveys. Additional surveyors are assigned based on the service(s) provided that is indicated on the application. Surveyors assigned will be discipline specific to the service(s) provided, which may result in a team of surveyors.

ACHC reserves the right to send a surveyor trainee as part of the survey team. Trainees are sent at no charge to the organization.

All ACHC surveyors/trainee's must disclose any potential conflict of interest with the applicant organization to ACHC before the surveyor is assigned to conduct the survey. Surveyors/trainee's with a confirmed conflict are not utilized for the survey being scheduled. Surveys are usually conducted 3 to 7 months after the application process has been completed and validated.

H. PER Review

After the survey is scheduled, the surveyor that has been selected to complete your survey will receive the application and PER that you submitted to your account manager. They will review your polices and all the information about your company. They will complete a desk review, which is a summary of any standards that may need to be corrected before he/she comes on site. This gives you as the provider a chance to make any changes up front to be compliant with ACHC's standards. You will receive the desk review at least 30 days prior the survey and you will be required to submit those changes back to your account manager. If your surveyor does not find any deficiencies in your PER review, you will be notified by your account manager and a survey can take place at anytime beyond that point.

I. Survey

Surveys are conducted by a single surveyor or a team of surveyors. Surveyors are selected based on the services being surveyed.

Entrance Conference

The surveyor(s) will conduct an entrance and exit conference with representatives of the organization. At the entrance conference, the lead surveyor will briefly introduce himself/herself, along with other members of the survey team (if applicable), discuss PER issues and tentative schedule, and answer questions regarding the survey.

Data Collection

The survey focuses on personnel files, client/patient records, financial management, service contracts, risk management, quality improvement activities, policies and procedures, onsite observations, operational and service delivery outcomes, and staff and client/patient interviews. All

applicants will be given explanation of findings/deficiencies throughout the survey process and again during the exit conference.

The applicant organization authorizes ACHC and/or its designated agents to access all records (including client/patient, personnel, financial management, risk management, utilization review, quality assurance and quality improvement) that are necessary to ascertain the degree of compliance with ACHC Standards. ACHC complies with all HIPAA, privacy and security regulations.

Exit Conference

During the exit conference, the surveyor(s) will discuss survey findings. While organization personnel are given the opportunity throughout the survey to provide information that does not appear readily available to the surveyor, the exit conference provides representatives of the organization a final opportunity to clarify information or present data that may not have been available to the surveyor during the survey. A final Summary of Findings will be sent to the organization that will include all details from the survey.

The surveyor does not render judgment as to whether the organization will be granted accreditation; rather, he/she may make a recommendation, based on observation, as to the organization's accreditation status. Her/his role is to review information presented and to clarify, observe, and verify data that supports compliance with applicable standards.

V. Accreditation Decision

A. Scoring

The lead surveyor ensures that all data collection tools and documentation are completed and submitted to ACHC for the scoring and document review process. Upon receipt of survey documentation ACHC staff reviews documentation for completeness and data is entered into the appropriate scoring tool for computation of survey scores.

B. Document Review

Accreditation staff reviews documentation and scoring and prepares a draft of the applicant organization's final written report (Summary of Findings) for review and final determination of status. The Summary of Findings indicates a finding of Met, Partially Met, Not Met or Not Applicable, to indicate the results of the data collected for each standard surveyed. Standards with findings of Not Met, Partially Met include a comment and recommendation to assist the organization in taking corrective action to meet the standard. A plan of correction (POC) is required for all standards that are not fully met.

The Senior Vice President of Clinical Compliance and Accreditation is responsible for review of accreditation results. The Standards and Review Committee (SRC) is responsible for oversight of the accreditation approval process. The SRC establishes guidelines for processing, scoring, reviewing, status determination and reporting results of accreditation applications. The Board of Commissioners reserves the right to make the final decision on all applications.

C. Accreditation Status Criteria

Approval of Accreditation

Full accreditation is awarded to an organization when the overall score and each section score are within a range of 90% or above. Submission of a plan of correction will be required for any standard not fully met. Accreditation is good for 3 years. Effective accreditation dates for new and renewal organizations are determined as follows:

New organization:

1. First day following the survey, if the organization passes survey on the first review.
2. First day after receipt of plan of correction once the plan of correction is approved from deferral status.
3. First day after the focus survey, if the deferral is cleared upon review.

Renewal organization:

1. First day following current accreditation expiration date if the organization passes survey on the first review.
2. First day following current accreditation expiration once the plan of correction is approved from deferral status.

Deferral of Accreditation

Deferral accreditation is given to an organization when the overall score is within the deferral range (80% up to 89.99%). Any individual section that scores below 90% or failure to meet any one Medicare Condition of Participation will also put the organization in deferral status. The organization is advised of the decision in writing and accreditation will be deferred pending submission of a plan of correction within 30 days and corrective documentation within 90 days of the date of ACHC's notification letter. Once all documentation has been received and reviewed, a determination of the need for an onsite survey will be made.

Deferral focus surveys are invoiced at a per-surveyor per-day fee. After the focus survey takes place, if the organization is subsequently found to be in compliance and has a passing score in accordance with approval criteria, full accreditation is awarded and a Certificate of Accreditation will be issued.

If a focus survey is not required, based on the review of the plan of correction and corrective documentation, ACHC will determine which deficiencies are cleared and make a final decision regarding accreditation status.

Denial of Accreditation

Denial of accreditation is given to an organization when the total overall score is below 80%. If a determination is made to deny accreditation, the organization is advised in writing.

When accreditation is denied, new applicant organization has the option of reapplying for accreditation at any time they feel they are ready for survey. At the time of re-application, a new application must be submitted with appropriate application fee. Reapplications are processed and accreditation fees charged in accordance with the application process. Organizations that are denied as a result of a reaccreditation survey will be handled on a case by case basis. The organization will be responsible for full payment of the reaccreditation survey before that survey is scheduled.

D. Accreditation Documentation

All documentation regarding the providers accreditation is described in the approval letter which is sent with the Certificate(s) of Accreditation and signed by the Senior Vice President of Clinical Compliance and Accreditation. Certificates of Accreditation are provided for all locations listed in the Application for Accreditation and included in the survey process.

Organizations will be notified in writing of the accreditation decision within four weeks of the last day of the survey. Accreditation survey scores are not sent with the decision letter.

When applicable, the accredited organization should send a copy of the Letter of Accreditation, Summary of Findings and Accreditation Certificate for all locations to the state governing body within 30 days of receipt.

E. Continued Compliance

Accreditation is contingent upon continued compliance with the standards and these accreditation policies and procedures.

Accreditation is not automatically renewable. Approximately 15 months prior to the organization's expiration of accreditation, ACHC will notify the organization in writing and include a renewal application and PER. If renewal applications are not submitted when specified in the renewal letter, sufficient time may not exist to schedule and complete a survey prior to the organization's expiration date. In this event, ACHC will automatically withdraw accreditation at the expiration of the current accreditation period. CMS and all appropriate regulatory agencies will be notified if an organization with deemed status loses its accreditation status. Renewal applications are processed through the accreditation process as stated in Section IV Accreditation/Survey Process.

After the organization is officially granted accreditation, ACHC reserves the right to make unannounced onsite visits at any time during a three-year accreditation cycle to determine continuing compliance with standards. If an interim visit reveals noncompliance with ACHC standards or Medicare COPs, a Plan of Correction and supportive documentation is required and full survey fees/expenses **will be billed** to the organization. ACHC conducts interim surveys based on a percentage of currently accredited organizations and/or patient complaints received by ACHC.

ACHC sends accredited organizations new/revised standards upon release, along with timeframes for organizations to come into compliance.

F. Appeals

Applicant organization may formally appeal the decision as provided in the Appeals Process.

Procedures for an Appeal of an ACHC decision are as follows:

1. An applicant organization or accredited organization must submit a written request to ACHC for an appeals hearing no later than 30 days from receipt of the letter informing them of the decision of their accreditation status.

2. ACHC will acknowledge, in writing, the receipt of the request and notify the Chairman of the Standards and Review Committee that an appeals hearing has been requested.

3. The Standards and Review Committee Chairman will consult with the Board Chairman to appoint a minimum of five members to an Appeals Hearing Committee. If the original decision was reached by members of the Standards and Review Committee, those members are not eligible to sit on the Appeals Committee.

4. The applicant organization or currently accredited organization has the option of submitting additional information or appear before the Appeals Hearing Committee. Any information submitted must have been in existence and available to the surveyor prior to the appeals hearing and during the latest site survey or interim site visit. Should the organization request an appearance before the Appeals Hearing Committee, a meeting will be scheduled and the organization will present explanations that will be considered by the committee.

5. The Appeals Hearing Committee will prepare a report of their findings for the Board.

6. The Board will review the findings of the Appeals Hearing Committee and make a final decision to uphold or reverse the original decision.

7. All appeal decisions made by the Board are final.

Any member of the Board or Standards and Review Committee who is affiliated with a organization under review or who has a conflict of interest must abstain from voting on the appeal under consideration.

VI. Notification of Changes

Post-Accreditation Changes

Accreditation is not automatically transferable when there is a merger or change in ownership. **ACHC requires the organization to provide written notification thirty (30) days prior to a branch office addition or deletion, service addition or deletion, or change in the name, location, ownership or control of the organization.**

Upon receipt of the appropriate documentation, including licensure and certification documentation from CMS/State Agency, ACHC will review for completeness and determine whether the organization's accreditation certificate is still accurate. If an updated certificate(s) is required, a processing fee may be charged prior to issuance of a new certificate(s). Change in ownership or control of the organization may result in ACHC conducting onsite survey(s), with applicable survey fees.

Failure of the organization to notify ACHC of post-accreditation changes or provide additional requested information may result in assessment of penalties up to and including revocation of accreditation.

A. Name/Location Changes

The organization's notification letter to ACHC must include the following:

1. Effective date of the change

2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter only for Name change or relocation to a different city.
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon written notification of a change in the organization's name, ACHC will review copies of the Articles of Incorporation and business license, if applicable. A new Certificate of Accreditation with the new name will be issued once ACHC receives the appropriate certificate re-issuance fee.

If the organization is relocated to a new city, ACHC will issue a new Certificate of Accreditation with the new location upon receipt of appropriate certificate re-issuance fees.

B. Merger/Ownership Changes

The organization's notification letter to ACHC must include the following:

1. Effective date of the change
2. Former name, as well as new legal name, if applicable
3. Former location as well as new location, if applicable
4. Any change of services, if applicable
5. Include original certificate of accreditation with the letter, if new certificate is required
6. Include copies of Articles of Incorporation, if applicable
7. Include copies of business license, if applicable

Upon execution of the state required filings of ownership change/merger, a letter documenting the transaction shall be submitted to ACHC, postmarked within 2 weeks of the effective date of filing.

Based on a review of documentation submitted, ACHC will make a determination whether an onsite survey, preparation of new Certificate of Accreditation, assessment of fees, and/or other action is required.

C. Branch Office Addition

ACHC defines a branch as a location serving clients/patients, maintaining client/patient and/or personnel records and accepting referrals and inquiries directly from potential clients/patients. **A branch office that opens after accreditation is granted will not advertise or otherwise consider itself an accredited entity until official notification from ACHC.**

If an organization adds a branch after its corporate accreditation takes place, ACHC requires the organization to provide written **notification at least thirty (30) days prior to the opening/acquisition/merger** which resulted in the new location. **Failure to notify ACHC of this branch addition in the 30 day timeframe could result in disciplinary action.** This letter should include the service(s) to be offered at each branch. Agencies that have deemed status will be surveyed after the CMS regional office approves the branch addition and authorizes ACHC to perform the survey, if applicable. Questions regarding this process should be directed to ACHC's Accreditation Department.

Upon receipt of the organization's written notification, ACHC will send the organization a Branch Addition Application, Branch Addition Requirements List specific to the organization's services provided, and notification of the fees required. The Branch Addition Requirements List outlines documentation necessary for ACHC to determine/conduct an offsite review or schedule an onsite survey of the new location.

ACHC reserves the right to conduct an onsite survey of any branch addition. If it is determined an onsite review is necessary, the normal unannounced survey scheduling process will apply and additional fees may be assessed.

A review of the documentation is performed and any missing information is requested from the organization in writing via fax/email/mail, along with timeframes for receipt. ACHC will hold the branch addition documentation without further processing until the missing information is received from the organization.

Upon approval, ACHC will mail a letter confirming accreditation of the new location for the duration of the corporate accreditation, and include an accreditation certificate.

D. Service Addition

ACHC requires the organization to provide written **notification at least thirty (30) days prior to the addition** of any service. Once ACHC is notified of the service addition, the company will receive the service addition application packet. Upon receipt of the completed application, the accreditation staff follows the application review, scheduling and contract preparation process.

ACHC will require a focused review and an onsite survey to determine if the organization is in compliance with applicable standards for the added service. If the data collected during the onsite survey reflects a passing score for the service(s), a certificate of accreditation for the service is issued for the duration of the current accreditation period.

E. Service Discontinuation

An accredited organization must notify ACHC in writing of any service that has been discontinued. A new service addendum may need to be completed for CMS purposes.

VII. Public Information

A. Logo/Advertising Language

An organization must accurately describe only the program(s), service(s) and branch office(s) currently accredited by ACHC and abide by the Guidelines for Use of ACHC's Logo when advertising its accreditation status to the general public. False or misleading advertising represents noncompliance with accreditation and will result in penalties up to and including withdrawal of accreditation. The Guidelines for Use of ACHC's Logo are sent to organizations in their accreditation notification packet. Branches and services accredited during the accreditation cycle can not be advertised as accredited until appropriate applications are submitted and accreditation certificates are received.

B. Press Releases

ACHC encourages organizations to publicize their accreditation status and provides a sample press release in the accreditation notification packet.

VIII. Nonconformance Policy

ACHC will process complaints, conduct investigations, discuss issues noted during surveys, and issue disciplinary actions according to the policies and procedures approved by the ACHC Board of Commissioners.

All disciplinary actions taken by ACHC will be reported on the ACHC Website. The information to be provided in these reports will include but is not limited to:

- organization name and address
- type of accreditation
- final action

A. Handling of Complaints

Complaints about accredited organizations are to be filed with the ACHC office. These complaints should identify facts or circumstances that relate to the complaint. ACHC will receive complaints by phone, mail, fax, email, the ACHC website or in person.

ACHC will investigate and/or review, and follow up on complaints from any source where an ACHC accredited organization appears to be out of compliance with its accreditation standards or Medicare COPs. As required by ACHC standards, accredited organizations must provide ACHC's telephone number to their clients/patients as part of their client/patient hand-out for purposes of reporting a complaint.

Complaints should document:

- The name, mailing address and phone number of the person filing the complaint;
- The name of the organization involved;
- A detailed description of the incident that is the subject of the complaint, including identification of date, time, and location of each incident, as well as the identity of other individuals with information about the incident.

Anonymous complaints will not be accepted. The complainants' identity will be kept confidential whenever possible. While under investigation by ACHC, a complaint is a confidential matter. However, ACHC cannot guarantee complainants that their identity will remain confidential if disclosed to ACHC. All substantiated findings become part of the permanent file of the organization involved and are public record.

Processing a Complaint

The ACHC Quality Assurance Manager or designee will inform the Senior Vice President of Clinical Compliance and Accreditation of the receipt of a complaint. Upon receipt of a complaint, a complaint file will be opened and the Quality Assurance Manager and the Senior Vice President of Clinical Compliance and Accreditation will conduct an initial review of the complaint to determine whether there is sufficient information presented to go forward with an investigation. This initial review consists of determin- ing if the information presented meets the elements necessary to

proceed with further inquiry. To determine if an investigation of a complaint is warranted, the information gathered will be analyzed to determine whether, if true, it would constitute a violation of ACHC standards or Medicare Conditions of Participation. If upon initial review there is no evidence that a violation has occurred, the complaint is closed and the complainant will be notified that no breach of standard has occurred.

If the Quality Assurance Manager and Senior Vice President of Clinical Compliance and Accreditation conclude that the information shows that a violation may have occurred, the Quality Assurance Manager shall notify the organization that an investigation has been initiated. The investigation will be performed by the Quality Assurance Manager, as directed by and with the help of the Senior Vice President of Clinical Compliance and Accreditation. The organization or other subjects of the investigation may be interviewed and the organization may be asked for records for review during the investigation. An onsite survey may be required in order to complete the investigation.

If no violation is found following investigation, the Quality Assurance Manager will confer with the Senior Vice President of Clinical Compliance and Accreditation, at which time the complaint file may be closed. If closed, the complainant and the organization will be notified and no further action will be taken.

If sufficient evidence exists that the organization has violated the ACHC standards or Medicare Conditions of Participation, the organization may be penalized. If the organization is penalized at any level above a warning, the penalty will be listed on the ACHC website and CMS and/or other appropriate regulatory agencies will be notified.

If upon review of information it is determined that immediate jeopardy to the client/patient is present and ongoing, ACHC will notify the CMS regional office (RO) and conduct its investigation within two (2) business days of authorization from the RO. If it is determined the situation is non-immediate jeopardy, the complaint will be prioritized within two (2) business days of receipt and ACHC will conduct an investigation of the matter within 30 days to determine the exact nature of the complaint and the action warranted. Depending upon the nature of the complaint, one or both of the following actions may be taken:

1. ACHC will contact the organization, notifying it of the complaint and address the following:

    - provide a description of the complaint(s)
    - request the organization's cooperation in resolving the complaint
    - request the organization respond to the complaint within the identified time frame
    - ask the organization if they were aware of the complaint and if they have taken action

2. ACHC may contact the organization via phone and/or fax or designate personnel to go unannounced to the organization and request immediate access to information and data related to the standards indicated in the complaint.

ACHC will review all the information and data collected relative to the complaint. If necessary, a summary report will be sent to the Standards and Review Committee for a final decision. If an investigation reveals the complaints allegations are substantiated and the patient's health, safety and welfare are in jeopardy, the organization may face disciplinary action, including suspension or revocation of accreditation.

If <u>any</u> noncompliance with ACHC standards or Medicare COPs is confirmed during the onsite

complaint investigation survey, a plan of correction and supportive documentation is required and survey fees/expenses **will be billed** to the organization. If ACHC makes the decision to withdraw accreditation, ACHC will notify the appropriate regulatory bodies of its decision.

B. Disciplinary Actions as a Result of Survey Findings

Disciplinary actions can also results from information gathered during a survey. Failure to adhere to certain standards and /or Medicare COPs, failure to follow ACHC policies and procedures or failure to submit and follow an appropriate plan of correction will result in a disciplinary action. Investigations regarding issues found during the survey process may be further investigated by a request for documentation, interviews and/or unannounced on-site surveys. The organization **will be billed** for surveys conducted as a result of a disciplinary action.

C. Overview of Disciplinary Actions

The following are Disciplinary Actions authorized by the Accreditation Commission for Health Care to discipline an organization for violations of ACHC standards and Medicare Conditions of Participation:

1. Warning
2. Reprimand
3. Probation
4. Suspension
5. Revocation

Warning

A warning is a written communication between ACHC and the organization that serves as notice that an ACHC standard or Medicare Condition of Participation may have been breached, but the conduct does not rise to the level which warrants public censure. A warning may be issued by the Senior Vice President of Clinical Compliance and Accreditation to an organization. It is a minimal disciplinary action and is not considered public information.

A warning will be issued following an investigation if the Senior Vice President of Clinical Compliance and Accreditation acting on behalf of ACHC, believes that there is insufficient evidence to support a disciplinary action against the organization, but there is sufficient evidence to notify the organization that continuing the activities which led to the complaint being submitted to ACHC may result in action against the organization.

Reprimand

A reprimand is a formal sanction that expresses concern about the actions of an organization but does not restrict accreditation certification. A reprimand is considered public information and will be reported to national and state regulatory agencies. A reprimand may be issued by the Senior Vice President of Clinical Compliance and Accreditation to an organization if there is sufficient evidence that a violation of a statute(s), accreditation standards, and/or rules has occurred, but the violation is not of sufficient seriousness to warrant suspension or revocation of the accreditation.

Probation

ACHC may determine that it is appropriate to allow an organization continued accreditation and not revoke or suspend the organization's accreditation. In assessing the appropriateness of a probationary penalty, ACHC will consider all the facts and circumstances of the conduct at issue and the organization's prior performance. In particular, ACHC will review the nature, severity, and scope of the violation, the degree and scope of harm to patients and the nature of the motivations of the organization that led to the conduct in question.

Further, in assessing the overall appropriateness of probation and in defining the appropriate duration of the probation, ACHC also will review the organization's service performance, prior history of violations of ACHC's standards or accreditation policies and procedures, especially prior violations of the provisions that relate directly to the conduct then in question, and also whether any probationary condition that might be imposed will provide sufficient safeguards to ensure the safety and welfare of the public as well as the successful remediation of the organization's conduct. A probationary sanction may be invoked for a period not to exceed three (3) years since situations that would require monitoring for a period longer than that are inappropriate for a probationary sanction. Probation may be offered to an organization by ACHC as part of the issuance of a new accreditation certification. Failure to comply with the stated conditions is grounds for suspension or revocation of the accreditation.

The Senior Vice President of Clinical Compliance and Accreditation may place an organization on probation after presenting the facts of the investigation to the Standards and Review Committee. Decisions regarding probation will be made by the Standards and Review Committee. Probation is considered public information and will be reported to the appropriate state and national regulatory agencies and listed on the ACHC website.

Suspension

When ACHC determines it is appropriate, it places an organization on suspension of accreditation for a fixed period of time up to six (6) months, with the understanding that at the end of the specified period of time, and with the completion of any additional conditions including, but not limited to, completion of corrective actions or monitoring of particular areas of practice or conduct that successfully demonstrate successful outcomes relative to investigational findings, the accreditation will automatically be reinstated and reissued upon the organization's payment of the standard cost for the issuance of a replacement accreditation certificate. The Senior Vice President of Clinical Compliance and Accreditation may place an organization on probation after presenting the facts of the investigation to the Standards and Review Committee. Decisions regarding suspension will be made by the Standards and Review Committee. Suspensions are considered public record and will be reported to all appropriate agencies and listed on the ACHC website.

Revocation

Revocation entails loss of accreditation for a specified period of time. Accreditation may be re-issued after the specified period has expired and the organization has petitioned for reinstatement, and provided sufficient evidence of compliance with accreditation standards, Medicare Conditions of Participation and any conditions imposed by ACHC at the time of the revocation. Decisions regarding revocation will be made by the Standards and Review Committee. Revocation decisions are considered public record and will be reported to all appropriate agencies and listed on the ACHC website.

Obtaining Records for Investigation

ACHC may request the organization to produce records to allow ACHC to investigate the organization. ACHC's Senior Vice President of Clinical Compliance and Accreditation is authorized by ACHC to request all needed records for investigation purposes. Each request will identify the pertinent document or records needed by ACHC. A time shall be specified in the request by which the documents shall be produced.

In issuing requests for documents, ACHC shall make every effort to limit its request to the minimum necessary information required in order to complete its investigation and will also otherwise comply with the Privacy Rule adopted by the United States Department of Health and Human Services and codified at 45 CFR § 164.500 *et seq.*

Reporting of Disciplinary Actions

All disciplinary actions taken by ACHC will be reported in the *Surveyor* Newsletter and on ACHC's website. In addition, as required by federal law, a report of actions will be made to all applicable local, state and federal regulatory agencies. ACHC will report any probation, revocation or suspension of an organization's accreditation to all appropriate regulatory bodies including Centers for Medicare and Medicaid, National Supplier Clearinghouse and state licensure agencies.
The information to be provided includes:

- Facility name and address
- Owner name(s) and address(s) and/or Board of Director(s)
- Type of accreditation (Initial or Renewal)
- Disciplinary action

Community Health Accreditation Program (CHAP)

CHAP

COMMUNITY HEALTH ACCREDITATION PROGRAM

1275 K Street, NW • Suite 800 • Washington, DC 20005 • tel: 202.862.3413 • fax: 202.862.3419 • www.chapinc.org

RECEIVED BY CALIF. BOARD OF PHARMACY 2010 APR -6 AM 8:36

March 26, 2010

Debbie Anderson

Site Licensing Manager

California State Board of Pharmacy

1625 N. Market Blvd. Suite N219

Sacramento, CA 95834

Dear Debbie,

The Community Health Accreditation Program (CHAP) is delighted to provide this application for renewal of our approval by the California State Board of Pharmacy as an accrediting agency. The following document and attachments address all of the criteria which you have shared with us. We are eager to discuss our application, answer any questions or provide any needed clarification, and look forward to continuing our relationship in support of quality and safety.

1. ***Periodic inspection***-CHAP policies require a site visit, with a minimum frequency of every 3 years. Please see our policies attached for further information. **ATTACHMENT A Accreditation Policy D2 and Site Visit Policy D5**

2. ***Documented accreditation standards***-CHAP has created accreditation Standards of Excellence for Pharmacy which reflect California law and the latest best practice information in the industry, as well as Medicare Supplier and Quality Standards. All organizations seeking CHAP accreditation are also assessed against CHAP's CORE standards. **ATTACHMENT B Standards of Excellence for Core and Pharmacy**

3. ***Evaluation of surveyor's qualifications***-CHAP site visitors are required to have at least 5 years middle-senior management experience in the service line in which they perform Site Visits. Only a pharmacist would be assigned to survey a pharmacy. All new staff receive a 5 day classroom

orientation and 4-6 site visits where they are assigned an experienced pharmacy site visitor preceptor. **ATTACHMENT C Site Visitor Job Description, Introductory Site Visitor Evaluation, Annual Performance Evaluation**

4. ***Acceptance by major California payers***-CHAP is accepted by major payers everywhere. CHAP works effectively and ongoing with all payers to educate them about CHAP, and the robustness of the accreditation process.

5. ***Unannounced inspections of CA accredited sites***-CHAP has 6 currently accredited pharmacy sites in CA, and over 90 total sites nationally. Our agreement with these organizations includes allowing oversight visits for organizations who monitor CHAP performance. CHAP welcomes this oversight and opportunity for learning, continuous improvement and accountability.

6. ***Board access to accreditor's report on individual pharmacies***-CHAP agreements allow CHAP to disclose accreditation reports to certain authorities, which would include the CA Board of Pharmacy. CHAP standards also required accredited organizations to disclose this information. Each CHAP organization has a copy of the written report available on site. A process for providing reports on demand can be established.

7. ***Length of time the accrediting agency has been operating***-CHAP was founded in 1965, as the first organization in the United States to accredit community based health care organizations. CHAP is authorized by the Centers for Medicare and Medicaid Services (CMS) to provide accreditation for home health, hospice, durable medical equipment and pharmacy.

8. ***Ability to accredit out of state pharmacies***-As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and the US Territories.

Debbie, I believe this information is responsive to your email request of March 23, 2010. We are eager to renew our approval as an accreditation agency for pharmacies that compound injectible sterile drug products by the California Board of Pharmacy. We look forward to your feedback after your April 2010 board meeting. Please do not hesitate to contact me with any questions or concerns at 202-862-3413.

Sincerely,

Terry A. Duncombe
President and CEO

ACCREDITATION POLICY

Policy

Accreditation is the systematic process by which home and community-based providers of health care services and products are evaluated. The accreditation process includes a 3 year contract cycle with a site visit at least every 3 years. The CHAP Standards of Excellence are the parameters by which organizations are measured. For Deemed Organizations, the Medicare Conditions of Participation are also built into CHAP Standards of Excellence, and are cited separately.

See Policy D.3 for further information on Accreditation with Deemed Status.

The accreditation process promotes the coordination and integration of quality health care delivery by all types of providers. It promotes the best possible use of available health personnel and products, and fosters a climate for ongoing self-study and improvement. CHAP Accreditation distinguishes the excellent organization from its competition because knowledgeable peers from across the country have judged it to have met the CHAP Standards of Excellence. This process identifies for the consumer those organizations that have measurable quality indicators for structure, process, and outcomes.

Procedure

The process of accreditation includes the following steps:

1. Submission of a CHAP application with non-refundable application fee
2. Signing of a three year contract (a 30 day review period is allowed by CHAP)
3. Assignment of each provider organization to a Customer Relations Representative, who is their main point of contact and support at CHAP
4. Submission of a Self Study (three months is allowed for its completion; extensions can be granted upon written request from the provider organization)
5. A site visit will be conducted after the submission of the completed Self-Study Report; with scheduling based self study received date.
6. Submission of an acceptable Plan of Correction for each Medicare deficiency and/or CHAP citation identified during the site visit.
7. Most documents can be completed electronically
8. Final accreditation determinations from the Board of Review (See BOR Policy-F1)
9. The accreditation period will be 3 years. This period begins with the date the acceptable Plan of Correction (if required) is submitted to CHAP, for initial organizations. For continuing organizations, the accreditation period begins the day following the end of the previous accreditation cycle.
10. On rare occasions, CHAP may adjust accreditation periods, and grant accreditation extensions, when necessary.

11. Written notification of provider of final accreditation results, including an Accreditation Report.
    a. Accreditation types include:
        - Accreditation without Required Actions
        - Accreditation with Required Actions
        - Accreditation with Required Actions& Focus Visit
        - Accreditation with Required Actions & Progress Report
        - Accreditation with Required Actions, Progress Report and Focus Visit
        - Defer Accreditation
        - Deny Accreditation
        - Withdrawal of Accreditation

12. Recognition of provider accreditation through CHAP accreditation certificate and posting on CHAP web site as accredited provider

13. Consultation with CHAP staff for training or questions may occur at any point in the cycle

14. Special circumstances:

    a. **Abort:** If Site Visitors arrive for an initial visit and active patient census of other requirements are not met, the visit will be aborted (terminated without completion); the agency will go to the bottom of the scheduling list, and the Site Visit day will be billed
    b. **Defer:** If Site Visitors arrive for an initial visit, and significant operational or care issues are found, yet the Site Visitors determines that the organization demonstrates willingness and ability to make changes needed to come into compliance with CHAP Standards of Excellence, the Site Visit will be completed and the BOR process will occur. The accreditation decision will be deferred, and the organization will be asked to implement corrective actions, and notify CHAP of readiness for another visit. CHAP allows 6 months for this process. Additional Site Visit fees will apply. If significant operational or care issues are identified at the subsequent visit, accreditation will be denied.
    c. **Withdrawal or termination of accreditation:** will occur if the following:
        - To demonstrate compliance with all Conditions of Participation after a condition level deficiency is cited
        - To prepare an acceptable Plan of Correction
        - Failure to make payment for accreditation services or site visits
        - These providers will be notified in writing of the denial/termination and informed of their opportunity to reapply for accreditation with CHAP or with another organization.

CHAP 3/99
Rev. 9/18/02
Rev. 9/26/06
Rev. 11/7/07
Rev. 2/23/2009
Rev. 5.28.2009
Rev. 9.22.2009
Rev. 11.16.2009

SITE VISITS

Purpose:

To determine the organization's current level of compliance with the CHAP accreditation standards and eligibility for initial or ongoing accreditation. To gather data through on site methods by site visitors, incorporating home visits, staff interviews, clinical, personnel and administrative record reviews, to determine the effectiveness of corrective actions implemented by an accredited organization

Policy

1. CHAP performs site visits to organizations to at various times in the accreditation cycle. The following table illustrates types of visits and related information.

Visit Type	Timing	Standards Reviewed	CARES Visit Loading	CMS Docs (1572, etc.)	ASSURE/ DMEPOS Database?	CMS Schedule	CHAP Docs
Comprehensive							
Comprehensive	Initially and Every 36 months	Core Service Specific	All CORE and Service Specific Standards	Standard Survey	Yes	Yes	POC Accred Letter
Core Only (Florida)	1-4 months after Self Study submitted	Core	Modified	No	No	No	POC Accred Letter
Follow-Up							
a. COMPLAINT	PRN	Core Service Specific	Modified CORE	Only if IJ	Yes	No	POC Accred Letter
b. ADD PRODUCT CODE	45 days after notification of readiness	Core Service Specific	Modified CORE	Product Code worksheet	Yes	No	POC Accred Letter
c. ADD SERVICE	1-4 months after Self Study submitted	Core Service Specific	Modified CORE	Standard Survey	Yes	Yes	POC Accred Letter
d. ADD LOCATION: HH/H (NEW/ADDITIONAL PROVIDER NUMBER) OR DMEPOS	1-4 months after organization notify CHAP of readiness	Core Service Specific	Modified CORE	Standard Survey (HH and H only)	Yes	Yes	POC Accred Letter

Visit Type	Timing	Standards Reviewed	CARES Visit Loading	CMS Docs (1572, etc.)	ASSURE/ DMEPOS Database?	CMS Schedule	CHAP Docs
e. STATE MANDATED ANNUAL (NEW JERSEY)	12 months after last scheduled site visit	Core Private Duty	Modified	New Jersey specific	No	No	POC Accred Letter
f. BOR REQUIRED FOCUS	6 months or 12 months after last site visit date	Former Required Actions POC with Agency Response	Prior Required Actions	No	No	No	POC Accred Letter
g. CHAP VALIDATION SURVEYS (INTER-RATER RELIABILITY)		UNDER DEVELOPMENT					
h. CONDITION LEVEL DEFICIENCY FOLLOW UP	< 90 days after end of visit with deficient finding	Standards and conditions cited	Modified	Yes	Yes	No	POC Accred Letter
i. HOSPICE ADDING IN-PT UNIT							
j. CHANGE OF OWNERSHIP							

2. A comprehensive visit is completed in the first year of the organization's accreditation agreement with CHAP, and repeated every 3 years. During that visit, all standards for CORE and whichever other services for which the organization has requested accreditation are reviewed. The number of days planned for the site visit is determined by applying organization statistics to a grid.

3. In general, the number of unduplicated patient service units in a 12 month period, as well as the number of service locations, determine the number of days needed to complete a site visit.

4. All site visit days except inter-rater reliability visits and trainee days are billable to the organization.

5. The CHAP BOR Required Follow Up (Focus) Visit targets previously cited required actions and Medicare COP tag items. Clarification and verification of corrective actions taken must be quantified, analyzed and documented in detail. New findings, pertinent to the accreditation status and/or Medicare Conditions of Participation (COPs) must be addressed and documented as well, (i.e.: change in ownership, administrative personnel and operational aspects of the organization, etc.).

7. All site visits are documented in a CARES service specific workbook.

8. All visits begin with an Entrance Conference to communicate the objectives of the Site Visit, set time frames and expectations of participation by all parties, and plan the Site Visit schedule.

9. All Site Visits end with an Exit Conference, where the Site Visitor makes the Formal Presentation of findings, shares the Site Visitor recommendation for accreditation, and sets expectations for what comes next in the accreditation cycle.

10. All site visits, except Complaint and BOR Required Focus visits, must follow the Clinical Record and Home Visit Record Review guidelines.

11. Complaint visits: consultation between the RDPS and the Director of Quality and Standards to analyze the specific complaint and determine the site visit process. The RDPS will instruct the site visitor

12. BOR Required Focus visits: The RDPS will instruct the site visitor on the site visit process

13. Site visits are NOT required when a deemed home health or hospice adds a CMS approved branch office. Records from branch office clients and staff are sampled for review during the comprehensive visit, specific to each provider number.

B

CORE

STANDARDS OF EXCELLENCE

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1275 K Street NW, Suite 800
Washington, DC 20005

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INTRODUCTION TO CHAP CORE STANDARDS

The Community Health Accreditation Program, Inc. (CHAP, Inc.) is an independent, non-profit accrediting body for community based health care organizations. The types of organizations accredited include: home health, hospice, public health, home care aide services, private duty services, supplemental staffing services, infusion therapy nursing, home medical equipment, pharmacy services, and community nursing centers.

This "first" accrediting body for community based health care organizations in the United States dates back to 1965. A joint venture between the American Public Health Association (APHA) and the National League for Nursing brought to fruition the futuristic view of their respective membership that accreditation was the needed mechanism to recognize excellence in community health practice. In 2001, CHAP became an independent corporation with the purpose of using the accreditation process to elevate the quality of all community-based health care in the United States.

The CHAP accreditation process utilizes the "CHAP Standards of Excellence" that are driven by considerations of management, quality, client outcomes, adequate resources and long term viability.

The goal is to assist all types of community-based health care organizations to:

- Strengthen internal operations
- Promote continuous quality improvement techniques and systems
- Promote consumer satisfaction
- Affirm public trust
- Meet community health needs in a cost efficient and effective manner
- Maintain the viability of community health practice nationwide

CHAP, Inc. is committed to ensuring that home and community based health care providers adhere to the highest standards of excellence and that they maintain compliance with the current standards. Ongoing professional assistance and guidance provided by CHAP promotes continuous organizational self-improvement.

CHAP Accreditation publicly certifies that an organization has voluntarily met the highest standards of excellence for home and/or community based health care. Additional benefits of Accreditation by CHAP, Inc. include management consultation of the highest quality, access to a broad network of professional resources, and guidance critical to building intra- and inter-organizational collaboration and strength.

Currency and Relevance of Standards

In keeping with its goal of elevating the quality of all community health care in the United States, CHAP, Inc. continually reviews and revises the "Standards of Excellence" to assure currency with the community health care industry. CHAP standards place a strong emphasis on organizational management and client outcomes. They are to be used as a blueprint to build and maintain a highly sophisticated home or community health care organization, thus assuring the viability of the organization.

The 2004 Edition revisions are designed to:

- Establish standards of excellence for a wide variety of home and community-based health care organizations and programs
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of individual and group consumers of home and community-based health care services
- Strengthen the long-term viability of all types of community-based health care organizations
- Advance the recognition of the importance of home and community-based health care organizations as integral components of the national health care delivery system

The re-engineered CORE Standards of Excellence address the scope and complexity of community-based health care providers in today's health care arena, are generic, and apply to all services and programs accredited by CHAP.

The core standards are used in conjunction with service specific standards to ensure compliance with:

- Federal, state and local regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

The service specific standards address requirements additional to Core which are unique to the specific service or industry.

Additional Requirements for Medicare-Certified Home Health and Hospice Services

CHAP has received authority from the Centers for Medicare and Medicaid Services (CMS) to deem certified home health services and certified hospice services to be in compliance with the Conditions of Participation (COPs). CHAP's Core/Home Health Standards and CHAP's Core/Hospice Standards contain standards which include the intent of the Medicare COPs for home health and hospice.

The home health agency that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 484 Medicare Conditions of Participation: Home Health Agencies. See Appendix I HH for a full text of the home health regulations and a cross walk to the CHAP Standards.

The hospice organization that elects to receive Medicare Certification through deeming authority from CHAP must comply with CFR 418 Medicare Conditions of Participation: Hospice. See Appendix I H for a full text of the hospice regulations and a cross walk to the CHAP Standards.

Underlying Principles

I. Structure and Function
II. Quality
III. Resources
IV. Long Term Viability

Four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content.

UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION

A. Statement of Mission
B. Organizational Structure And Functional Mechanisms
C. Organizational Relationships/Chart
D. Administrative Authority and Responsibility
E. Organizational Policies
F. Communication
G. Ethical Issues
H. Research Initiatives

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

A. Business and Clinical Practices
B. Client Access to Care, Services and Products
C. Prioritization of Care Delivery
D. Coordination, Planning, Implementing, Monitoring, and Evaluating Care and Services Provided
E. Client Records
F. Performance Improvement
G. Safety of Employees and Clients
H. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

A. Human Resources Support Workload Demand
B. Contracts
C. Financial Management
D. Financial Information System
E. Physical Facilities
F. Management Information System

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic Planning
B. Annual Evaluation of the Organization

As you study and apply these standards to your own organization, give consideration to the following "*THEMES*" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element – Additional statements that provide more definition of selected elements.

Examples

Standard:.....CI.1
Criterion:.....CI.1a
Element:.....1)
Sub element:.....(a) (not all standards have sub-elements)

Main Sources of Evidence

D = Documents
I = Interviews
O = Observations
S = Surveys

Substantiation of Findings

Clarification
Verification
Quantification

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and to the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

The Site Visit Report

The Site Visit Report is a legal document that states the level of compliance with the CHAP Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation:	A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.
Required Action:	A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.
Recommendation:	A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.

Medicare Deficiencies for Home Health and Hospice Organizations:

Tag Items:

Identifiers used by CMS that indicate non-compliance with one or more Medicare Conditions of Participation or Standards are defined as Tag Items.

Tag Item designation applies only to Home Health and Hospice Organizations.

- G-Tags are specific to Home Health
- L-Tags are specific to Hospice

Tag Item designations are used in the Site Visit Report and on all CMS required documents for deemed organizations.

THE PROCESS REQUIRED TO ACHIEVE CHAP ACCREDITATION

CREATES PROFESSIONAL REWARDS FOR YOUR ORGANIZATION.

Abbreviations

Common abbreviations used throughout the CORE Standards include:

ADA Americans with Disabilities Act
Admin. Administration

CDC Centers for Disease Control and Prevention

FDA Federal Drug Administration

GB Governing Board

HBV Hepatitis B Vaccine

MC Medicare
MD Medicaid
MDA Medical Device Act
Mgmt. Management

N.B. "Note Well"

OSHA Occupational Safety and Health Act

P&Ps Policy(ies) and Procedure(s)

TO Table of Organization
TB Tuberculosis

CI.

THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORT ITS CONSUMER ORIENTED PHILOSOPHY, MISSION AND PURPOSE

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.1

D:	Current Mission statement includes a consumer focus and orientation to quality. (CI.1)
D:	Consumers are defined as individuals, groups and communities. (CI.1)
D:	Governing body minutes document actions taken on the Mission: a) Review and approval at least every 36 months b) Revisions and updates as applicable (CI.1b)

CI.1	Published mission statements clearly identify a commitment to providing high quality services and products which address consumer needs as an organizational priority.

CI.1a Programs and services provided reflect the organization's written mission.

CI.1b The mission statement is reviewed, revised as indicated, and approved by the governing body at least every 36 months.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.2

D: **Legal documents, specific to the organization, delineate applicable elements of CI.2b which may include: partnership agreement, articles of incorporation, bylaws, state charter, state licensure, tax license, trade name registration, business license, amendments, medicare certification and special waivers.**

D: *Note: Governing Body may be a governmental entity.(CI.2c)*

D & I: Name, address, credentials and professional/business affiliation of each member is identified. (CI.2d)
Note: Owner/Operator of a business may constitute the governing body. Governmental Boards of Health may be advisory in nature and/or may be elected or appointed officials.

D &I: New member orientation is validated in writing. Governing body members describe the orientation experience and articulate key issues affecting the organization. (CI.2e)
Note: Independent owner(s) may only have principal(s) as governing body, and orientation in CI.2e may not apply.

I: Governing body members articulate responsibilities and describe the types of actions taken by the board. (CI.2f)
Note: Selected elements may not apply to owner/operator businesses, i.e., selecting the chief administrator.

D: Current signed and dated annual disclosure statements are on file for all governing body members and executive staff. (CI.2g)

D &I: Governing body members confirm adherence by governing body members to legal documents which may describe notice of scheduled and special meetings, attendance requirements at meetings, appointment of officers, terms of office, committee structure and function, quorum determination. (CI.2h)

D: Governing body minutes reflect agenda items, discussion, and action taken. (CI.2i)
Note: Closed sessions are to be documented and distributed/filed per organizational policy.

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(c), 484.14(b), 484.14(i), 484.16, 484.52. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.52, 418.72. See Appendix IH for a full text of the regulations and a crosswalk.

CI.2	The organization has the structure and functional mechanisms necessary to support and accomplish its stated mission.

CI.2a The organization has the legal authority to operate and is in compliance with local, state and federal regulations.

CI.2b The applicable governance structure is defined in legal documents specific to the organization.

CI.2c An identified governing body assumes full legal authority, responsibility, and accountability for organizational performance; appoints a qualified administrator and designates advisory group membership as applicable.

CI.2d The governing body is made up of individuals with relevant expertise, business acumen, and professional relationships specific to the stated mission of the organization.

CI.2e Governing body members are oriented to the organization and are knowledgeable and responsive to key issues affecting the organization.

CI.2f The governing body carries out responsibilities specific to the organization including:

1) Establishing policies consistent with organizational mission
2) Approving new and/or revised policies and procedures as indicated and necessary
3) Holding management accountable for the fiscal solvency of the organization and adequacy of financial resources
4) Approving budgets and capital expenditures
5) Selecting and evaluating the chief administrator
6) Evaluating organizational performance
7) Developing and approving strategic plan
8) Reviewing legal and business documents in light of real or potential changes to the organization on a periodic basis but not less frequently than every 36 months:
   (a) Articles of incorporation
   (b) Bylaws
   (c) Legal agreements

C1.2g Annually, the members of the governing body and executive staff provide written disclosure of all professional or personal relationships or interests, direct or indirect that might present a conflict of interest. Statements are on file in the office.

CI.2h The governing body complies with organizational bylaws or other legal documents.

CI.2i Accurate, complete, and signed minutes are kept of all official meetings of the governing body, document actions taken, are distributed in accordance with organizational policy, and are retained for minimum of five (5) years or consistent with state regulations.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.3

D: A current organizational chart reflects lines of authority and accountability for all personnel. (C1.3a)

D: Amendments to the organizational chart are documented as applicable. (CI.3b)

I: Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (CI.3c)

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.14. See Appendix I HH for a full text of the regulations and a cross-walk.

CI.3	**Intra-organizational relationships are clearly defined.**

CI.3a **A current organizational chart delineates the lines of authority and accountability of all personnel.**

CI.3b **The organizational chart is reviewed and changed as needed.**

CI.3c **Personnel understand and use the organizational structure as outlined in the organizational chart.**

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.4

D: **Current job descriptions are on file for administrative and management positions. (CI.4a, b)**

D: **CEO/Administrator/Management resumes validate experience, knowledge, and qualifications required for the job. (CI.4b)**

Note: This standard may pertain to the Chief Health Care Administrator in Public Health Organizations.

D: **Written policy and procedure defines assignment of administrative responsibilities in the absence of the CEO/Administrator. (CI.4c)**

I: **Designated alternate to the CEO/Administrator understands his/her role and describes experiences specific to the alternate role. (CI.4c)**

I: **CEO/Administrative and Management personnel describe their respective areas of responsibility. (CI.4d)**

Note: The Medicare Certified home health agency must comply with CFR 484.12, 484.12(a), 484.14(c). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c). See Appendix IH for a full text of the regulations and a crosswalk.

CI.4	Authority and responsibility for overall administration and management is vested in qualified individuals.

CI.4a The chief executive/administrator's credentials include appropriate industry experience and knowledge of applicable local, state and federal laws.

CI.4b Qualifications for administrative and management positions are clearly defined in writing and are consistent with the scope of responsibility and the complexity of the organization, and administrative and management personnel have equivalent combinations of education, training and experience to qualify for their assigned responsibilities.

CI.4c A qualified individual is designated in writing to be administratively responsible in the absence of the chief executive/administrator.

CI.4d Administrative and management responsibilities are clearly defined and delegated as specified and include:

1) Organizing and directing the organization's ongoing operations to assure the availability and provision of care and services
2) Implementing governing body directives and organizational policies and procedures
3) Complying with applicable laws and regulations
4) Recruiting, employing, and retaining qualified personnel to maintain appropriate staffing levels
5) Ensuring adequate staff education
6) Completing performance evaluations on subordinate staff in accordance with organizational policy
7) Directing and monitoring organizational Performance Improvement activities
8) Managing operations in accordance with established fiscal parameters
9) Planning, developing, implementing, administering and evaluating programs
10) Representing the organization to other groups, organizations and the general public
11) Ensuring the accuracy of public information materials
12) Informing the governing body and staff of current organizational, community, and industry trends

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5

I: Management and advisory/governing body members describe process for development, revision and annual review of policies. (CI.5a)

D: Administrative policies and procedures address the areas delineated in CI.5b.

D: A written safety program sets the parameters for monitoring environmental conditions and identifying potential hazards/risks in accordance with elements such as biomedical waste management, storage and handling of environmental cleaning supplies, fire safety, preventive maintenance of equipment, reporting of malfunctioning equipment, environmental controls to prevent client or staff accidents and or incidents and safety of clients and employees in the community. (CI.5b)

D: Operational policies and procedures detail planning, delivery and evaluation of care and include the 16 elements of CI.5c.

D: Personnel policies address the 9 elements of CI.5d.

Note: The Medicare Certified home health agency must comply with CFR 484.10(d), 484.11, 484.12(b-c), 484.14(e), 484.16, 484.18, 484.18(b-c), 484.48(a-b), 484.52, 484.52(b), 484.55. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c), 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CI.5	Organizational policies and procedures reflect an emphasis on quality and ethical practice and relate directly to the mission of the organization.

CI.5a Policies and procedures are developed, revised, and reviewed annually to assure currency of information.

CI.5b Administrative policies and procedures delineate administrative authority and responsibility for governance, planning, financial control and personnel. Policies include at a minimum:

1) Written Disclosure of conflict of interest
2) Public Disclosure of information
3) Responsibilities of ethical issues review group
4) Rights and responsibilities of clients
5) Internal and External Complaint Management
6) Exposure control plan
7) Formal safety program
8) Financial policies and procedures
9) Research activities/investigational studies as applicable.

CI.5c Operational policies and procedures form the framework for planning, delivery and evaluation of care and services provided. Policies include at a minimum:

1) Non-discrimination statement addressing admission of clients to service
2) Defined criteria for the acceptance or non acceptance of clients
3) Admission, continuation of service and discharge
4) Standardized assessment process
5) Referral to other providers of care or services
6) Medical orders, verbal orders and physician oversight as applicable
7) Emergency service
8) After hours service
9) Confidentiality of protected health information
10) Emergency/disaster preparedness
11) Health, safety and security of staff during all hours of work
12) Services/products provided directly and under contract
13) Standards of practice for all disciplines as applicable
14) Standards of operation for all products as applicable
15) Infection control
16) Accepted medical term abbreviations

CI.5d Personnel policies are developed and revised in response to organizational change and include:

1) Conditions of employment
2) Respective obligations between employer and employee
3) Non-discrimination information
4) Grievance procedures
5) Employee orientation
6) Employee exit interviews
7) Maintenance of health reports and protected employee information
8) Employee record confidentiality and record retention
9) Recruitment, retention and performance evaluation of staff

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5 (Continued)

D: Written TB Exposure Control Plan includes the elements in CI.5e.

D: Written policy and procedure define the requirements of Medical Device Act reporting. (CI.5f)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA which may include an incident that results in death and when the manufacturer is unknown. (CI.5f)

D: Written infection control policies and procedures include the elements in CI.5g.

CI.5e The organization's written TB Exposure Control Plan is in compliance with the most current Centers for Disease Control & Prevention (CDC) applicable recommendations and requirements for occupational exposure to Tuberculosis. The plan addresses:

1) Definition of employees at risk of occupational exposure to TB
2) Process for identifying suspected or confirmed cases of TB
3) Control of employee exposure when a patient is suspected/confirmed as having infectious TB
4) Provision of education and training to all employees to the hazards of exposure to TB at the time of employment and annually thereafter
5) Pre-employment and subsequent periodic TB screening of employees in accordance with written policy
6) Provision of follow up care to employees exposed to TB
7) Provision of follow up care to employees who convert to active disease
8) Provision of appropriate personal protective equipment when caring for a suspected/confirmed TB client
9) Provision of work practice oversight to minimize occupational exposure to TB
10) Adherence to reporting and record keeping requirements per state and federal law

CI.5f Organizational policy and procedure address the requirements of the Medical Device Act (MDA) and delineate the mechanisms for reporting incidents, which result in serious injury, illness or death.

1) Reports are filed with the Federal Drug Administration according to regulation
2) A designated person is responsible for ensuring compliance with reporting requirements
3) Criteria for designation of reportable events are clearly defined
4) Written protocols for the investigation of events are clearly defined
5) Investigative activities are initiated on a timely basis
6) Accurate documentation of findings include:
   (a) Investigative findings
   (b) Copies of reports sent to the manufacturer
   (c) Copies of reports to FDA
7) Retention and retrieval of findings and reports
8) In-service education on Medical Device Act reporting is provided to staff on an annual basis
   (a) Written curriculum outlines describe training content
   (b) Records of attendance are maintained

CI.5g Infection Control policies and procedures detail systems designed to promote the prevention and control of infections, monitor the occurrence of infections and evaluate the effectiveness of infection control practices.

1) Current infection control practices and strategies
2) Identification and investigation of breaks in technique
3) Sources of infection:
   (a) Nosocomial
   (b) Home acquired
   (c) Professional exposure
4) Types of infection
5) Modes of transmission of infection

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.5 (Continued)

D: Written policy and procedure define the parameters for ensuring the safety, security, and confidentiality of clinical hardcopy, automated, and/or travel records. (CI.5h).

D: Written policies and procedures define the parameters that ensure the client's right to access client record information and to release client record information. (CI.5h)

D: Written policy and procedure and local/state /federal regulations dictate the secure retention of all types of clinical records. (CI.5h)

D: Written policy and procedure details the process for release of information. (CI.5h)

I: Records administrator or other designated party describes adherence to policy and procedure. (CI.5h)

I: Staff describe process for accessing policies and procedures. (CI.5i)

CI.5g Cont'd

6) Contributing causes of infection
7) Data collection, analysis, and tracking and trending of findings
8) Reporting requirements per state and federal regulations
9) In-service education for staff
   (a) Dates and times of programs
   (b) Curriculum outline of training content
   (c) Records of staff attendance
10) Client and/or family teaching
11) Use of personal protective equipment
12) Accepted hand hygiene techniques

CI.5h Administrative, financial, client and personnel records are secured, retained and retrievable in accordance with a formal record retention policy that is in compliance with organizational policy and local, state and federal law.

1) Minutes of all official meetings of the governing body are retained for a minimum of five (5) years.
2) Client adult records are retained for a minimum of five (5) years after provision of service.
3) Client records of minors are retained for a minimum of seven (7) years after the age of majority is reached.
4) Mechanisms for client access and release of client records are defined.
5) Authorization for client record documentation and entry and signature authorization and authentication for automated client record system in accordance with individual state law are defined.
6) Process for maintaining safety and security of client records is defined.
7) Confidential records for employees experiencing an occupational exposure are retained for the duration of employment plus thirty (30) years.
8) Annual training records for exposure prone employees are retained for a minimum of three (3) years.
9) Client records involved in litigation are retained until after settlement.

CI.5i Staff members have access to policies and procedures.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.6

D:	Informational materials, written in different languages are available and provided to clients/families as appropriate. (CI.6a)
I:	Administrative/management personnel articulate cultural diversity in the community population and describe the organization's ability to meet special needs. (CI.6a)
I:	Staff members demonstrate awareness and use of available resource materials, and clients/families verbalize knowledge of pertinent resources. (CI.6a)
I:	Clients/families of different cultures acknowledge receipt of language specific materials and care provided by bi-lingual staff, family members and/or the use of interpreters as appropriate and necessary. (CI.6b)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

CI.6	Information is provided to clients/families identifying availability of organizational and community resources to assist in meeting client needs

CI.6a Language specific written materials, as necessary and appropriate, are available for distribution to client/families.

CI.6b Interpretive services are provided, as indicated and necessary, to ensure accurate communication between the client/family/caregiver and other types of health services personnel.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.7

D:	Written policy delineates the make up and function of the designated group to review ethical issues. Authority may be self-vested in the governing body, in an independent entity or in an advisory group. (CI.7a, b)
I:	Administrative/management/staff personnel describe the structure of the ethical group and the process for handling ethical concerns and issues. (CI.7b)
D:	Meeting minutes document discussions of and actions taken by the group, as applicable. (CI.7c)

CI.7	The organization's business, clinical, disease prevention and health promotion activities are conducted according to ethical standards.

CI.7a A group of qualified professionals is designated by the governing body to review ethical issues as they arise.

CI.7b Organizational policy and procedure outlines the responsibilities of the group and delineates the process for submitting ethical concerns and issues for action.

CI.7c Meeting minutes clearly document group activities and are referred to the governing body for review and final action as indicated and necessary.

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CI.8

I:	Administrative/management personnel describe that careful consideration is given to providing a site for relevant research, that human subjects involved in any part of research activities provide written informed consent, and that specific parameters for protection of participants and confidentiality of personal information are clearly defined. (CI.8a)
D:	Policy and procedure establish the parameters for research initiatives as applicable. (CI.8b)
D:	Current research activities as applicable ensure compliance with CI.8a,b, c, d.
I:	Administrative/management personnel describe current research initiatives as applicable. (CI.8c)
I:	Staff describes use of research knowledge which was integrated into practice as applicable. (CI.8e)

CI.8	The organization considers requests for research in the area of community/public health as appropriate.

CI.8a A mechanism is in place for reviewing, processing, and approving internal and external research proposals.

CI.8b Organizational policy and procedure defines parameters for participation in research activities and investigative studies.

1) Research protocols, as applicable, for internally and externally sponsored activities are on file
2) Potential participants are provided with written information regarding the nature, process, and benefits of the research outcomes
3) Risks associated with the project are clearly delineated

CI.8c Organizations participating in research or investigative studies ensure that clients and staff are fully informed.

CI.8d Formal written consents for participants in research and/or investigative studies are obtained and retained on file in the organization.

CI.8e New knowledge from internal and external research is integrated into practice as applicable.

CII.

THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.1

D: **Current Public Disclosure Policy addresses applicable elements of CII.1a.**

D: **The Client Bill of Rights includes the elements of CII.1b.**

I: **Clients confirm the timely receipt of the Client Bill of Rights and other admission information. (CII.1c)**

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

D: **Documented evidence in the client records confirms receipt of the Client Bill of Rights and other admission information. (CII.1d)**

Note: Advising clients of their rights is not applicable under conditions of emergency/disaster intervention and mass clinics.

I: **Clients/families articulate understanding of the information provided and describe how they have found the information to be helpful. (CII.1d)**

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.10(a-e), 484.12. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(c). See Appendix IH for a full text of the regulations and a crosswalk.

CII.1 The mission drives the activities of the organization and ensures public disclosure, client rights and ethical standards of business and clinical practice.

CII.1a A public disclosure policy defines the availability and accessibility of public information which includes ownership information, statement of the organization's mission, and licensure and accreditation status, as applicable.

CII.1b A written Client Bill of Rights is designed to recognize, protect, and promote the right of each client to be treated with dignity and respect.

1) Written policy and procedure defines the rights and responsibilities of clients.
2) Notice of rights is provided to clients in advance of providing pre-planned care.
3) The client is knowledgeable of the right to exercise his/her rights at any time.
4) The organization maintains documentation of compliance of distribution of required information to clients.
5) The client/client's designated representative is authorized to exercise their rights.
6) Confidentiality of the client record/data is maintained by the organization.
7) Access to care/service is based upon non-discrimination.
8) Clients are informed that they have the right to voice complaints/grievances to the organization regarding treatment/care/service without fear of discrimination or reprisal for doing so.
9) The organization provides the client the telephone number for the CHAP hot line, including the hours of operation and the purpose of the hotline to receive complaints or questions about the organization.
10) Clients are informed that they have the right to participate in the development of care and service plans.
11) Clients are informed verbally and in writing of billing and reimbursement methodologies prior to start of care and as changes occur, including fees for services/products provided, direct pay responsibilities, and notification of insurance coverage.

CII.1c Written admission documents, provided to the client or the client's representative prior to or at the time of initiation of care/service, ensure organizational compliance with the Client Bill of Rights and other regulatory requirements.

CII.1d A reasonable attempt is made and documented to ensure that the client and family understand their rights and responsibilities which are reviewed with the client prior to or at the time of initiation of care and periodically thereafter.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.2

I:	Clients/families describe methods used to contact the organization during regular hours of service, after hours, weekends and holidays. (CII.2a)
I:	Professional, technical, and support staff describe coordination and collaboration between disciplines. (CII.2b)
I:	Professional, technical, and support staff describe coordination and collaboration with sub-contract and/or independent contractor providers of care. (CII.2b)
I:	Clinical supervisors and staff describe the on-call system for services after normal organization hours. (CII.2c)
O:	Testing the after hours on call system validates compliance with organizational policy and procedure. (CII.2c)

CII.2	Care, services, and products are available to and accessible by the client/client representative.

CII.2a Care, services, and products are provided within an established time frame, as specified by organizational policy, organizational standards, medical directives or individual physician orders. Consideration is given to client and/or family needs in scheduling and providing care.

CII.2b Collaboration and networking with other providers enhance provision of care and services as applicable.

CII.2c Supervisory and clinical/service staff demonstrate knowledge of organizational policy and procedure for ensuring delivery of care, services and products to clients.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.3

D:	Written information distributed to clients/families address disasters/emergencies as applicable to the organization's service area. (CII.3a)
I:	Clients/families are aware of their responsibilities in the event of an emergency episode. (CII.3a)
D:	Staff are oriented to written protocols that ensure the safety and security of personnel. (CII.3b)
D:	Disaster drills are documented as applicable to the organization. (CII.3c)
I:	Administrative/management staff describe roles and responsibilities of personnel during an emergency episode. (CII.3c)
I:	Staff members at all levels demonstrate awareness of responsibilities to ensure the safety of self and others. (CII.3c)

Note: The Medicare Certified hospice organization must comply with CFR 418.100. See Appendix IH for a full text of the regulations and a crosswalk.

CII.3	A geographic specific plan defines the protocols for prioritizing the delivery of care and services to clients and protects the safety of staff during disasters, emergencies and/or environmentally challenging situations.

CII.3a Detailed written instructions are given to clients and/or family members to ensure an appropriate and timely response on the part of the client and/or family in the event of a natural disaster, inclement weather, and/or other emergent event that might cause an interruption in the provision of services.

CII.3b Written protocols define management responsibilities in ensuring the safety and security of staff prior to or during an emergent event.

CII.3c Staff are knowledgeable of the practices and procedures relating to emergency preparedness responsibilities and emergent events.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.4

D: **Client records document coordination of care activities. including planning, implementation, monitoring and evaluation of care/service as appropriate. (CII.4)**

I: **Clinical/service, financial, and operational staff describes collaboration and support among all disciplines and organizational divisions. (CII.4a)**

O: **Organizational planning meetings as available and appropriate. (CII.4a)**

Note: The Medicare Certified home health agency must comply with CFR 484.14(g). See Appendix I HH for a full text of the regulations and a cross-walk.

CII.4	**Inter and intra organizational coordination is evident in the planning, implementation, monitoring, and evaluation of care and services provided.**

CII.4a Coordination between the clinical/service, financial, and operational components of the organization is evident.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.5

I: Professional, technical, and support staff describe protocols that protect client/family information regarding confidentiality of information, use of travel record and transport and storage of travel record. (CII.5a).

I: Office staff describe ongoing security of client record information. (CII.5a)

I: Staff is knowledgeable of the client's right for access to and release of client information. (CII.5a)

O: Active and inactive client records are maintained in a secure area during working and non-working hours that is inaccessible to unauthorized individuals. (CII.5a)

S: Random sample of client records reviewed provides evidence of compliance with organizational policy, standards and regulatory requirements. (CII.5c,d)

O: Automated client record systems include safeguards. (CII.5e)

I: Client records administrator describes process for ensuring consistent, ongoing validation and protection of automated records data including prevention of lost data due to equipment failure and storage of backed-up files. (CII.5e)

I: Evidence is provided validating periodic review and updating of the record format used. (CII.5f)

I & O: Managers/staff describe and demonstrate compliance with policy and procedure governing the coordination, transport, and security of information shared with and between alternate sites. Staff describe the type of information that is maintained and the procedures for coordination, communication, exchange, and retrieval of required information with the parent organization. (CII.5g)

Note: The Medicare Certified home health agency must comply with CFR 484.10, 484.11, 484.14, 484.18(c), 484.48, 484.48(b), 484.52(b).. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.74, 418.74(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CII.5	Client records, maintained for each client or client group, are utilized as a tool for coordination of services, as a legal document that is descriptive of care and services provided, and as a resource document for billing and reimbursement.

CII.5a All protected health information or client records, hardcopy or automated, are kept confidential and are safeguarded against loss or unauthorized use in accordance with organizational policy and local, state or federal regulations.

CII.5b Clients have access to their records and are informed of the process.

CII.5c The client record documentation provides client information specific to care and services/products provided, current client status, and progress toward goals and outcomes of care.

CII.5d Entries to client record documentation is made only by authorized staff and in accordance with organizational policy and procedure.

CII.5e Automated client record systems ensure consistent and ongoing security and protection of data.

CII.5f The format for maintenance of client records is reviewed and updated as necessary.

CII.5g Organizations with alternate sites ensure consistent documentation, communication, coordination, and retrieval of significant administrative and client/family information.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.6

D: Data reflect measurement of quality of services outcomes. (CII.6a)

I: Performance improvement manager describes rationale for the performance improvement process and the definition of specific client/service outcomes. (CII.6b,d,e)

D: A structured framework exists. (CII.6c)

D: A client satisfaction survey for the current year is available for review and includes, at a minimum, client satisfaction with care and services provided and satisfaction with providers of care. (CII.6f)

I: The organization describes the mechanism for monitoring client satisfaction. (CII.6f)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/ products. (CII.6g)

D: Organizational committees and governing body minutes document reporting of trends of performance improvement findings. (CII.6h)

Note: The Medicare Certified home health agency must comply with CFR 484.52, 484.52(a).. See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66, 418.66(a, b, c). See Appendix IH for a full text of the regulations and a crosswalk.

CII.6	A comprehensive Performance Improvement process integrates the organization's mission and promotes an organizational wide approach that selects, reviews, and analyzes outcomes specific to organizational needs and the scope of services and products.

CII.6a Quality is defined and measured in terms of client/service outcomes.

CII.6b Specific outcomes are targeted for improvement or replication.

CII.6c The organization develops a structured framework for the investigation of target outcomes.

CII.6d The organization identifies outcomes to benchmark by utilizing internal standards, processes and protocols; practice or service guidelines; industry research and/or best practices.

CII.6e The organization continually evaluates progress toward outcomes and identifies new areas to improve or replicate as indicated by results of data analysis.

CII.6f A process for monitoring and measuring the satisfaction levels of clients is conducted at least annually.

CII.6g Performance Improvement findings are used to resolve identified problems, improve quality of services and products, and are incorporated into program planning, modification and /or enhancement.

CII.6h Trends of Performance Improvement findings are reported to appropriate organizational committees and the governing body.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY
CII.7

D: Personnel records include evidence of adherence to regulatory requirements of Federal OSHA and CDC. (CII.7a)

D: Written plans define parameters for exposure control, adherence to standard precautions, adherence to work practice controls, HBV prophylaxis and TB exposure control. (CII.7b)

D: Potential for employee exposure is determined by job classification, which defines the potential for risk and includes: (CII.7c)
a) Definition of types of tasks and/or procedures that place an employee at risk for exposure.
b) Description of job classifications in which all employees have the potential for occupational exposure.
c) Description of job classifications in which employees have the potential for occasional exposure.
d) Description of job classifications in which employees have no risk for occupationally related exposure.

O: Staff demonstrate adherence to standard precautions as determined by organizational policy: (CII.7d)
a) Use of gloves
b) Use of and accessibility to masks and protective eyewear
c) Use of protective gowns and aprons
d) Hand hygiene/hand washing techniques including the use of chemical substances
e) Techniques for minimizing needle sticks
f) Use of puncture resistant sharps containers
g) Proper transportation and storage of sharps
h) Disposal of contaminated supplies and equipment on site

S: Random sample of employee records provides evidence of compliance with Hepatitis B (HBV) prophylaxis program. (CII.7f)

I: Designated person describes procedures followed to ensure compliance with investigative requirements and protection of the rights of the employee who has experienced an occupational exposure. (CII.7f)

D: Education and training records document compliance with training requirements. (CII.7g)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.50(b), 418.100 (c), 418.100(i). See Appendix IH for a full text of the regulations and a crosswalk.

CII.7	The health and safety of employees and clients is promoted and enhanced through education, current application of infection control practices and implementation of appropriate safety measures.

CII.7a Adherence to State and/or Federal Occupational Health and Safety Administration (OSHA) and Centers for Disease Control & Prevention (CDC) requirements as applicable that address the health and safety of employees and clients and their protection from blood borne pathogens are validated.

CII.7b The organization implements its written Exposure Control Plan.

CII.7c The potential for occupational exposure is determined for all job classifications in accordance with state, federal and Occupational Health and Safety Administration (OSHA) mandate.

CII.7d Adherence to the use of Standard Precautions by job classification is documented.

CII.7e Adherence to work practice and engineering controls is evident in practice.

1) Physical work sites are maintained in a clean and sanitary condition
2) Use of disinfectant solutions
3) Handling, transporting, storage and processing of soiled/contaminated materials, supplies and equipment
4) Use of non-leak infectious waste containers as applicable
5) Identification and labeling of infectious waste as applicable

CII.7f Employer and employee responsibilities relating to Hepatitis B prophylaxis (HBV) are defined in writing and include:

1) HBV vaccination and post exposure follow up program
2) Employer/employee responsibilities
3) Declination of HBV statement is signed by employees as applicable and filed in personnel health records
4) Complete and detailed documentation of all exposure events
5) Confidential records are maintained on HBV vaccination and post exposure follow up

CII.7g Education and training programs ensure that new employee orientation addresses all aspects of the Exposure Control Plan and that annual training is mandated for all exposure prone employees based on applicable job classification.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.7 (Continued)

D: Occupational exposure information is maintained in confidential records that are retained for the duration of employment plus thirty (30) years. (CII.7h)

I & O: Clinical, technical and support staff describe potential hazards in the home setting identified during the assessment of the client's living environment. (CII.7k)

D & I: Evidence exists that the organization monitors and reports information related to adverse events.
Adverse events include but are not limited to:
- provision of care errors
- unusual occurrences
- vehicular crashes
- other types of accidents or injury
- safety hazards

Serious Adverse Events include but are not limited to:
- unexpected death not resulting from the client's medical condition
- loss of body part
- permanent or partial loss of body function
- blindness

Reports document data on adverse events that predispose the organization to real or potential liability.
- Data are collected within 30 days of an event
- Data are analyzed within 60 days of the event to determine underlying factors leading to the adverse event
- Performance Improvement processes, as applicable, include evidence of organizational changes subsequent to an adverse event

(CII.7l)

D: Medical Device Act reports, as applicable, are on file in the organization and include validation of submission to the FDA. (CII.7m)

I & O: Staff demonstrate knowledge of and compliance with the organizational infection control practices and procedures . (CII.7n)

CII.7h The organization demonstrates compliance with its Occupational Exposure Control policies, plan and procedures.

1) HBV is provided at no cost to all employees, potentially subject to occupational exposure, within ten (10) working days of assignments
2) Provision of personal protective equipment as appropriate to all employees with the potential for an occupational exposure as determined by their job classification
3) A confidential medical evaluation and follow-up care is offered to employees who experience an occupational exposure:
   (a) Counseling
   (b) Testing of source individual if allowable under local and/or state law
   (c) Blood testing of the exposed employee with written consent, if medically indicated
4) Accurate, confidential, and timely documentation of:
   (a) Circumstances leading to exposure
   (b) Routes of exposure
   (c) Medical follow-up
   (d) Opportunity for counseling
   (e) Other related interventions as indicated and necessary

CII.7i The organization demonstrates compliance with its TB Exposure Control Plan.

CII.7j The organization demonstrates compliance with its safety program to monitor environmental conditions for identifying potential hazards/risks.

CII.7k A routine assessment is made of the client's living environment to identify and evaluate potential safety hazards related to the physical space as applicable.

CII.7l A system is in place for monitoring and reporting information related to adverse events that endanger the health and safety of clients and/or employees and pre-dispose the organization to real or potential liability.

1) Adverse Events and Serious Adverse Events are defined in organizational policy
2) Data for all events is collected, analyzed tracked and trended as a part of risk management
3) Corrective actions are implemented and evaluated as indicated and necessary
4) Adverse event reports detail each episode and are distributed to advisory boards as applicable

CII.7m The organization demonstrates compliance with its policy and procedure for the Medical Device Act (MDA).

CII.7n The organization demonstrates compliance with its Infection Control policies and procedures.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CII.8

D: **Examples of complaint documentation logs. (CII.8a)**

D: **Formal documentation of investigative findings and reports as applicable. (CII.8a)**

D: **Resolution information is documented as communicated to the complainant. The communication to complainant may be in writing or by telephone. (CII.8b)**

I: **Staff describes an understanding of the complaint process. (CII.8c)**

Note: The Medicare Certified home health agency must comply with CFR 484.10(b). See Appendix I HH for a full text of the regulations and a cross-walk.

CI1.8	Client/ family complaints/concerns are responded to and resolved in a timely manner.

CII.8a The complaint process includes intake, investigation, and corrective action as applicable, complaint resolution, written reports, organizational trending and follow-up.

CII.8b Resolution/outcome information is communicated to the complainant.

CII.8c Staff are aware of organizational mechanisms for receiving and resolving complaints.

CIII.

THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL AND PHYSICAL RESOURCES WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION/PURPOSE

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.1

D: Policy, procedure and recruitment documents support a non-discriminatory approach to hiring. (CIII.1a)

I&O: Interviews with staff and observation of client practice/service validate adherence to discipline specific practice standards and to regulatory guidelines and requirements specific to respective areas of responsibility. (CIII.1b)

I: Staff confirm clear understanding of responsibilities and lines of authority. (CIII.1c)

I: Management explains turnover rate variances as applicable, and describes impact on recruitment and retention activities. (CIII.1d)

D: Employee records validate the opportunity for a formal exit interview for terminating employees in accordance with organizational policy and procedure. (CIII.1e)

I: Employees validate receipt of conditions of employment and describe the process for obtaining personnel related information. (CIII.1f)

D: Employee files are complete and current and include documents specific to CIII.1g. Evidence of verification of education/training may include copies of diplomas, transcripts or telephone validation.

O: Specified personnel documents are secured in accordance with organizational policy. (CIII.1h)

Note: The Medicare Certified home health agency must comply with CFR 484.12(c), 484.14(c,e), 484.30(a), 484.32, 484.32(a), 484.34, 484.36(b). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.64, 418.70(a,b). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.1	The organization has adequate and appropriate human resources to meet caseload and workload demands.

CIII.1a A non-discriminatory recruitment and selection process, as defined in policy and procedure, is adhered to.

CIII.1b Personnel are employed and assigned responsibilities commensurate with their education and experience.

CIII.1c Job Descriptions for each employee category delineate lines of authority and reporting responsibilities, duties to be performed, and educational and experiential qualifications specific to the position.

CIII.1d Employee turnover rates are monitored tracked and trended, as applicable.

CIII.1e The opportunity for exit conferences are offered to terminating employees, are documented and trended, as applicable.

CIII.1f Personnel policies/conditions of employment are provided to employees at the time of hire and thereafter as updates/revisions are needed.

CIII.1g Evidence of the following employee information is maintained in accordance with organizational policy and regulatory guidelines.

1) Individual job qualifications
2) Verification of education/training
3) Certification for specialty areas of practice as applicable
4) Statement of formal training for non-professionals
5) Two (2) reference checks
6) Pre-employment interview(s)
7) Current license or certification as applicable
8) Validation of competency skills testing as applicable
   (a) Time of hire
   (b) Annual
9) Validation of performance evaluation at end of probation and annually
10) Validation of malpractice coverage for independent contractors
11) Validation of completion of the orientation process (new and reassigned personnel)
12) Validation of signed and dated confidentiality statements
13) Validation of in-service/continuing education participation as applicable
14) Validation of exit interview as applicable
15) Miscellaneous items per state, federal or organizational requirements
16) Criminal background checks in accordance with organizational policy and procedure and local and/or state law
17) Immigration and naturalization statement (I-9)

CIII.1h Specified personnel documents and employee health reports may be retained in separate files per organization policy.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.1 (Continued)

D: Annual evaluation form addresses elements of CIII.1i as applicable to the job category.

I: Sample of employee and supervisory staff personnel records confirms adherence to the annual evaluation process. (CIII.1i, 1j)

D: A written plan details the orientation of new personnel and for personnel assigned to a new job classification. Components of the orientation plan may include mission and purpose of the organization, table of organization, lines of authority and responsibility, hours of work, job-related responsibilities, and personnel policies. (CIII.1k)

I: Recent hires describe their orientation as comprehensive and pertinent to meeting job responsibilities. (CIII.1k)

I: Staff assigned to a new job classification describe their orientation to the new responsibilities. (CIII.1k)

I: Staff validate receiving applicable hours of in-service programming and describe the types of experiences available to them. (CIII.1l)

O: Federally required in-services include OSHA mandated. Staff Development opportunities may include: independent study, satellite learning, specialized conferences, formal courses of study and mentoring. (CIII.1l)

D & I: Policy and managers describe the process for assuring that personnel are identified. Service contracts with organizations detail the process that the sub-contract organization will assure sub-contract organization identification of staff. (CIII.1m)

CIII.1i An annual written performance evaluation process is completed on all employees by the respective supervisor and includes:

1) Supervisor assessment of employee performance in accordance with established criteria (Job Description)
2) Achievement of previously established goals
3) On site evaluation reports/competency testing for clinical/field/service staff
4) A signed, dated validation of the evaluation process by the employee and employer representative

CIII.1j An annual performance evaluation process provides an opportunity for active participation by employees through:

1) Employee development planning/new goal setting
2) Employee response to evaluation

CIII.1k A written plan details the orientation process for all new and reassigned employees which addresses applicable elements pertinent to each job classification.

CIII.1l The organization shall provide in-service and staff development as needed and as required by local, state and federal regulation and national and/or professional standards as applicable.

CIII.1m Personnel are provided with identification badges or are identified as working for the organization.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.2

D: A review of a randomized sample of written contracts for the provision of care, services and/or products validates adherence to CIII.2, a, b.

I: Contract manager or other designated party describes the ongoing management and control of contractual agreements. (CIII.2a)

Note: The Medicare Certified home health agency must comply with CFR 484.14, 484.14(f, h), 484.36(d). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56, 418.56(b,c,d,e), 418.80). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.2	Formal written contracts, executed by the primary organization with other professionals and entities for the provision of care, services, and products to clients of the primary organization, detail specific responsibilities of the parties involved.

CIII.2a Written service contracts with individuals and/or other entities are signed and dated by authorized principals of each party and are reviewed annually.

CIII.2b The executed document stipulates the terms of the contract which include:

1) Specific services/products to be provided
2) Contractor is required to adhere to applicable primary organization's policies and procedures
3) Assurance by the contractor of the education, training, qualifications and identification of personnel designated to provide care, services, and products
4) Mechanisms for the contractor parties to participate in Performance Improvement activities as applicable
5) Procedures for the documentation and submission of documented notes that verify the provision of services/products in accordance with the written service contract
6) Procedures for the submission of bills and related information and reimbursement for care, services and products provided
7) Effective dates of the contract including terms of renewal and/or termination

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.3

D: Organizational policy and procedure detail the fiscal activities and responsibilities of the organization. (CIII.3a)

I: The chief financial manager confirms credentials and experience background for the responsibilities assigned and describes the budget planning process. (CIII.3b)

D: Governing Body minutes confirm approval of budgets and other financial agenda items referred to the Governing Body. (CIII.3c)

D: The organization has a current operating budget and capital expenditure plan. (CIII.3d)

D: Financial, statistical and productivity reports are used to facilitate oversight of the organization's operations. (CIII.3e)

I: The chief financial manager describes the use of financial, statistical or productivity reports. (CIII.3e)

I: The chief financial manager validates the adequacy of insurance coverage. (CIII.3f)

D: Review of annual financial review validates that the review was conducted by an organization external to the organization within the most recent twelve month period. (CIII.3g)

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.52, 418.56(d). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.3	The organization's sources of financial support are managed and monitored on an ongoing basis to ensure the availability of adequate funding.

CIII.3a Financial policies and procedures govern the fiscal activities of the organization.

CIII.3b The chief financial manager has the appropriate qualifications, credentials and expertise to oversee, manage, and direct the fiscal operations of the organization.

CIII.3c Major participants in developing and monitoring the budgetary process include the governing body, the chief executive, the chief financial manager, program directors and other designated staff as appropriate.

CIII.3d The operating budget and operating capital expenditure plan is developed using methodologies commensurate with the scope and complexity of the organization's services, programs, and products and is used to forecast financial and operating successes and challenges.

CIII.3e Financial management tools are used to provide operational feedback to administrative and management personnel, financial committees and the governing body.

CIII.3f Adequate insurance coverage is maintained.

CIII.3g An annual external review is required and conducted.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.4

D: Financial reports detail information used to measure operational performance. (CIII.4a, b)

I: The chief financial manager or other designated party describes the effectiveness of the financial management information systems, the types of reports generated and their use, and internal financial controls (CIII.4a, b, c)

D: Organizational financial procedures used for internal control may include segregation of duties, reconciliation of control accounts, approval levels for disbursements and adjustments, collection of accounts receivable, budgeting, receipt of funds, disbursement of funds, cash and asset account reconciliation and cash management. (CIII.4c)

I: Financial /billing staff confirms timely billing procedures, ongoing monitoring of accounts receivable, implementation of collection efforts as appropriate, and adherence to accounts receivable guidelines. (CIII.4d)

D: Financial reports include payroll and vendor disbursements in accordance with CIII.4e.

Note: The Medicare Certified home health agency must comply with CFR 484.14(i). See Appendix I HH for a full text of the regulations and a cross-walk.

CIII.4	A financial management information system is used to document and monitor all financial components and provide appropriate and timely reports to all levels within the organization.

CIII.4a The financial reporting system produces detailed data regarding actual transactions specific to care, services and products provided by each program including site/ location activity.

CIII.4b Periodic financial statements contain key indicators and show a reasonable match between revenue and expense line items.

CIII.4c Internal financial controls are in effect.

1) Internal audit procedures and annual review of budget are conducted.
2) Adherence to organizational financial policies and procedures is monitored.

CIII.4d Reimbursable services are billed on a timely basis in accordance with designated fee structures and are monitored, tracked and aged.

CIII.4e Payroll and vendor disbursements are recorded and processed in a structured and timely manner.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.5

D: Applicable statements indicating compliance with OSHA, CDC, ADA, are available and may include:

1) **Fire drill and health inspection reports indicate compliance.**
2) **Certificates of occupancy are posted in accordance with local requirements.**
3) **Fire and emergency exits clearly detail areas of entrance and egress.**
4) **Hazardous area access is controlled.**
5) **Hazardous chemicals and solutions are properly labeled and kept in locked storage.**
6) **Adequate space and privacy is provided to employees and clients receiving services.**
7) **Facilities are barrier free and/or special arrangements are made to provide access as indicated and necessary.**
8) **Safety and security procedures for employees are implemented as necessary.**

(CIII.5a)

O: Tour of facility validates compliance with OSHA, CDC, and ADA guidelines and applicable local requirements. (CIII.5a)

Note: The Medicare Certified home health agency must comply with CFR 484.12(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.56(c), 418.100(c). See Appendix IH for a full text of the regulations and a crosswalk.

CIII.5 Physical facilities are adequate to support the operations.

CIII.5a Physical facilities meet the OSHA (Federal/State), CDC, ADA and/or State or Local regulations for environmental protection and safety of employees and recipients of service.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIII.6

D&I: MIS manager or other designated party explains and demonstrates how data are collected, processed and secured on and off site. (CIII.6a)

I: Management describe how information system is used to ensure organizational accountability. (CIII.6)

CIII.6 A management information system is utilized to ensure accountability at all levels of the organization.

CIII.6a A manual or automated system utilizes established standards and defined data elements for the collection and processing of information.

CIV.

THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIV.1

I: Management and staff describe the planning process. (CIV.1a)

I&O&D: The assessment of the strengths, weaknesses, opportunities and threats may include the following components:

1) Assess and analyze service area demographics.
2) Maintain current knowledge of organization's market penetration.
3) Identify new and/or changing consumer and community needs.
4) Collect data and information for analysis.
5) Garner input from all levels of staff.
6) Determine organizational priorities.

(CIV.1b)

I: The CEO and/or governing body representative describes the long term vision and goals for the organization. (CIV.1b)

CIV.1	**Strategic planning reflects the organizational mission and includes a comprehensive evaluation of both internal and external environments.**

CIV.1a Current budgetary, business and marketing activities are integrated into the process.

CIV.1b An assessment of the organization's strengths, weaknesses, opportunities and threats is conducted on a periodic basis.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

CIV.2

D: The organization provides evidence that a current annual evaluation was conducted timely and in accordance with its organizational policies and process.(CIV.2a)

D: The annual evaluation report validates the inclusion of service/product, risk management, human resources and financial and operational components in the evaluation process. (CIV.2b)

I: Administrative/management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D&I: Minutes and interview confirm that the annual evaluation report was presented to the appropriate advisory and governing bodies. (CIV.2d)

Note: The Medicare Certified home health agency must comply with CFR 484.16. 484.16(a), 484.52, 484.52(a). See Appendix I HH for a full text of the regulations and a cross-walk.

Note: The Medicare Certified hospice organization must comply with CFR 418.66. See Appendix IH for a full text of the regulations and a crosswalk.

CIV. 2	An Annual evaluation of the organization provides the basis for future planning.

CIV.2a Organizational policies drive the process for the annual program evaluation by an authorized group and identify the components to be evaluated.

CIV.2b The complexity of the organization and the scope of care, services, and products provided define the parameters for data collection and utilization and includes service/product, risk management, human resources and financial data.

CIV.2c Variances from usual and expected patterns of performance are analyzed and explained.

CIV.2d The Annual Evaluation Report is presented to advisory and governing bodies as appropriate.

CIV.2e The Annual Evaluation Report is retained as an administrative record.

PHARMACY

STANDARDS OF EXCELLENCE

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INTRODUCTION TO CHAP PHARMACY STANDARDS

In keeping with its goal of elevating the quality of all community health care in the United States, the Community Health Accreditation Program, Inc. (CHAP) continually reviews and revises the "Standards of Excellence" to ensure currency with and relevance to the community health care industry. The service-specific Pharmacy Standards 2004 Edition are designed to:

- Establish standards of excellence for all types of Pharmacy services (Open Door, Long Term Care, Mail-Order, Internet, Specialty, Compounding, Infusion)
- Promote ease of application, interpretation and use of standards
- Emphasize the importance of the interests and rights of Pharmacy clients
- Strengthen the long-term viability of all types of Pharmacy organizations
- Advance the recognition of the Pharmacy organization as an integral component of the national health care delivery system

The re-engineered Pharmacy Standards of Excellence, 2004 Edition, address the scope, complexity and challenges of providing comprehensive Pharmacy services in a variety of community-based settings. When used in conjunction with the CORE Standards, 2004 Edition, compliance is ensured with:

- Pharmacy regulatory requirements
- Regulatory requirements that address the health and safety of employees and clients

CHAP standards incorporate most current professional, clinical, industry and regulatory standards and/or requirements.

Underlying Principles

Four key principles form the framework for the revised standards:

I. Structure and Function
II. Quality
III. Resources
IV. Long Term Viability

The four key "Underlying Principles" (UP) continue to drive each set of the CHAP Standards of Excellence. Sub-categories in each section further define the content. The four key underlying principles are used consistently throughout the CHAP accreditation documentation process in the Standards, Self-Study, Workbooks and Site Visit Reports.

UP I. THE ORGANIZATION'S STRUCTURE AND FUNCTION CONSISTENTLY SUPPORTS ITS CONSUMER ORIENTED MISSION AND PURPOSE.

A. Statement of Pharmacy Scope of Products/Services
B. Organizational Structure And Functional Mechanisms
C. Intra-Organizational Relationships
D. Pharmacy Program Director
E. Pharmacy Specific Policies and Procedures
F. Ethical Issues
G. Student Education/Research

UP II. THE ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY SERVICES AND PRODUCTS.

A. Public Disclosure, Client Rights, Ethical Standards
B. Services Provided
C. Emergency Preparedness & Response
D. Access to Services/Inter & Intra Organization Coordination
E. Assessment, Plan of Care, Verbal Orders
F. Client Records
G. Effectiveness of Services
H. Health & Wellbeing of Employees & Clients
I. Complaints

UP III. THE ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES TO ACCOMPLISH ITS STATED MISSION AND PURPOSE.

A. Human Resources Support Workload Demand
B. Staffing Contracts
C. Financial Resources
D. Physical Facilities
E. Information Systems

UP IV. THE ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY.

A. Strategic/Operational Planning
B. Annual Evaluation of the Pharmacy Operations and Structure
C. Innovations

As you study and apply these standards to your own organization, give consideration to the following "*THEMES*" that flow through all sections of the CHAP Standards of Excellence and Self Studies.

Composition of a Standard

Each standard statement may be comprised of four (4) parts.

1. Standard statement - A blueprint for success that recognizes excellence
2. Criterion - A statement that defines in detail the requirements of the standard
3. Element - A component of each criterion that delineates requirements
4. Sub-element – Additional statements that provide more definition of selected elements.

Examples
Standard:.....HMEI.1
Criterion:.....HMEI.1a
Element:.....1)
Sub element:.....(a) (not all standards have sub-elements)

Main Sources of Evidence

D = Documents
I = Interviews
O = Observations
S = Surveys

Substantiation of Findings

Clarification
Verification
Quantification

Evidence Guidelines

The Standards are formatted with relevant Evidence Guidelines on pages opposite the standards. The evidence guidelines are not standards or criteria. They are intended to provide guidelines and examples of evidence to the organization and the CHAP site visitor which may be used to determine organizational compliance with the standards. The letter preceding each evidence guideline identifies one of four sources of information to be used by the site visitor in the accreditation process: D, I, O, S.

The Site Visit Report

The Site Visit Report is a written legal document that states the level of compliance by the Pharmacy organization with both the CORE and Pharmacy Standards of Excellence. The composition of the report includes a brief organizational profile, statements of organizational strengths and challenges and the written citations.

Citations include:

Commendation:	A statement indicating that the organization has significantly exceeded the requirements of a specific standard or criterion.
Required Action:	A statement indicating partial or total non-compliance with a CHAP standard or criterion. Organizations are required to make changes to comply with CHAP standard or criterion.
Recommendation:	A statement of advisement that identifies a potential problem related to a standard or criterion that may increase in scope and severity if not addressed. Organizations are not required to make changes but should give serious consideration to the recommendation.

DI.

THE PHARMACY ORGANIZATION'S STRUCTURE CONSISTENTLY SUPPORTS A CONSUMER ORIENTED MISSION AND PURPOSE

PHARMACY

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DI.1

D:	A printed definition of the organization's scope of products and services is available. (DI.1)
D:	Governing body minutes document actions taken on the scope of products and services statement: (a) Review and approval within the past twelve months. (b) Revisions and updates as applicable. (DI.a)
I:	Management and staff describe the process for making scope of products and services statement available upon request. (DI.1b)

DI.1	A written statement by the Pharmacy Organization identifies the scope of products and services provided to clients.

DI.1a The scope of services statement is periodically reviewed, revised and approved by the governing body but no less than every twelve (12) months.

DI.1b The pharmacy's scope of services statement is made available upon request to clients, referral sources and other interested parties.

LEGEND:
D - DOCUMENTATION
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DI.2

D: Required County/State/Federal licenses, authority documents, and Medicare/Medicaid/reimbursement certification (if applicable) are current as required. (DI.2a)

Note: County/State specific licenses may include Sellers Permit, Occupational License, etc.

D: Review of recent findings of other reviewing bodies confirm compliance. (DI.2a)

D: The disclosure statement is current, signed and dated by the chief executive and on file. (DI.2b)

D: Minutes or other formal governing body documents reflect that the governing body authorized an advisory committee. (DI.2c)

Note: Advisory Committee may be the governing body as a whole, a subcommittee of the governing body or a separate committee.

D: Membership in the advisory committee includes a physician, a pharmacist, a registered nurse and at least one community representative. (DI.2c)

D: Official documentation or minutes reflect annual review of policies and evaluation of the Pharmacy program. (DI.2c)

DI.2	The Pharmacy Organization has the structure and functional mechanisms necessary to accomplish its stated scope of services.

DI.2a The Pharmacy Organization has the legal authority to operate and is in compliance with local, state and federal regulations.

1) State Board of Pharmacy License
2) Business License
3) DEA Narcotic License
4) d/b/a, Trade Name registration, if applicable
5) Tax ID number
6) Medicare & Medicaid provider numbers, where applicable
7) Specific county and state required authorities

DI.2b The Pharmacy Organization is required to prepare and maintain a current written disclosure statement signed by the chief executive, addressing applicable elements as frequently as required by state regulations but no less frequently than every three years.

1) Names and addresses of individuals or corporations having a combined direct or indirect ownership or controlling interest of 5% or more in the organization
2) Names and address of subcontractors in which the organization has a direct or indirect ownership of 5% or more
3) Names and addresses of individuals, who are related as spouse, parent, child or sibling to individuals described in (1) and (2) above
4) Names and addresses of individuals in (1), (2), and (3) above with an ownership or controlling interest in a Medicare or Medicaid facility
5) Names and addresses of officers, directors or partners
6) The circumstances of any criminal offense conviction involving Medicare/Medicaid programs on the part of any person(s) or organization(s) in (1), (2) or (3) above and/or, on the part of any managing employee of the organization
7) The dates of any changes in ownership or control during the previous twelve (12) months
8) The dates of anticipated changes of ownership or control in the next twelve (12) months

DI.2c An Advisory Committee of professionals is authorized by the governing body to advise the organization on policies and to evaluate the Pharmacy Program.

1) Responsibilities of the committee include establishment and annual review of pharmacy policies and participation in the annual evaluation of the Pharmacy program.
2) Membership of the committee includes a physician, a pharmacist, a registered nurse and at least one community representative who is not an employee
3) Committee meeting minutes reflect the committee's fulfillment of its responsibilities
4) The Advisory Committee meets at least once annually.

LEGEND:
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S - SURVEY

DI.2 cont'd

I:	Management and staff describe and cite examples of how current clinical and organizational data are assessed and used in revision of policies and practices. (DI.2d)

DI.2d Systems exist for obtaining and integrating the most current information into the professional practice to be used in planning, evaluation and decision making in all aspects of the program.

LEGEND:
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DI.3

D:	A current organizational chart is available and clearly delineates the lines of authority and accountability for all organizational positions. (DI.3a)
I:	Staff members are familiar with the organizational chart and state their individual lines of authority and accountability. (DI.3a,3b)

DI.3	Intra-organizational relationships of the Pharmacy Organization are clearly defined in writing.

DI.3a A current organizational chart illustrates the lines of authority and accountability for all administrative, professional, technical, clinical and clerical personnel.

DI.3b The complexity of the Pharmacy organization's administrative structure is appropriate for efficient delivery of product and service.

LEGEND:
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DI.4

D: Pharmacy Program Director's resume, diploma, reference checks and current professional license verify compliance with requirements for the position. (DI.4a, DI.4b)

Note: The Pharmacy Program Director may be a regional position in multi-state organizations. In that instance, the Program Director would have a current active Pharmacist license in a state. The Pharmacist in Charge at the specific site will have an active Pharmacist license in that state. The Pharmacy Program Director and the Pharmacist in Charge may be the same or separate position in the organization..

I: Pharmacy Program Director demonstrates knowledge of local, state and federal pharmacy regulations. (DI.4b)

D: The Pharmacy Program Director's job description and/or policies include responsibilities as specified in elements 1-11, or the responsibilities are clearly delegated to other specific positions. (DI.4c)

I & O: The Pharmacy Program Director demonstrates understanding of his/her role. (DI.4c)

D: Written policy and procedure defines assignment of administrative responsibilities in the absence of the Pharmacy Program Director. (DI.4d)

I: Designated alternate to the Director understands his/her role and describes experiences specific to the alternate roles. (DI.4d)

Note: DI.4 may appear to be a duplication of CI.4; however, CI.4 pertains to the CEO of an organization, and DI.4 pertains to the Pharmacy Program Director, which may be the same or separate position in the organization.

DI.4	Authority and responsibility for the overall executive management of the Pharmacy Organization is vested in qualified individuals.

DI.4a The Pharmacy Program Director is a graduate of a pharmacy program accredited by the American Council of Pharmaceutical Education or has passed a Foreign Pharmacy Graduate Equivalency Examination given by the National Association of Boards of Pharmacy, is currently licensed as a Pharmacist in the state.

DI.4b A qualified pharmacist with appropriate knowledge, expertise and experience is responsible for the management, direction, coordination and general supervision of all professional services.

DI.4c The Pharmacy Program Director is responsible for the following areas either directly or by clear delegation:

1) Organizing and directing the Pharmacy program's operations to assure the availability of services and products provided
2) Assuring adequate inventory of pharmaceuticals and supplies necessary to compound and dispense prescriptions appropriately, including periodic inspection for outdated products.
3) Assuring all equipment utilized in the delivery of the organization's products and services is properly maintained
4) Assuring pharmacy services are provided in compliance with applicable laws, regulations, accreditation standards and ethical standards of practice
5) Assuring adequate and appropriate staffing, including recruitment, orientation, in-service education and completion of annual performance appraisal
6) Coordinating with other program areas and managers as appropriate, consistent with organizational structure
7) Assuring the implementation of a pharmacy performance improvement program including evaluation of the home pharmacy program services
8) Assuring Drug Control system consistent with policies and regulatory requirements
9) Assuring Drug Dispensing system consistent with policies and regulatory requirements
10) Assuring appropriate pharmacy supervision at all times
11) Assuring safe and appropriate service policies are developed and implemented

DI.4d A qualified individual is designated in writing to act in the absence of the Pharmacy Director.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
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S - SURVEY

DI.5

D:	Policies reflect the current practice, professional standards of Service, and scope of service.(DI.5a)
D:	Pharmacy administrative policies and procedures at a minimum address items 1-4. (DI.5b)
D:	Pharmacy operational policies and procedures at a minimum address items 1–25. (DI.5c)
D:	Policy is available and includes temperature, light and security. (DI.5c.1)
D:	Policy is available when the pharmacy has a contractual relationship with a nursing agency. (DI.5c.8)

DI.5	Pharmacy policies and procedures reflect an emphasis on quality and ethical practice, relate directly to the scope of the Pharmacy program, and ensure client rights, and ethical standards of business and clinical practice.

DI.5a Organizational literature, policies and procedures accurately reflect the current practice, current professional standards of service and scope of the Pharmacy program.

DI.5b Pharmacy Program administrative policies and procedures include:

1) Regulatory Compliance
2) Capital Short-fall Contingency Plan
3) Pharmacy Reference Materials
4) Annual Evaluation

DI.5c Pharmacy Program operational policies and procedures covering the scope of services provided are developed and include at a minimum:

1) Storage of final pharmaceutical products
2) First dose new drug administration
3) Handling investigational drugs
4) Client/caregiver instruction
5) Timely assessment of client eligibility and provision of service
6) Notification of referral source if client does not meet admission criteria
7) Delivery of services/products, as applicable
8) Contents, dispensing and maintenance of infusion emergency kits
9) Acquisition, storage, disposition & dispensing of controlled substances
10) Selection, maintenance, use & control of infusion control devices for drug administration, as applicable
11) Client identification confirmation
12) Availability of latex-free supplies
13) Prescription labeling
14) Materials/Inventory Management
15) Equipment cleaning, testing and tracking
16) After Hours Coverage
17) Dispensing Records
18) Sterile Admixture Procedures for monitoring for medication errors, surface testing, environmental air sampling and product sterility
19) Preparation of injectables from sterile solutions
20) Preparation of injectables from non-sterile powders
21) Preparation of respiratory drugs from non-sterile powders
22) Clinical competency testing
23) Competency testing of sterile product preparation
24) Medication Error
25) Recall

LEGEND:
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S - SURVEY

DI.5 cont'd

D: Pharmacy clinical policies and procedures at a minimum address items 1 –6. (DI.5d)

D: Pharmacy quality improvement policies and procedures at a minimum address items 1-4. (DI.5e)

D: Written policy is available for first dose drug. (DI.5f)

DI.5d Clinical policies and procedures consistent with professional standards of practice are developed and include at a minimum the following:

1) Client Assessment
2) Medication Assessment
3) Drug Profile Review
4) Care Planning, as appropriate
5) Development of a comprehensive care plan
6) Clinical monitoring

DI.5e Quality Improvement policies and procedures consistent with professional practice and regulatory mandates are developed and include at a minimum:

1) Performance Improvement Plan
2) Structure and routine maintenance of compounding areas
3) Maintenance of Laminar Flow Hood
4) Infection control, safety for preparation, dispensing, disposal of pharmaceuticals

DI.5f Policies identify when a physician or other qualified professional is required to be present for the administration of the first dose of a new drug to detect, monitor and respond to adverse drug reactions.

LEGEND:
D - DOCUMENTATION
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S - SURVEY

DI.6

D:	Meeting minutes document discussions of and actions taken by the group, as applicable. (DI.6a)
I &O:	Staff demonstrates knowledgeable of and compliance with reimbursement and regulatory guidelines. (DI.6b)

DI.6	The Pharmacy Organization's business and clinical activities are conducted according to ethical standards.

DI.6a A designated and qualified group of professionals/individuals address ethical issues relating to the business and clinical practices of the Pharmacy Organization.
The issues include but are not limited to:

1) Care delivery issues
2) Product and service related issues
3) Billing and collecting issues
4) Medical necessity authorization issues
5) Statistical data trending and tracking issues

DI.6b Staff are knowledgeable about and carry out their responsibilities for providing products and services in accordance with reimbursement and regulatory guidelines.

LEGEND:
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DI.7

I: Pharmacy Director/pharmacists describe the process for assuring that clients are fully informed and provide written consent prior to participating in research or investigative studies. (DI.7a)

D: Written contract or agreements pertaining to Pharmacy educational experiences for non-employees (i.e., students) exist as applicable. (DI.7b)

D & I: Documents and interviews validate that current research initiatives exist as applicable. (DI.7c)

D & I: Pharmacy employees publish research findings as applicable. (DI.7d)

DI.7	The Pharmacy Organization contributes to the development and expansion of knowledge in Pharmacy practice, as appropriate.

DI.7a	A Pharmacy Organization participating in research or investigative studies ensures that clients are fully informed and provide written consent.
DI.7b	Arrangements for student education experiences are formalized in written contracts or agreements that specify the responsibilities of the Pharmacy organization and the educational institution.
DI.7c	The Pharmacy organization demonstrates a positive attitude regarding research initiatives and considers requests for research in the area of pharmaceutical practice as appropriate.
DI.7d	The Pharmacy organization encourages the publication of significant outcomes related to the management and practice of pharmacy.

DII.

THE PHARMACY ORGANIZATION CONSISTENTLY PROVIDES HIGH QUALITY PRODUCTS AND SERVICES

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.1

D: Current Public Disclosure policy includes the element of DII.1a, if applicable, in addition to the elements of CII.1a. (DII.1a)

D: The Client Bill of Rights statement and/or other admission documents includes elements of DII.1b in addition to the elements of CII.1b . (DII.1b)

D: Record review confirms that the Client Bill of Rights is signed by the client or client representative and is filed in the record. (DII.1c)

O: Observation of the open door pharmacy validates that the Client Bill of Rights is posted in a public area. (DII.1d)

D: Record review validates that pharmacy products and services are provided to clients consistent with the organization's stated scope of service. (DII.1e)

DII.1	The Scope of Services drives the activities of the Pharmacy Organization and ensures public disclosure, client rights, and ethical standards of business and clinical practice.

DII.1a The written public disclosure policy makes the Annual Report for C Corporations, if applicable, available to the public on request.

DII.1b A written Client Bill of Rights statement or other written admission documents are provided to the client or the client's representative at the start of care or at the time of initiation of care and include the right to be fully informed of:

1) Services and products being provided
2) Organization's ownership and control
3) Names and qualifications of individuals providing products and services

And the right to:

4) Participate in one's own care
5) Continuity of products and services
6) Education about the products and services to be provided
7) Refuse part or all of the products and services to be provided
8) Receive products and services in a timely manner and in accordance with organizational policy
9) Be referred to another organization
10) Be free from abuse or exploitation of any kind
11) Receive information, both verbal and written, in an understandable format.

DII.1c The Client Bill of Rights is signed by the client or a representative of the client and made a permanent part of the client's record.

DII.1d For clients receiving open door pharmacy services, the Client Bill of Rights is posted in a public area accessible to those clients.

DII.1e The Pharmacy organization's products and services are provided in accordance with the organization's scope of services.

1) Statistical reports confirm that products and services are provided consistent with the Pharmacy organization's scope of services.
2) Staff at all levels are knowledgeable about and support the Pharmacy organization's mission and scope of services.

LEGEND:
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DII.2

I & O: Interview and observation of practice confirms that the pharmacy organization is providing services as defined in DII.2a.

D: Job descriptions and/or other policies identify duties and responsibilities of each discipline, which are consistent with national practice standards. (DII.2b)

I & O: Interviews and direct observation of staff in practice confirms staff understanding and fulfillment of responsibilities. (DII.2b)

D: Clinical record documentation by respective disciplines verifies fulfillment of assigned responsibilities. (DII.2b)

DII.2	Pharmacy services are provided in accordance with organizational policies and procedures, to clients in their place of residence, and may include dispensing at the pharmacy site, transported delivery to home/client site or mailed delivery.

DII.2a Pharmacy services include but are not limited to:

1) Interpretation and evaluation of the prescription order
2) Drug product selection, compounding, dispensing, storage
3) Distribution of drugs and devices
4) Advising the prescriber and other health care professionals, the client and/or caregiver as to therapeutic actions, utilization and possible adverse reactions and interactions in order to encourage a positive client outcome.

DII.2b Pharmacy services are provided by or under the direction and supervision of a qualified pharmacist.

1) Professional pharmacy service is provided by a registered pharmacist and include:
   (a) Overseeing the drug control system including:
      1) Receipt of prescription drugs and prescription orders
      2) Storage of medications
      3) Packaging of medications
      4) Preparation and dispensing of prescriptions
      5) Labeling
      6) Preparation of prescriptions for delivery
   (b) Instruction/counseling clients and caregivers regarding specific drug therapy including possible adverse reactions and/or interactions
   (c) Providing information regarding the safe and appropriate use of medications to other health care professional
   (d) Identifying appropriate outcomes of drug therapy.
   (e) Consulting on drug therapy and coordinating with other health care professionals
   (f) Monitoring and documenting ongoing drug therapy including the assessment of:
      1) The therapeutic appropriateness of the choice of drug(s)
      2) Therapeutic duplication in the client's drug routine
      3) Appropriateness of the dose, frequency and route of administration
      4) Adherence to drug regimen
      5) Potential drug, food or diagnostic test interactions of disease limitations to drug use
      6) Laboratory or clinical monitoring methods to detect drug effectiveness, side effects, toxicity or adverse effects
      7) Preparing and maintaining clinical records
   (g) Prescribing activities consistent with state/federal regulations.

2) Pharmacy technical services are provided by pharmacy technicians who have been trained for all tasks performed in compliance with state law, job description and organizational policy.

LEGEND:
D - DOCUMENTATION
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DII.2 cont'd.

I:	Procedures for ensuring availability of drugs, supplies and Equipment are described. (DII.2c)
I:	Job descriptions and/or policies include the indicated delivery personnel responsibilities (DII.2d)
I & O:	Interviews and direct observation of delivery services during home visits confirms staff understanding and fulfillment of responsibilities. (DII.2d)
I:	Clients relate satisfaction with delivery services. (DII.2d)
I:	Procedures for ensuring availability of drugs, supplies and infusion devices when not available from the organization are described. (DII.2e, DII.2f)

DII.2c The Pharmacy Program provides pharmaceutical care, related supplies and equipment to clients.

DII.2d Delivery services are provided directly or by arrangement in compliance with laws and regulations and include:

1) Safe and clean transport of pharmaceuticals and supplies to and from client homes/designated sites.
2) Timely delivery of pharmaceuticals and supplies
3) Record keeping
4) Setting up equipment in client homes, if applicable

DII.2e The organization has a process in place for assuring the availability of drug and supplies to clients in their designated sites not available from the organization.

DII.2f The organization has a process in place for assuring the provision of infusion devices to clients in their homes/designated sites when not available from the organization.

LEGEND:
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S - SURVEY

DII.3

I:	Staff describe how necessary services (pharmacy and delivery) are made available to clients at all times (on-call practices). (DII.3a)
D:	Review of documents (complaint log, client satisfaction survey, on-call logs) validate that response times are consistent with policies and meet client needs. (DII.3a)
D & I:	An on-call plan is available, and staff describe the on-call plan. (DII.3b)
O:	Testing of the on-call plan validates that the organization is in compliance with its on-call coverage plan and policy. (DII.3b)
I:	Client/family describes service availability after hours. (DII.3c)
D:	Written contingency plan protocols are available and include items 1 – 3. (DII.3d)

DII.3	Clinical services and products are accessible and available to clients on an emergency basis 24 hours a day, 7 days a week.

DII.3a The Pharmacy Organization is accessible and responsive to the needs of Clients during normal work hours and after hours which includes:

1) Timely telephone response
2) Timely on-site response, if indicated
3) Product and service delivery prior to scheduled use

DII.3b There is a plan for on-call coverage for after hours, weekends and holidays.

DII.3c Clients are informed of the process for accessing service during normal work hours and after hours.

DII.3d Written contingency plans delineate protocols for prioritizing delivery of product and services to clients including:

1) Disaster preparedness
2) Inclement weather events
3) Unexpected critical staffing deficits

LEGEND:
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DII.4

D: Written policy identifies admission criteria and referral process when the organization does not provide the needed product or service. (DII.4a)

D: Policies and procedures define the responsibilities of the pharmacists, and record review confirms documentation by the pharmacist. (DII.4b)

O: Observation validates assumption/fulfillment of responsibilities. (DII.4b)

D: Policies and/or procedures define the responsibilities for service coordination. (DII.4c, DII.4d)

D: Review of records confirms that care coordination activities are performed. (DII.4c, DII.4d)

Note: Appropriate referrals involves referrals for additional services as indicated. (DII.4d.4).

D: Client records document interdisciplinary coordination as appropriate. (DII.4 e)

I & O: Pharmacists indicate how drug profile information is made accessible to other appropriate professionals, the mechanisms for coordination, the procedures for coordinating delivery of medications, equipment and supplies and that that they are delivered and available as appropriate. (DII.4e)

DII.4	The Pharmacy Organization admits clients whose service needs can be met and ensures continuity of care/service through coordination of client services.

DII.4a Clients are admitted to service and continued on service, based on the reasonable expectation that their needs can adequately and safely be met by the program.

DII.4b A pharmacist assumes responsibility for planning, implementing therapy, evaluating the outcomes of therapy provided as applicable and documenting in the client record.

DII.4c Care is coordinated for each client by the pharmacist and includes at a minimum:

1) Periodic verbal, telephone or electronic communication with other professionals involved in the care of the client
2) Timely documentation of the coordination of care activities
3) Involvement of the client/client representative when indicated

DII.4d For other than open door pharmacies, care coordination includes elements 1-3 of DII.4c plus the following additional components:

1) Initial assessment of the client, family and, if applicable, the home environment
2) Development of a plan of care
3) Determination of expected outcomes
4) Appropriate referral and follow up
5) Implementation of the care plan
6) Ongoing evaluation
7) Plan of termination of care

DII.4e The pharmacist works collaboratively with other health care professionals to assure coordination of care.

1) The client drug profile information is available to professionals participating in the care of the client:

   a) at a minimum, during operating hours for all pharmacies
   b) at all times, including after hours for infusion pharmacies

2) The delivery of medications, equipment, and supplies is coordinated with other professionals involved with the care of the client to ensure that proper products and supplies are available when needed.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
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S - SURVEY

DII.5

D: Client assessment policies and record review validate the inclusion of specified items for all pharmacies. (DII.5a)

D: Client assessment policies and record review validate the inclusion of specified items in DII.5a and DII.5b for infusion and long term care pharmacies. (DII.5b)

D: Medication assessment policy and record review validate the inclusion of elements 1-6. (DII.5c)

D, I &O: Interview, observation and record review confirm that client assessments and medication assessments are conducted prior to dispensing. (DII.5a,DII.5b,DII.5c)

D: Policies establish mechanisms for obtaining written physician verification of and approval for verbal orders. (DII.5d)

D: Record review documents that required prescriptions were received prior to dispensing medications. (DII.5d)

D: Record review documents that verbal orders are taken and signed by the Pharmacist prior to filling orders. (DII.5d)

DII.5	The Pharmacy Organization defines the plan of care process, including assessments, physician oversight, dispensing and client training.

DII.5a An initial client assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Name, address, telephone number, gender, age/date of birth of client
2) Allergies/sensitivities of client
3) Medication Order
4) Physician name, telephone number

DII.5b For infusion and long term care pharmacies, an initial client assessment is made by the pharmacist prior to dispensing which includes elements 1-4 of DII.5a plus the following additional components as appropriate:

1) Chief Complaint/Medical history/Diagnosis
2) Height and weight of client
3) Client Infection, Sensitivities obtained as available
4) Significant Lab Results

DII.5c A medication assessment is made by the pharmacist prior to dispensing which includes at a minimum:

1) Potential drug interaction
2) Potential for poly-pharmacy
3) Appropriate dose and frequency
4) Appropriate time of administration
5) Appropriate route and method of administration
6) Appropriate infusion device of administration, if applicable

DII.5d Pharmaceuticals are dispensed according to the prescription of a physician or physician designee legally authorized to prescribe in compliance with state regulation:

1) Written, verbal or faxed prescriptions are available to the pharmacist before dispensing the medication
2) Verbal orders taken from a physician or physician designee are recorded and signed by the pharmacist prior to filling the medication order

LEGEND:
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DII.5 cont'd

D: Written policy is available and includes elements 1-11. (DII.5e)

D: Drug labels include the indicated items. (DII.5e)

D: Plans of care are available for each client and include items 1-6. (DII.5f)

Note: Review by physician may include review of orders, copies of plans of care mailed/faxed to physician. (DII.5f.6)

D: Written policy and procedure define the process for confirming client Identification. (DII.5g)

I & O: Pharmacy and delivery staff explain the process for confirming client identification prior to dispensing. (DII.5g)

D: Policies and procedures with specifications detailed are available for emergencies for pharmacy infusion services. (DII.5h)

I: Staff are familiar with emergency procedures and provide examples of their appropriate use. (DII.5h)

D: Drug information and instructional materials are prepared for all types of products and services provided. (DII.5i)

D: Review of documents validates that the client or caregiver was instructed in self-administration of therapy when self-administration was indicated. (DII.5j)

D: Client training/education is documented. (DII.5i, DII.5j)

I & O: Clients understand their regimes. (DII.5i, DII.5j)

DII.5e All pharmaceutical products dispensed to clients are appropriately labeled according to state and federal regulations and, at a minimum, include:

1) Name, address and telephone number of the pharmacy
2) Date the prescription was dispensed
3) Expiration date of the medication
4) Pharmacy's prescription number
5) Client's full name
6) Name of the drug, brand, strength, if applicable, and the amount dispensed
7) Directions for use
8) Prescriber's name
9) Other pertinent information or cautionary labels
10) Rate, route and method of administration
11) For IV mixture drugs, rate of administration and expiration date of the fluid

DII.5f A comprehensive plan of care is developed by infusion pharmacies which includes:

1) Establishment of Therapy Specific Goals
2) Determination of Expected Outcomes
3) Determination of Educational Needs
4) Establishment of Monitoring Plan
5) Determination of Achievement of Goals/Outcomes
6) Periodic Review by Prescribing Physician

DII.5g Client identification is confirmed prior to dispensing.

DII.5h For pharmacy infusion services, there are policies and procedures for emergency situations including, ordering of emergency kits with appropriate drugs by the physician and placement of these kits in the client's home, where appropriate.

DII.5i Drug information and instructional materials for administration are provided to the client or client caregiver at the time of dispensing.

DII.5j Client training/education in self-administration is provided upon initiation of therapy, as applicable

LEGEND:
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DII.6

D: Client records document that appropriate clinical services were provided to clients. (DII.6a)

D: Client records are current and include elements 1-4 . (DII.6a)

D: Client records document adherence to all clinical written policies and procedures. (DII.6a)

D: Client drug profiles are current and include items 1. a– h. (DII.6a.1)

D: Pharmacy dispensing records include items 2.a-k. (DII.6a.2)

D Records document adherence to first dose policy for new drug therapies. (DII.6a.2)

D: Pharmacy dispensing records for other than open door pharmacies include items a-k of DII.6a.2 and elements a-d of DII.6a.3. (DII.6a.3)

Note: Compounding instructions may be found in protocols, policies and/or specific instructional forms. (DII.6a.3c)

Documentation exists that a pharmacist oversees the process for dispensing, i.e., Pharmacist signature/initials on the label, on the compounding sheet, etc. (DII.6a.3d)

D: Narcotic records include items specified. (DII.6a.4)

I & O: Controlled substance records are maintained in compliance with state, federal and practice regulations. (DII.6a.4)

DII.6	Client records are maintained for each client and are utilized as a tool for coordination of services, as legal documentation of products and services provided and as a basis for billing and reimbursement procedures.

DII.6a Adequate and appropriate pharmacy records are maintained

1) Drug profiles are maintained for all clients and include the following information:

   (a) Name, gender, birth date and weight (when appropriate)
   (b) Address and client identification
   (c) Allergies or sensitivities
   (d) Diagnosis
   (e) Current drug regimen
   (f) Dosages
   (g) Relevant clinical information regarding drug therapy
   (h) Physician's name

2) Dispensing records are maintained for pharmaceuticals which include:

   (a) Client's identification, name and address
   (b) Name of medication
   (c) Strength and dosage form
   (d) Quantity dispensed
   (e) Physicians' name
   (f) Dispensing pharmacist/technician identification
   (g) Prescription number
   (h) Date dispensed
   (i) Directions for use
   (j) Expiration date
   (k) Number of refills authorized

3) Dispensing records for other than open door pharmacies are maintained for pharmaceuticals which include elements a-k of DII.6a2 plus the following:

   (a) Lot number(s) of drugs
   (b) Date of the addition(s) to intravenous admixture drugs
   (c) Special compounding instructions as applicable
   (d) Documentation of verification procedures

4) Controlled substance records are maintained in accordance with state, federal and practice regulations documenting that:

   (a) A controlled substance inventory is performed in compliance with state or federal regulation.
   (b) The pharmacist in charge is held accountable for the exact count of Schedule II pharmaceuticals
   (c) The pharmacist in charge is held accountable for an approximate count of Schedule III, IV, and V pharmaceuticals.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.6 cont'd.

D: Policy is current and describes signature authentication. (DII.6b)

I: Records/system administrator describes the inclusion of the 9 items in the ongoing process of ensuring protection of data. (DII.6b)

O: Pharmacy staff protect data consistent with policy and state law. (DII.6b)

I & O: A back-up and storage system is in place. (DII.6b)

DII.6b Automated clinical record systems ensure consistent and ongoing protection of data.

1) Written policy describes signature authentication in accordance with individual state law
2) Safeguards prevent unauthorized access to inputted information
3) Individual and protected access codes are assigned to individuals designated to perform data entry
4) Automated programs designate and control areas of access by authorized personnel based on a personal identifier and position in the organization
5) The computer's internal clock designates date and time of entries
6) Automated controls prevent a change in entry, allowing only corrections
7) Hardcopies of automated data are retrievable by designated personnel
8) A system for validation of inputted data is in place
9) An automated system for backup and storage of data is controlled, and the data is stored in a safe environmental place.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.7

I: The Pharmacy Director describes the performance improvement process for the pharmacy program. (DII.7a)

D: Evidence exists of utilization of performance improvement findings to resolve problems and improve quality of service/products. (DII.7a)

D: The performance improvement program include items specified in DII.7a.

D: The performance improvement plan includes items specified in DII.7b.

D: Evidence exists of monitoring and analysis of findings as specified in DII.7c.

I: Pharmacy Director and staff describe use of findings to identify problems and to improve performance. (DII.7c)

D: Staff orientation and in-service programs validate discussion of improvement program and indicators. (DII.7d)

D & I: When the pharmacy is part of a larger organization, evidence is provided demonstrating integration of quality improvement plans. (DII.7e)

DII.7	The adequacy, appropriateness, effectiveness and outcomes of products, services and supplies provided are routinely assessed.

DII.7a The Pharmacy Program has a formalized quality improvement program which is designed to:

1) Identify desired outcomes
2) Identify strategic and at-risk activities
3) Establish monitoring parameters for these activities
4) Establish minimal standards or criteria to be met
5) Describe methods used to improve the quality of service and to achieve the desired outcomes.

DII.7b The Pharmacy Program has a written performance improvement plan which includes:

1) Description of specific monitoring and evaluation activities
2) Specification of how results are to be reported and evaluated
3) Identification of appropriate follow-up mechanisms when thresholds are exceeded
4) Delineation of individual responsibilities for each aspect of the program.

DII.7c The Pharmacy Program's performance improvement program includes but is not limited to:

1) Monitoring for medication errors
2) Monitoring and analysis of the findings from surface testing, environmental air sampling and end product testing that includes sterility and pyrogens.

DII.7d Staff orientation and in-service programs integrate a focus on quality.

DII.7e The Pharmacy Program's performance improvement plan is integrated into the overall organizational quality improvement plan, as applicable.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.8

D: Written policies exist and include items 1-10. (DII.8a)

D: Observation of staff performing responsibilities confirms that staff adhere to infection control and safety policies and procedures. (DII.8a)

D: Record review confirms that home environment assessments were conducted when indicated and that safety hazards were identified and precautionary instructions were provided to the client and documented. (DII.8b)

D: Policy requires the designated stipulation for the disposal of controlled substances. (DII.8c.1)

D: Records confirm adherence to policy. (DII.8c.1)

D: A Material Safety Data Sheet clearly outlines protocols for disposal of hazardous products. (DII.8c.2)

O: The Material Safety Data Sheet is available in the pharmacy. (DII.8c.2)

Note: The Material Safety Data Sheet information may be available on the pharmacy website as long as each pharmacy employee has access to the information.

D: Written instructions regarding disposition of hazardous substances in homes are provided to appropriate clients. (DII.8c.3)

I: Staff and client are aware of disposition procedures for hazardous Substances, if indicated. (DII.8c.3)

D. Records confirm adherence to policy and regulation. (DII.8c.4)

D: Client instructions regarding preparation of sterile solutions, storage methods, and durations are documented. (DII.8d)

I: Clients preparing sterile solutions at home are able to describe appropriate preparation and storage precautions. (DII.8d)

DII.8	The health and well being of employees and clients is promoted and maintained through education and implementation of current infection control policies and safety measures.

DII.8a Infection control and safety measures for the preparation, dispensing and disposal of pharmaceuticals include but are not limited to:

1) Observation of standard precautions
2) Adequate hand hygiene/hand washing
3) Procedures for preventing exposure to blood borne pathogens
4) Glove, gown and eye shield use while compounding hazardous products and chemotherapeutic substances
5) Use of aseptic technique
6) Appropriate use of particulate and/or bacterial filtration
7) Hood decontamination practices
8) Venting of the laminar flow hood outside the building or use of a Class II Biological Safety Cabinet when compounding cytotoxic drugs
9) Proper disposal of needles used in the preparation of pharmaceuticals done by disposing of needles in a tamper proof, puncture resistant container
10) Proper disposal for hazardous waste products

DII.8b When applicable, the home environment is assessed to evaluate potential safety hazards and to instruct the client and/or those associated with the care of the client about safety precautions. The assessment and client teaching is documented in the client's record.

DII.8c Disposal of outdated drugs, controlled substances or hazardous wastes is documented and conforms to state and federal requirements.

1) Controlled substances are returned to the Drug Enforcement Administration if required. Documentation of the disposal of controlled substances on site is witnessed by two individuals and includes the amount and type of the drug.
2) Material Safety Data Information is kept in the pharmacy and identifies procedures for disposal of hazardous products
3) Clients are instructed regarding the proper disposal of hazardous products in the home
4) Records are maintained, as required

DII.8d When clients and caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:

1) Instructions regarding the preparation of the sterile solution
2) Storage methods
3) Duration and stability of the prepared solution

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.8 cont'd

D: Written infection control and safety policies for equipment/delivery service are available. (DII.8e)

I & O: Staff demonstrate an understanding of infection control procedures and policies. (DII.8f)

D: Policies specify elements 1 – 5 of DII.8f. (DII.8f)

D: Policies specify maintenance, testing, and repair specifications for each type of equipment. (DII.8f)

I & O: Equipment is maintained, tested, and repaired according to manufacturer's recommendations. (DII.8f)

D & O: Review of records and observation of practice confirms adherence to organizational policies and that activities are conducted on a routine basis. (DII.8f)

DII.8e Infection control and safety control policies are established and implemented for the equipment/delivery service, including:

1) Maintenance, testing and repair of equipment according to manufacturer's guidelines
2) Cleaning and storage of reusable equipment between usage
3) Inspection of equipment prior to delivery.

DII.8f The Pharmacy Program that prepares compounded sterile products conducts the following activities on a routine basis:

1) Routine disinfection and quality testing of direct compounding environment
2) Visual confirmation of personnel processes regarding gowning, and other infection control/safety measures
3) Review of orders and packages of ingredients to assure correct identity and amounts of ingredients
4) Visual inspection of compounding sterile products
5) Media-fill test procedure performed at least annually for each person

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DII.9

D: Documentation validates that the complaint process includes elements 1-9. (DII.9a)

D: Review of complaint log validates that complaints have been responded to consistent with the organization's policy and process. (DII.9a)

DII.9	Client complaints and concerns are responded to and resolved in a timely manner.

DII.9a The complaint process includes:

1) Designation of the individual(s) responsible for responding to the complaint
2) Procedures for responding to complaints
3) Time frame for responding to complaints
4) Assurance that corrective action is taken as appropriate
5) Assurance that client and family rights are protected
6) Follow-up activities
7) Resolution of the complaint
8) Complainant is informed of the outcome
9) Trending of justified complaints

DIII.

THE PHARMACY ORGANIZATION HAS ADEQUATE HUMAN, FINANCIAL, AND PHYSICAL RESOURCES, WHICH ARE EFFECTIVELY ORGANIZED TO ACCOMPLISH ITS STATED MISSION

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.1

D: Staffing assignments are available. (DIII.1a)

I: Mechanisms for evaluating workload demands are described. (DIII.1a)

I: Mechanisms for employee selection are described. (DIII.1b)

D: Documentation of required elements 1-10 validates compliance and inclusion in the personnel files, health files, or the administration files. (DII.1b)

D: Records include diplomas/transcripts, current licenses and continuing education attendance (if required) for all clinical/professional staff. (DIII.1b.3, 4, 5)

D: Documentation of certification or adequate training is available for Pharmacy Technicians and Delivery personnel identifying training provided for all tasks performed by the technician and the Driving personnel. (DIII.1b.6, 8)

I: Delivery and equipment service personnel selection process is described, including driving record checks, and compliance with relevant motor carrier safety regulations. (DIII.1b.7)

I: Mechanisms for assessing and updating clinical competencies/skills are described. (DIII.1c)

D: Documentation of clinical competency/skill assessment at time of hire and annually thereafter is available. (DIII.1c)

D: Documentation of clinical competency assessment including elements 1-5 at time of hire and annually thereafter is available. (DIII.1d)

I; Mechanism for assessing clinical competency is described by manger and pharmacy personnel. (DIII.1d)

DIII.1	The Pharmacy organization has adequate and appropriate human resources to meet workload demands.

DIII.1a Staffing guidelines are developed and implemented to adequately meet workload demand.

DIII.1b Qualified personnel are recruited and retained. Documentation is found in the personnel files, health files or administration files of the following:

1) Budgets allocate sufficient funds to ensure staffing at all levels and are maintained to adequately meet workload demands
2) Positions, new and vacant, are filled on a timely basis to sustain organizational performance goals
3) Clinical staff show evidence of graduation from colleges approved or accredited by their respective professional organization
4) Clinical staff maintain and show evidence of current licensure
5) Clinical staff show evidence of continuing education when required
6) Pharmacy technicians show evidence of certification, or have evidence of adequate training, for all tasks performed in conformance with applicable laws
7) Delivery personnel, when utilized, have a clean driving record and maintain a current driver's license
8) Delivery personnel, when utilized, show evidence of adequate training for all tasks performed
9) Professional & technical personnel show evidence that professional skills are assessed and updated
10) Compounding personnel show evidence of skills, training, and competency testing to perform and document compounding duties.

DIII.1c Clinical competency evaluations are performed to assess employee basic skill levels for all staff providing client care/services:

1) At time of hire
2) Annually, thereafter

DIII.1d Clinical competency evaluations of pharmacy personnel who use laminar flow hoods and/or Class II Biological safety cabinets are conducted at time of hire and annually thereafter and include at a minimum:

1) Written test to verify employee's understanding of the concepts of aseptic technique
2) Observation of employee's aseptic technique
3) Sterility validation testing for all employees who make sterile products
4) Observation of cleaning, testing and calibration of infusion equipment
5) Observation of cleaning, testing and calibration of compounding equipment

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.1 cont'd

D: An orientation plan is available and includes elements 1-5. (DIII.1e)

D & I: There is an appropriate supervision plan for all levels of staff and each employee. (DIII.1f)

D: Records show documentation of state/organizational required in-service attendance by pharmacists. (DIII.1g)

Note: In-services may be provided by the organization or other approved entities.

D: Records show documentation of organization's provision of annual in-service program and pharmacist's attendance at the in-service. (DIII.1h)

DIII.1e The orientation plan addresses at a minimum:

1) Mission statement
2) Organizational Chart
3) Lines of authority and responsibility
4) Job related responsibilities (job description)
5) Human Resources policies/conditions of employment

DIII.1f There is adequate supervision of all pharmacy personnel.

1) Professional Pharmacy services are provided by or under the direction and supervision of a qualified Pharmacist.
2) Staffing ratios of pharmacists to pharmacy technicians are in compliance with state regulations.

DIII.1g Pharmacists show evidence of participation in formal in-service programs required by state regulation and organization policy.

DIII.1h The organization provides a minimum of one medication safety in-service annually.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.2

D: Contracts for Pharmacy services contain all elements in CIII.2a-b, DIII.2a and DIII.2b. (DIII.2b)

D: Contracts for Delivery services contain all elements in CIII.2a-b, DIII.2a and DIII.2c. (DIII.2c)

I: Pharmacy Director describes mechanism for assuring compliance with responsibilities. (DIII.2)

DIII.2

DIII.2	Formal written contracts and agreements with other organizations and/or individuals for the provision of pharmacy products and services to pharmacy organization clients detail specific responsibilities of the parties involved.

DIII.2a Formal written contracts and agreements with other organizations and/or individuals for provision of pharmacy services includes specific responsibilities as defined in CIII.2a-b and, in addition, the following specific responsibilities:

1) Which organization has the authority to accept and terminate client services
2) Services provided under contract must be in compliance with professional standards
3) The manner, in which products and services will be controlled, coordinated and evaluated
4) Designation of responsibilities for orientation

DIII.2b Pharmacy services when provided under arrangement are in accordance with CHAP Pharmacy Standards and are in compliance with CIII.2a-b, DIII.2a and, in addition, include the provisions for:

1) Who is responsible for teaching the client about pharmaceuticals
2) Assurance that personnel meet the pharmacy program's educational and training requirements
3) Maintenance of current licensure and certification where required
4) On site supervision of pharmacy personnel
5) Hours when pharmaceutical services are available to the client, including arrangements for services during "off hours"
6) Time frames for response to new referrals
7) Responsibilities of contractor and contractee, including:
   (a) Who assesses the need for pharmaceuticals
   (b) Who contacts the pharmacy
   (c) Who obtains the written physician orders
   (d) Who generates drug profiles and to whom they will be made available of those involved with the client's care
   (e) Who maintains records for investigational drugs and controlled substances
   (f) Procedure to follow assuring the availability of drugs and supplies to the clients in their home when not available from the pharmacy
   (g) Mechanisms for evaluating the contracted service

DIII.2c Delivery of products and supplies when provided to clients under arrangement are in compliance with CIII.2 a-b, DIII.2a and, in addition, include the provisions for:

1) Ensuring clean and safe transport of equipment and supplies
2) Timely delivery of products and supplies
3) Setting up equipment in client's homes, where appropriate
4) Adequately trained delivery personnel
5) Client education, where appropriate
6) Appropriate documentation

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.3

D: Policies pertaining to cash management and contingency planning are available. (DIII.3a)

I: Pharmacy Director describes how the organization manages its cash and cites examples of contingency planning. (DIII.3a)

D&I: Pharmacy Director and/or Financial Manager describe and document the insurance coverage and discuss the rationale for the amounts. (DIII.3b)

D: New Pharmacy product/service plan proposals include specified elements. (DIII.3c)

I: Management team describes examples of recognition of inter-relationship of finance, quality, product and service operations. (DIII.3d)

DIII.3	The Pharmacy Organization/Program has adequate and appropriate financial resources to meet its stated mission.

DIII.3a The organization has a contingency plan and/or policies and procedures to adequately address cash or operating short falls that may impact the products and services it provides.

DIII.3b Insurance coverage is maintained for the loss due to general liability, product liability, professional liability and work related injuries.

DIII.3c New program, product or service planning and development occurs prior to implementation which includes analysis of effectiveness and profitability of the project.

DIII.3d The management team's performance reflects an understanding of the interrelationship of finances, quality, product and service operations and long term viability of the organization.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.4

O: Observation of the physical facility validates that elements 1 -7 are in evidence and in conformance with state/federal requirements. (DIII.4a)

D: Written policies specify elements 1-5. (DIII.4b)

O: Work surfaces and equipment are cleaned and disinfected in compliance with pharmacy policy. (DIII.4b)

Note: Compounding environment includes walls and floors. (DIII.4b.2)

D,I&O: Interview, observation and review of reference data validate that professional/community standards of practice are followed. (DIII.4c)

O: Observation validates that sterile and non-sterile preparation areas are separate and adequate. (DIII.4d)

D&O: Observation of injectible drug work areas and review of end product testing results validate compliance with the specifications designated in elements 1-3. (DIII.4e)

DIII.4	The Pharmacy organization has adequate and appropriate physical facilities to accomplish its stated mission.

DIII.4a The Pharmacy organization has the necessary space, equipment and supplies for safe preparation, dispensing, storage and delivery of pharmaceuticals in compliance with state and federal requirements, and includes at a minimum:

1) Preparation of sterile products for dispensing *is within an ISO Class 5 environment*
2) Hot and cold running water with sink
3) Walls, ceilings and floors made of non-porous cleanable surfaces
4) Accurate balance and measuring devices
5) Adequate ventilation and lighting
6) Disposable hand drying towels
7) Adequate storage facilities
   (a) Parenteral compounding items stored to maintain integrity of aseptic environment
   (b) Adequate refrigerator/freezer capacity to meet storage requirements for all refrigeration-required materials.
   (c) Shelves and storage containers made of washable, non-porous materials, including non-use of corrugated cardboard/styrofoam

DIII.4b The Pharmacy organization maintains adequate and clean compounding areas in compliance with its policies which specify:

1) The adequacy of workspace per state regulations
2) Frequency, types of cleaning agents and procedures of how work surfaces, equipment and compounding environment are cleaned and disinfected
3) Work surfaces are kept free of equipment, supplies, records and other material unrelated to the preparation of a given drug
4) Certification of laminar flow hood per organizational policy and/or state/federal regulation
5) Validation of cleaning and compounding practice including surface sampling, environmental air sampling and end product sterility testing for pyrogens.

DIII.4c Storage of the final pharmaceutical product is in accordance with acceptable professional/community standards of practice which are supported by reference data, including temperature, light and length of time.

DIII.4d Areas for compounding of sterile products are functionally separate from areas for the preparation of non-sterile products and are constructed to minimize opportunities for contamination of products.

DIII.4e There are adequate work areas for the preparation and manipulation of injectable drugs, which includes the following:

1) Methods for inspecting ingredients and final products for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination
2) Use of laminar flow hoods
3) Use of Class II Biological Safety Cabinets for the preparation of cytotoxic drugs

Revised: 3/13/06

LEGEND:

D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.4 cont'd

D: Documentation of semi-annual inspections and pre-filter changes as required is available. (DIII.4f)

D: Certification reports from the most current three year period are available. (DIII.4f)

I & O: Pharmacy personnel are knowledgeable of and use appropriate techniques when using a hood or cabinet. (DIII.4g).

I&O: Interviews with staff and observation of practice confirms compliance with policies. (DIII.4h, DIII.4i, DIII.4j)

D: Written policies specify elements 1-5. (DIII.4k)

O: Products are shipped in compliance with the pharmacy's policy. (DIII.4k)

O: Client service areas are private, clean, safe and in compliance with ADA regulations. (DIII.4l)

DIII.4f Laminar Flow Hoods and Class II Biological safety cabinets are inspected at least every six months and certified by an independent agency that they are operating according to specifications. Certification records are retained for a minimum of three years.

DIII.4g Pharmacy personnel using a laminar flow hood or a Class II Biological safety cabinet use proper techniques consistent with professional standards of practice to ensure a continuous aseptic environment during the admixing of sterile pharmaceuticals.

DIII.4h Preparation of injectables from sterile solutions includes the use of filters when removing solutions from ampules.

DIII.4i Injectables prepared from non-sterile powders are:

1) Dissolved in sterile solution for injection
2) Filtered through a 0.2 micron filter.

DIII.4j Respiratory medications prepared from non-sterile powders are prepared in an ISO 5 environment and are:

1) Dissolved in sterile solution
2) Filtered through a 0.2 micron filter
3) Packaged under ISO 5 environment conditions
4) Periodically end product tested

DIII.4k Adequate shipping containers and shipping processes are used in accordance with regulations and manufacturers guidelines to assure drug stability and potency which includes the following:

1) Assurance of stability and potency of the products being shipped
2) Temperature control
3) Non-exposure to light
4) Non-exposure to contaminants
5) Packaging of medications in a tamper evident manner

DIII.4l The organization's physical facilities provide a safe environment for staff and clients and allow for the efficient provision of services.

1) Space and privacy are adequate for the services being provided
2) Physical facilities and resources permit effective and efficient function of the personnel
3) Provisions are made to accommodate clients and staff with disabilities

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIII.5

D: External databases are available and used for comparison. (DIII.5a)

D: Benchmark reports are available. (DIII.5b)

Note: Organizations may use internal standards, professional standards of practice guidelines, research findings or professional references to determine benchmarks.

Organizations may use multiple sites, divisions and/or professional reference data to benchmark against.

DIII.5	An effective and efficient management information system is utilized to ensure accountability at all levels of the organization.

DIII.5a When available, the organization uses external databases that provide information relevant to the organization's products and services and creates a basis for comparative analysis.

DIII.5b The organization participates in a benchmarking system.

1) Benchmark data are consistent with organizationally defined goals and objectives
2) Benchmark collected data, when available, are measured against data from other organizations

DIV.

THE PHARMACY ORGANIZATION IS POSITIONED FOR LONG TERM VIABILITY

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.1

D:. The pharmacy operational plan is available. (DIV.1a)

D: Governing Body meeting minutes document approval of the initial pharmacy operational plan and changes. (DIV.1b)

DIV.1	Operational planning reflects the Pharmacy's mission.

DIV.1a The planning process focuses on performance expectations and is consistent with organizational needs.

DIV.1b The written plan is developed, and the initial plan and changes are approved by the governing body.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.2

D: An annual evaluation of the pharmacy organization's program and operations is conducted. (DIV.2)

I: Management describes the annual evaluation process and the way it is used for future planning for the organization. (DIV.2a)

I: Management personnel describe how the complexity of the organization relates to data collection and utilization. (CIV.2b)

D & I: Evidence exists that product and service pricing is routinely evaluated. (DIV.2c)

D: The interrelationship between the pharmacy program evaluation and the overall organizational evaluation is evident when the pharmacy is part of a larger organization. (DIV.2d)

DIV.2	An annual systematic evaluation of major aspects of the Pharmacy Organization's program and operations provides the basis for future planning.

DIV.2a Mechanisms are established in writing for the collection, dissemination and use of information for the purpose of management, quality improvement, planning and future evaluation purposes.

DIV.2b Data appropriate to the complexity and scope of the Pharmacy organization is collected and monitored.

DIV.2c Pricing of products and services is routinely evaluated.

DIV.2d Results of the Pharmacy organization's evaluation findings are integrated into the corporate organization's report, if applicable.

LEGEND:
D - DOCUMENTATION
I - INTERVIEW
O - OBSERVATION
S - SURVEY

DIV.3

O:	Innovations have been developed and implemented. (DIV.3)

DIV.3	The Pharmacy Organization management team fosters innovation within the organization and brings strong leadership to industry-related activities.

DIV.3a A common and futuristic vision of the organization is established and sustained.

1) A learning environment for all staff is promoted and supported
2) Staff development is encouraged
3) Governing body members have expertise specific to the enhancement of the organization's mission

DIV.3b An atmosphere of mutual respect permeates the organization throughout.

1) Interaction between staff, administration and governing body is evident and is facilitated

DIV.3c The organization has positioned itself to participate in public forums that shape health care policy and educate consumers.

DIV.3d The organization actively networks with other providers and provider organizations.

Community Health Accreditation Program, Inc.

Job Description
Site Visitor Per Diem

Position Description:

Under the direction of the Regional Director of Professional Services the Site Visitor plans, organizes, coordinates and conducts community based health care organization accreditation site visits in accordance with assigned activities. Accreditation activities are executed in accordance with CHAP Policies and Procedures governing the accreditation process. The CHAP Site Visitor ensures the protection of the confidentiality of all related site visit information except as otherwise required by law.

Qualifications

- Five (5) years experience in middle to upper management position in a health care field in at least one program or service accredited by the Community Health Accreditation Program, Inc. (CHAP).
- Bachelor's Degree in a related specialty area required. Master's Degree preferred.
- Active license to practice in home state, where required by discipline.
- Demonstrates analytical, consultative, conflict resolution, mediation, written and verbal articulation skills with effective critical thinking aptitude.
- Ability to work effectively as part of the accreditation team.
- Successful completion of the CHAP site visitor orientation program which includes: didactic classroom, competency testing and mentored site visit(s).
- Exceptional organizational and time management skills.
- Ability to travel independently.
- Demonstrates excellent interpersonal skills.
- Demonstrates proficiency with computer skills and office applications.
- Requires availability of a minimum of ten site visit days per month

Responsibilities:

1. Represent CHAP in a professional mannerAccept assignments
    a. Report availability to CHAP Scheduler in established time-frame
    b. Confirm travel arrangements in a timely manner in relation to when the assignments are made
2. Prepare for assignments to include as appropriate:
    a. Review agency self-study to assist in planning visit
    b. Collaborate with team members
3. Complete site visit requirements and documentation in an organized and timely manner
4. Submit required site visit documentation within required time frame
5. Demonstrate knowledge and application of CHAP accreditation process, Standards of Excellence, State and/or Federal Regulations.
6. Provide clarification, verification and quantification of site visit findings.
7. Participates in scheduled CHAP meetings
8. Performs other functions as assigned

This position involves part time work which will require full time independent travel by air or car or other means. Due to the nature of this job, lifting of materials and equipment of up to 50 pounds is required. Extended periods of sitting/standing are required.

Speaking in fluent English is required as are excellent writing skills for written correspondence. The candidate must be able to hear, see and comprehend written documents to effectively perform this job. Extensive work on a PC and telephone, at a desk, is required.

The physical demands and work environment that have been described is representative of those an employee encounters while performing the essential functions of this position. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions in accordance with the Americans with Disabilities Act.

I have reviewed the above job description and had an opportunity to have my questions answered. I understand and agree to perform all essential functions to the best of my ability.

Signature Date

Introductory Site Visitor Evaluation

This evaluation is completed within 90 days of hire. Each Site Visitor is expected to have completed 4-6 site visits by then.

Site Visitor Name:_____

Date(s) of the Site Visit (s): _____

The rating scale is as follows:

5= Always
4= Frequently
3= Sometimes
2= Rarely
1= Never
0= Not Applicable/Unable to Assess

1. Demonstrated preparedness to work as a member of team in conducting the site visit.	5	4	3	2	1	0
2. Demonstrated introductory knowledge of CHAP standards specific to the site visit.	5	4	3	2	1	0
3. Accurately interpreted and applied State and Federal Regulatory requirements specific to the site visit.	5	4	3	2	1	0
4. Demonstrated accuracy, appropriateness and objectivity in collecting, clarifying, quantifying, interpreting, and reporting data.	5	4	3	2	1	0
5. Used appropriate decision making processes.	5	4	3	2	1	0
6. Developed relationships with co-team members and agency staff that facilitated the site visit process.	5	4	3	2	1	0
7. Carried out responsibilities related to the site visit in an organized and professional manner	5	4	3	2	1	0
8. Demonstrated effective time management skills.	5	4	3	2	1	0
9. Was a professional role model for CHAP.	5	4	3	2	1	0
10. Employed effective interpersonal skills when dealing with patients, families, staff, and administrative personnel.	5	4	3	2	1	0
11. Articulated findings in a clear, succinct and professional manner.	5	4	3	2	1	0
12. Provided valuable consultation to staff and administrative personnel.	5	4	3	2	1	0

Strengths:_____

Goals: _____

Cleared for Independent Site Visits: ☐ **Yes** ☐ **No**

Service Director Signature and Date: _____

Site Visitor Signature and Date _____

CHAP

Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800 Washington, DC 20005

Performance Evaluation For Site Visitors

- ✓ **Self Evaluation**
- ✓ **90 Day Evaluation**
- ✓ **Annual Evaluation**
- ✓ **Interim Evaluation**

CHAP PERFORMANCE MANAGEMENT AND EMPLOYEE DEVELOPMENT PROGRAM

The primary objective of CHAP's Performance Management Program is to improve future performance – align resources, increase skills, provide support and encouragement, and challenge ourselves to stretch. This program is a tool for both supervisors and employees to periodically develop goals and objectives, identify strengths, recognize achievement, and define training or improvement plans for areas requiring development. The program is designed to communicate performance expectations across the organization and provide opportunity for employees to achieve their goals. This is accomplished through a process that includes the following:

Performance Planning (ongoing):	Managing Daily Performance (ongoing):	Performance Summary:
• expected results • expected behaviors • individual development planning	• constructive feedback • coaching • recognition • removing obstacles • discipline when necessary • documentation	• to be done for the following review periods (first 90 days and annually): • documentation by employee and supervisor • discuss results and behaviors used to achieve results

PERFORMANCE SUMMARY

Step 1. Each employee prepares a self-assessment by completing an annual Performance Summary document and submits to his/her supervisor.

Step 2. The manager reviews the self-assessment that the employee submits and then completes an annual Performance Summary document.

Step 3. The employee and manager jointly review performance, ensuring all relevant information is considered. Any agreed upon changes should be made on the Performance Summary, which is the official document.

Step 4. The supervisor submits the Performance Summary to the Chief Operating Officer who will forward to HR.

Step 5. Merit increases, based on performance, economics and company factors will go in effect once approved by the Chief Operating Officer.

MEASURES

Measures are an important component of performance management. Measures not only provide information, they influence performance. The company has developed performance criteria for all positions to measure employee performance. The company recognizes that how an employee accomplishes tasks is as important as the results. The company has identified the following five competency areas that are critical to our success. Each employee's performance is measured relative to each of these:

- Customer Satisfaction (both internal and external)
- Job Acumen
- Results
- Team Success
- Professional Development (of self and others)

In addition, we have identified management competencies that are paramount to the individual and company's success that will be evaluated. You and your supervisor jointly will set annual goals which will also be evaluated.

SUPPORTING CHAP OBJECTIVES

Each of the five core competencies helps support our overall Company Mission. Additionally, they also support the key objectives that CHAP is focused on which include:

- Quality
- Customer Satisfaction
- Financial Success
- People Success
- Growth

CHAP

Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800 Washington, DC 20005

Performance Evaluation For Site Visitors

Type of Review: Choose an item.

			Employment Status
Employee:	Click here to enter text.		Choose an item.
Job Title:	**Site Visitor**		Type of Review
Supervisor:	Click here to enter text.		Choose an item.
Period of Performance:	Starting Date	Ending Date	Next Review Date:
	Click here to enter a date.	Click here to enter a date.	Click here to enter a date.

The following rating definitions are to be used when valuating performance in the core competencies. Please carefully read each definition and fairly use the following to complete your assessment.

LEVEL OF PERFORMANCE	RATING
Exceptional: Employee's results and behaviours are extraordinary in all key areas relative to requirements and expectations and in comparison to the results of other top performers. This rating is used as recognition for those who are proactive, take initiative, and have accomplished tasks and/or projects that have significant impact on the organization. The individual has taken responsibility for ensuring that goals were achieved when, otherwise, they may not have been attained. This individual is a role model for others.	E
Commendable: Frequently exceeds established departmental performance expectations. Often excels in demonstrating the knowledge, skills and abilities that result in the effective performance of the position requirements. This individual regularly takes responsibility for ensuring goals were achieved and continually improves his/her performance and models appropriate behaviors for other team members.	C
Solid: Employee's results and behaviors consistently meet expectations in all key areas. The individual has reliably contributed to the agency's outcomes and to the overall effectiveness of the branch/department by applying the skills necessary to complete assigned tasks. The individual strives to continually improve his/her own performance and the performance of the team. This individual is a valued member of the organization.	S
Needs Improvement: Some aspects of the employee's performance, within their ability to influence or control, did not meet requirements and expectations. This rating describes performance that needs improvement and guidance, coaching, and/or corrective action planning in order for the employee to meet or exceed the agency's expectations in the future.	N
Unacceptable: The individual has demonstrated little or no contribution to team, branch, department and/or organizational goals and has failed to meet assigned tasks. Requires a Performance Improvement Plan w/ 30-60 day plan of correction.	U

SECTION I - OVERALL PERFORMANCE OBJECTIVES & RESULTS - Consider the accomplishments achieved throughout the performance period and document what was accomplished and how well it was accomplished.

Customer Satisfaction	Rating
• Takes initiative to meet agency needs • Responds to internal and external requests in a timely manner • Proactively recognizes potential problems and takes action to resolve them • Is recognized positively by internal and external customers	Select Rating
Evaluation of Achievement	

Job Acumen	Rating
• Performs all essential functions of the job accurately • Develops and maintains expert level of knowledge about Standards of Excellence • Develops and maintains expert level of knowledge about CMS Conditions of Participation and/or Quality and Supplier standards • Interprets and analyzes standards and evidence consistently and accurately • Provides applicant and accredited organization education on performance improvement	Select Rating
Evaluation of Achievement	

Results	Rating
• Submits required Site Visit documentation within 2 Business days • CARES documentation is accurate and complete. Includes a Summary and Accreditation Recommendation and as per documentation guidelines, organization strengths and challenges • Site visits are conducted effectively • Evidence is fact based and relevant • Written documentation is clear and substantiates cited evidence • CMS documents are complete and accurate	Select Rating
Evaluation of Achievement	

Team Success	Rating
• Builds positive relationships and team morale • Asks for and offers help • Sets a good example and motivates others • Coordinates and collaborates with all team members • Provides updated license, as required, and consulting detail timely • Actively avoids any appearance of Conflict of Interest	Select Rating
Evaluation of Achievement	

Professional Development	Rating
• Takes the initiative to share professional knowledge and information with others • Formally or informally mentors other employees • Seeks out opportunities to improve expertise (i.e., keep up to date w/ regulations, read books/trade magazines, etc., attend training, seminars, meetings) • Attends and participates in CHAP teleconferences and Mandatory Meetings • Meets requirement for 8 hours of continuing education in addition to attending CHAP annual meeting for 20 hours of education	Select Rating
Evaluation of Achievement	

SECTION II - COMPETENCIES AND MANAGEMENT SKILLS - Evaluate the extent to which competencies and/or management skills were demonstrated in achieving desired results.

Competencies			
Accepting Supervision	Select Rating	Meeting Schedules and Deadlines	Select Rating
Accuracy	Select Rating	Motivating Others	Select Rating
Attention to Detail	Select Rating	Planning and Organizing	Select Rating
Authority and Presence	Select Rating	Positive Attitude	Select Rating
Business Acumen	Select Rating	Problem Solving and Innovation	Select Rating
Clear Written and Verbal Communication	Select Rating	Professionally Represents CHAP	Select Rating
Conducting Entrance/Exit Conferences	Select Rating	Providing Constructive Feedback	Select Rating
Dependability	Select Rating	Quality of Work	Select Rating
Development/Mentoring	Select Rating	Recognizing Performance	Select Rating
Flexibility and Adaptability	Select Rating	Supporting Organizational Goals	Select Rating
Integrity	Select Rating	Taking Initiative	Select Rating
Judgment / Decision Making	Select Rating	Team Building	Select Rating
Leadership	Select Rating	Treating Others With Respect	Select Rating
Managing Change	Select Rating	Working Independently	Select Rating

Fill in the number of times the individual received each rating.

Exceptional	*Commendable*	*Solid*	*Needs Improvement*	*Unacceptable*	*Total*

SECTION III – GOAL ACCOMPLISHMENT and PROFESSIONAL DEVELOPMENT- Evaluate the extent to which specific annual goals and professional development for the evaluation period were accomplished. Next, set goals and identify areas of professional development for the upcoming year and describe the action plan for meeting those goals and any resources needed to support professional development.

GOAL ACCOMPLISHMENTS		
Goals For Past Year	Evaluation of Achievement	Rating
		Select Rating
		Select Rating
		Select Rating

GOAL DEVELOPMENT	
Goals For Upcoming Year	Action Plan

SECTION V - EVALUATION & SIGNATURES – Considering accomplishment of objectives set during the performance period and contribution to organizational results, evaluate the overall performance of the individual being reviewed.

EVALUATION SUMMARY		
Please transfer your ratings to the left side and then choose the overall ratings on the right side by checking the appropriate box.		
EVALUATION COMPONENTS		OVERALL EVALUATION
Customer Satisfaction	Select Rating	Select Rating
Job Acumen	Select Rating	
Results	Select Rating	
Team Success	Select Rating	
Professional Development	Select Rating	
Competencies	Select Rating	
Goal Accomplishment	Select Rating	

SIGNATURES	
The original signed and dated Annual Review is to be forwarded by the Supervisor to HR for signatures and then placement in the employee's personnel file.	
Employee: (all reviews)	*Date:*
Supervisor: (all reviews)	*Date:*
Chief Operating Officer: (annual review only)	*Date:*
Human Resources: (annual review only)	*Date:*

EMPLOYEE COMMENTS (optional)

Our Mission is to provide leadership for enhancing the health and well being of diverse communities.
Thank you for being a part of our team and assisting to further our mission.
Your efforts directly impact the success of CHAP!

New -- Det Norske Veritas (DNV)

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.

SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.

SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.

SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.

SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
    - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
    - *All non-controlled substances are to be locked when a patient care area is not staffed.*
    - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
    - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
    - *Labeling of medications*
    - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
    - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;*
- *Availability of up-to-date medication information;*
- *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;*
- *Avoidance of dangerous abbreviations;*
- *Alert systems for look-like and sound-alike drug names;*
- *Use of facility approved pre-printed order sheets whenever possible.*
- *That orders to "resume previous orders" are prohibited;*
- *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- *The preparation, distribution, administration and proper disposal of hazardous medications;*
- *Drug recalls;*
- *That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- *Identification of when weight-based dosing for pediatric populations is required;*
- *Other relevant performance improvement activities*

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- *Verify the process for ensuring correct patient identification*
- *Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.*
- *Review the process followed when medications are not given on time and what action(s) are taken*

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- *name and strength of the drug;*

- *lot and control number equivalent; and,*
- *expiration date.*

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- *Patient's full name;*
- *the prescriber's name;*
- *strength and quantity of the drug dispensed; and,*
- *appropriate accessory and cautionary statements are included as well as the expiration date .*

Review and verify that medications provided in floor stock include:

- *the name and strength of the drug;*
- *lot and control number of equivalent; and*
- *expiration date.*

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals

Review the transfusions and intravenous medications practices

- *Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices*
    - *Review the course content to ensure that the following information is included at a minimum:*
        - *Fluid and electrolyte balance*
        - *Blood components*
        - *Venipuncture techniques, returned demonstration and supervised practice*

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.

SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- *Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*

- *Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*

- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*

- *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.

SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.

SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.

SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- *Name of patient;*
- *Age and weight of patient, when appropriate;*
- *Date and time of the order;*
- *Drug name;*
- *Dosage form (e.g., tablets, capsules, inhalants);*
- *Exact strength or concentration;*
- *Dose, frequency, and route;*
- *Quantity and/or duration;*
- *Indication for use when appropriate;*
- *Specific instructions for use; and*
- *Name of prescriber.*

Hospitals should establish policies and procedures that:

- *Describe limitations or prohibitions on use of verbal/telephone orders;*
- *Provide a mechanism to ensure validity/authenticity of the prescriber;*
- *List the elements required for inclusion in a complete verbal/telephone order ;*
- *Describe situations in when verbal/telephone orders may be used;*
- *List and define the individuals who may send and receive verbal/telephone orders; and,*
- *Provide guidelines for clear and effective communication of verbal/telephone orders.*

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

SR.1 The practitioner caring for the patient must determine the urgency of administration.

SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.

SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.

SR.4 All high-risk medications in this area shall be segregated and unavailable.

SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:

SR.5a potential drug-drug interactions;
SR.5b potential allergies or cross sensitivities;
SR.5c proper dose ranges; and,
SR.5d proper indications for administration.

SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.

SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- *The practitioner caring for the patient must determine the urgency of administration;*
- *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
- *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*

- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
  - *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
  - *All high-risk medications in this area shall be segregated and unavailable;*
  - *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
    - *potential drug-drug interactions;*
    - *potential allergies or cross sensitivities;*
    - *proper dose ranges, and*
    - *proper indications for administration.*
  - *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
  - *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.

SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.

SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:

SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and

SR.3b is reasonable considering the intended use of the compounded medication; and

SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:

SR.4a Active ingredients to be used.
SR.4b Inactive ingredients to be used.
SR.4c Process and/or procedure used for preparation of the drug product.
SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
SR.4e Post-compounding process or procedures required, as applicable.
SR.4f Dates of expiration/use by dates as required.

Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.

SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.

SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.

SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.

SR.11 For each compounded drug product, the pharmacy records shall include:

SR.11a The master formula record.
SR.11b The date the drug product was compounded.
SR.11c The name of the pharmacy personnel who compounded the drug product.

SR.11d The name of the pharmacist reviewing the final drug product.
SR.11e The quantity of each component used in compounding the drug product.
SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
SR,11g The equipment used in compounding the drug product.
SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
SR.11i The expiration date of the final compounded drug product.
SR.11j The quantity or amount of drug product compounded.

SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.

SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).

SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.

SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:

SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.

SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.

SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.

SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.

SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .

SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.

SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.

SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.

SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.

SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.

SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.

SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:

SR.22a Clean Room and Work Station Requirements.

SR.22b Construction of walls, ceilings and floors.

SR.22c Maintain appropriate ventilation of the preparation area.

SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.

SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.

SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.
SR.24a(2) Monitoring of refrigerator and freezer temperatures.
SR.24a(3) Certification of the sterile compounding environment.
SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).
SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
SR.25b Name and concentrations of ingredients contained in the sterile injectable product.
SR.25c Instructions for storage and handling
SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.
SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
SR.26c Equipment and supplies used.
SR.26d Training of staff regarding the preparation of sterile injectable products.
SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).
SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation
SR.27b Storage and handling of products and supplies.
SR.27c Storage and delivery of final products.
SR.27d Process validation of processes.
SR.27e Personnel access and movement of materials into and near the controlled area.
SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
SR.27j Sterilization.
SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:

SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.

SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.

SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.

SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.

SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.

SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:

SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
SR.30b Clean room attire must be donned and removed outside the designated area.
SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).

SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

SR.32a(1) Use of aseptic preparation technique and procedures.
SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
SR.32a(4) Documentation of Sterile product compounding.
SR.32a(5) Appropriate use of sterilization techniques.
SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
SR.32a(7) Selection of containers, equipment, and closure system.
SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.
SR.34b Storage of compounded sterile injectable products in the Pharmacy
SR.34c Periodic documentation of refrigerator temperatures.
SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.
SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.
SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- *Altering the dosage form or delivery system of a drug*
- *Altering the strength of a drug*
- *Combining components or active ingredients*
- *Combining components or active ingredients*
- *Preparing a drug product from chemicals or bulk drug substances*

""Compounding" does not include:

- *does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.*

- *does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.*

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product:

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

> *ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."*
>
> *ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."*

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- *compounding of drugs*
- *compounding sterile injectable products from one or more non-sterile ingredients*
- *preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.

SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.

SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.

SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.

SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
    - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
    - *All non-controlled substances are to be locked when a patient care area is not staffed.*
    - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
    - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
    - *Labeling of medications*
    - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
    - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;*
- *Availability of up-to-date medication information;*
- *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;*
- *Avoidance of dangerous abbreviations;*
- *Alert systems for look-like and sound-alike drug names;*
- *Use of facility approved pre-printed order sheets whenever possible.*
- *That orders to "resume previous orders" are prohibited;*
- *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- *The preparation, distribution, administration and proper disposal of hazardous medications;*
- *Drug recalls;*
- *That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- *Identification of when weight-based dosing for pediatric populations is required;*
- *Other relevant performance improvement activities*

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- *Verify the process for ensuring correct patient identification*
- *Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.*
- *Review the process followed when medications are not given on time and what action(s) are taken*

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- *name and strength of the drug;*

- *lot and control number equivalent; and,*
- *expiration date.*

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- *Patient's full name;*
- *the prescriber's name;*
- *strength and quantity of the drug dispensed; and,*
- *appropriate accessory and cautionary statements are included as well as the expiration date .*

Review and verify that medications provided in floor stock include:

- *the name and strength of the drug;*
- *lot and control number of equivalent; and*
- *expiration date.*

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals

Review the transfusions and intravenous medications practices

- *Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices*
    - *Review the course content to ensure that the following information is included at a minimum:*
        - *Fluid and electrolyte balance*
        - *Blood components*
        - *Venipuncture techniques, returned demonstration and supervised practice*

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.

SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- *Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*

- *Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*

- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*

- *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.

SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.

SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.

SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- *Name of patient;*
- *Age and weight of patient, when appropriate;*
- *Date and time of the order;*
- *Drug name;*
- *Dosage form (e.g., tablets, capsules, inhalants);*
- *Exact strength or concentration;*
- *Dose, frequency, and route;*
- *Quantity and/or duration;*
- *Indication for use when appropriate;*
- *Specific instructions for use; and*
- *Name of prescriber.*

Hospitals should establish policies and procedures that:

- *Describe limitations or prohibitions on use of verbal/telephone orders;*
- *Provide a mechanism to ensure validity/authenticity of the prescriber;*
- *List the elements required for inclusion in a complete verbal/telephone order ;*
- *Describe situations in when verbal/telephone orders may be used;*
- *List and define the individuals who may send and receive verbal/telephone orders; and,*
- *Provide guidelines for clear and effective communication of verbal/telephone orders.*

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

SR.1 The practitioner caring for the patient must determine the urgency of administration.

SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.

SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.

SR.4 All high-risk medications in this area shall be segregated and unavailable.

SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:

SR.5a potential drug-drug interactions;
SR.5b potential allergies or cross sensitivities;
SR.5c proper dose ranges; and,
SR.5d proper indications for administration.

SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.

SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

  - *The practitioner caring for the patient must determine the urgency of administration;*
  - *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
  - *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*

- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
  - *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
  - *All high-risk medications in this area shall be segregated and unavailable;*
  - *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
    - *potential drug-drug interactions;*
    - *potential allergies or cross sensitivities;*
    - *proper dose ranges, and*
    - *proper indications for administration.*
  - *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
  - *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.

SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.

SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:

SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and

SR.3b is reasonable considering the intended use of the compounded medication; and

SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:

SR.4a Active ingredients to be used.
SR.4b Inactive ingredients to be used.
SR.4c Process and/or procedure used for preparation of the drug product.
SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
SR.4e Post-compounding process or procedures required, as applicable.
SR.4f Dates of expiration/use by dates as required.

Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.

SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.

SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.

SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.

SR.11 For each compounded drug product, the pharmacy records shall include:

SR.11a The master formula record.
SR.11b The date the drug product was compounded.
SR.11c The name of the pharmacy personnel who compounded the drug product.

SR.11d The name of the pharmacist reviewing the final drug product.
SR.11eThe quantity of each component used in compounding the drug product.
SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
SR,11g The equipment used in compounding the drug product.
SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
SR.11i The expiration date of the final compounded drug product.
SR.11j The quantity or amount of drug product compounded.

SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.

SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).

SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.

SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:

SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.

SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.

SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.

SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.

SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .

SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.

SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.

SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.

SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.

SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.

SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.

SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:

SR.22a Clean Room and Work Station Requirements.

SR.22b Construction of walls, ceilings and floors.

SR.22c Maintain appropriate ventilation of the preparation area.

SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.

SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.

SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.
SR.24a(2) Monitoring of refrigerator and freezer temperatures.
SR.24a(3) Certification of the sterile compounding environment.
SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).
SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
SR.25b Name and concentrations of ingredients contained in the sterile injectable product.
SR.25c Instructions for storage and handling
SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.
SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
SR.26c Equipment and supplies used.
SR.26d Training of staff regarding the preparation of sterile injectable products.
SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).
SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation
SR.27b Storage and handling of products and supplies.
SR.27c Storage and delivery of final products.
SR.27d Process validation of processes.
SR.27e Personnel access and movement of materials into and near the controlled area.
SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.

SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..

SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.

SR.27j Sterilization.

SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:

SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.

SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.

SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.

SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.

SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.

SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:

SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.

SR.30b Clean room attire must be donned and removed outside the designated area.

SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).

SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

SR.32a(1) Use of aseptic preparation technique and procedures.
SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
SR.32a(4) Documentation of Sterile product compounding.
SR.32a(5) Appropriate use of sterilization techniques.
SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
SR.32a(7) Selection of containers, equipment, and closure system.
SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.
SR.34b Storage of compounded sterile injectable products in the Pharmacy
SR.34c Periodic documentation of refrigerator temperatures.
SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.
SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.
SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- *Altering the dosage form or delivery system of a drug*
- *Altering the strength of a drug*
- *Combining components or active ingredients*
- *Combining components or active ingredients*
- *Preparing a drug product from chemicals or bulk drug substances*

""Compounding" does not include:

- *does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.*

- *does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.*

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product.

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

> *ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."*
>
> *ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."*

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- *compounding of drugs*
- *compounding sterile injectable products from one or more non-sterile ingredients*
- *preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

DNV: [redacted]

Code	Description	NIAHO℠ Standard
1735 (a)	"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:	IG - Definition
1735 (a)1	Altering the dosage form or delivery system of a drug	IG - Definition
1735 (a)2	Altering the strength of a drug	IG - Definition
1735 (a)3	Combining components or active ingredients	IG - Definition
1735 (a)4	Preparing a drug product from chemicals or bulk drug substances	IG - Definition
1735 (b)	"Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.	IG - Definition
1735 (c)	"Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.	IG - Definition
1735 (d)	The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7(Section 1735 et seq.).	IG - Definition
1735.1 (a)	"Integrity" means retention of potency until the expiration date noted on the label.	IG - Definition
1735.1 (b)	"Potency" means active ingredient strength within +/- 10% of the labeled amount.	IG - Definition
1735.1 (c)	"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.	IG - Definition
1735.1 (d)	"Strength" means amount of active ingredient per unit of a compounded drug product.	IG - Definition

1735.2 (a)	Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.	MM.8 SR.1
1735.2 (b)	A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.	MM.8 SR.2
1735.2 (c)	Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:	MM.8 SR.3
1735.2 (c)1	is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and	MM.8 SR.3a
1735.3 (c)2	is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and	MM.8 SR.3b
1735.2 (c)3	for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.	MM.8 SR.3c
1735.2 (d)	A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:	MM.8 SR.4
1735.2 (d)1	Active ingredients to be used.	MM.8 SR.4a
1735.2 (d)2	Inactive ingredients to be used.	MM.8 SR.4b
1735.2 (d)3	Process and/or procedure used to prepare the drug.	MM.8 SR.4c

1735.2 (d)4	Quality reviews required at each step in preparation of the drug.	MM.8 SR.4d
1735.2 (d)5	Post-compounding process or procedures required, if any.	MM.8 SR.4e
1735.2 (d)6	Expiration dating requirements.	MM.8 SR.4f
1735.2 (e)	Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.	MM.8 SR.11
1735.2 (f)	The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.	MM.8 SR.5
1735.2 (g)	All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.	MM.8 SR.7
1735.2 (h)	Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.	MM.8 SR.8
1735.2 (i)	The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.	MM.8 SR.5

1735.2 (j)	Prior to allowing any drug product to be compounded in a pharmacy, the pharmacistin-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.	MM.8 SR.10
1735.3 (a)	For each compounded drug product, the pharmacy records shall include:	MM.8 SR.11
1735.3 (a)1	The master formula record.	MM.8 SR.11a
1735.3 (a)2	The date the drug product was compounded.	MM.8 SR.11b
1735.3 (a)3	The identity of the pharmacy personnel who compounded the drug product.	MM.8 SR.11c
1735.3 (a)4	The identity of the pharmacist reviewing the final drug product.	MM.8 SR.11d
1735.3 (a)5	The quantity of each component used in compounding the drug product.	MM.8 SR.11e
1735.3 (a)6	The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.	MM.8 SR.11f
1735.3 (a)7	The equipment used in compounding the drug product.	MM.8 SR.11g

1735.3 (a)8	A pharmacy assigned reference or lot number for the compounded drug product.	MM.8 SR.11h
1735.3 (a)9	The expiration date of the final compounded drug product.	MM.8 SR.11i
1735.3 (a)10	The quantity or amount of drug product compounded.	MM.8 SR.11j
1735.3 (b)	Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.	MM.8 SR.12
1735.3 (c)	Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.	MM.8 SR.13
1735.3 (d)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.	MM.8 SR.12
1735.4 (a)	In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).	MM.8 SR.14
1735.4 (b)	A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.	MM.8 SR.15
1735.4 (c)	Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.	MM.8 SR.16

1735.5 (a)	Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.	MM.8 SR.17
1735.5 (b)	The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.	MM.8 SR.17
1735.5 (c)	The policy and procedure manual shall include the following:	MM.8 SR.17
1735.5 (c)1	Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.	MM.8 SR.17a
1735.5 (c)2	Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.	MM.8 SR.17b
1735.5 (c)3	The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.	MM.8 SR.17c
1735.5 (c)4	Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.	MM.8 SR.17d
1735.5 (c)5	Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.	MM.8 SR.17e
1735.6 (a)	Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.	MM.8 SR.18
1735.6 (b)	Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.	MM.8 SR.18a

1735.6 (c)	Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each	MM.8 SR.18b
	such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.	MM.8 SR.18b
1735.7 (a)	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.	MM.8 SR.19
1735.7 (b)	The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.	MM.8 SR.19a
1735.7 (c)	Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product.	MM.8 Sr.19a
1735.8 (a)	Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.	MM.8 SR.20
1735.8 (b)	The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.	MM.8 SR.20a
1735.8 (c)	The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.	MM.8 SR.20b

1735.8 (d)	The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.	MM.8 SR.20c
1751 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.	MM.8 SR.21
1751 (b)	Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:	MM.8 SR.22
1751 (b)1	Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22a
1751 (b)2	Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22b
1751 (b)3	Be ventilated in a manner in accordance with Section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations.	MM.8 SR.22c
1751 (b)4	Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.	MM.8 SR.22d
1751 (b)5	The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.	MM.8 SR.22e

1751 (b)6	A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22f
1751 (b)7	There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.	MM.8 SR.22g
1751 (c)	Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.	MM.8 SR.23
1751.1 (a)	Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.	MM.8 SR.24
1751.1 (b)	In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:	MM.8 SR.24a
1751.1 (b)1	The training and competency evaluation of employees in sterile product procedures.	MM.8 SR.24a(1)
1751.1 (b)2	Refrigerator and freezer temperatures.	MM.8 SR.24a(2)
1751.1 (b)3	Certification of the sterile compounding environment.	MM.8 SR.24a(3)
1751.1 (b)4	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).	MM.8 SR.24a(4)
1751.1 (b)5	Inspection for expired or recalled pharmaceutical products or raw ingredients.	MM.8 SR.24a(5)
1751.1 (b)6	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.	MM.8 SR.24.a(6)
1751.1 (c)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.	MM.8 SR.24

1751.2	In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile products shall include the following information on the labels for those products:	MM.8 SR.25
1751.2 (a)	Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.	MM.8 SR.25a
1751.2 (b)	Name and concentrations of ingredients contained in the sterile injectable product.	MM.8 SR.25b
1751.2 (c)	Instructions for storage and handling.	MM.8 SR.25c
1751.2 (d)	All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly."	MM.8 SR.25d
1751.3 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:	MM.8 SR.26
1751.3 (a)1	Compounding, filling, and labeling of sterile injectable compounds.	MM.8 SR.26a
1751.3 (a)2	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.	MM.8 SR.26b
1751.3 (a)3	Equipment and supplies.	MM.8 SR.26c
1751.3 (a)4	Training of staff in the preparation of sterile injectable products.	MM.8 SR.26d
1751.3 (a)5	Procedures for handling cytotoxic agents.	MM.8 SR.26e
1751.3 (a)6	Quality assurance program.	MM.8 SR.26f
1751.3 (a)7	Record keeping requirements.	MM.8 SR.26
1751.3 (b)	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.	MM.8 SR.1a

1751.3 (c)	Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.	MM.8 SR.27
1751.3 (d)	Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:	MM.8 SR.27
1751.3 (d)1	All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.	MM.8 SR.27
1751.3 (d)2	All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.	MM.8 SR.27
1751.3 (d)3	Policies and procedures must address at least the following:	MM.8 SR.27
1751.3 (d)3(A)	Competency evaluation.	MM.8 SR.27a
1751.3 (d)3(B)	Storage and handling of products and supplies.	MM.8 SR.27b
1751.3 (d)3©	Storage and delivery of final products.	MM.8 SR.27c
1751.3 (d)3(D)	Process validation.	MM.8 SR.27d
1751.3 (d)3(E)	Personnel access and movement of materials into and near the controlled area.	MM.8 SR.27e
1751.3 (d)3(F)	Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).	MM.8 SR.27f
1751.3 (d)3(G)	Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.	MM.8 SR.27g

1751.3 (d)3(H)	Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area..	MM.8 SR.27h
1751.3 (d)3(I)	For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.	MM.8 SR.27i
1751.3 (d)3(J)	Sterilization.	MM.8 SR.27j
1751.3 (d)3(K)	End-product evaluation and testing.	MM.8 SR.27k
1751.4 (a)	No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.	MM.8 SR.23
1751.4 (b)	During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.	MM.8 SR.28a
1751.4 (c)	All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.	MM.8 SR.28b
1751.4 (d)	Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.	MM.8 SR.28c

1751.4 (e)	Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications, Certification records must be retained for at least three years.	MM.8 SR.29
1751.5 (a)	When preparing cytotoxic agents, gowns and gloves shall be worn.	MM.8 SR.30a
1751.5 (b)	When compounding sterile products from one or more non-sterile ingredients the following standards must be met:	MM.8 SR.30
1751.5 (b)1	Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.	MM.8 SR.30a
1751.5 (b)2	Cleanroom garb must be donned and removed outside the designated area.	MM.8 SR.30b
1751.5 (b)3	Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.	MM.8 SR.30c
1751.5 (b)4	Head and facial hair must be kept out of the critical area or be covered.	MM.8 SR.30d
1751.5 (b)5	Gloves made of low-shedding materials are required.	MM.8 SR.30a
1751.5 (c)	The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.	MM.8 SR.30
1751.6 (a)	Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.	MM.8 SR.31

1751.6 (b)	The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.	MM.8 SR.31
1751.6 (c)	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.	MM.8 SR.32
1751.6 (d)	The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.	MM.8 SR.32
1751.6 (e)	Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:	MM.8 SR.32
1751.6 (e)1	The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:	MM.8 SR.32a
1751.6 (e)1(A)	Aseptic technique.	MM.8 SR.32a(1)
1751.6 (e)1(B)	Pharmaceutical calculations and terminology.	MM.8 SR.32a(3)
1751.6 (e)1(C)	Sterile product compounding documentation.	MM.8 SR.32a(4)
1751.6 (e)1(D)	Quality assurance procedures.	MM.8 SR.32a(8)
1751.6 (e)1(E)	Aseptic preparation procedures.	MM.8 SR.32a(1)
1751.6 (e)1(F)	Proper gowning and gloving technique.	MM.8 SR.32a(2)
1751.6 (e)1(G)	General conduct in the controlled area.	MM.8 SR.32a(2)
1751.6 (e)1(H)	Cleaning, sanitizing, and maintaining equipment used in the controlled area.	MM.8 SR.32a(6)
1751.6 (e)1(I)	Sterilization techniques.	MM.8 SR.32a(5)
1751.6 (e)1(J)	Container, equipment, and closure system selection.	MM.8 SR.32a(7)

	Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and	MM.8 SR.32
1751.6 (e)2	continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.	MM.8 SR.32
1751.7 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:	MM.8 SR.32
1751.7 (a)1	Cleaning and sanitization of the parenteral medication preparation area.	MM.8 SR.34a
1751.7 (a)2	The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.	MM.8 SR.34b / SR.34c
1751.7 (a)3	Actions to be taken in the event of a drug recall.	MM.8 SR.34d
1751.7 (a)4	Written justification of the chosen expiration dates for compounded sterile injectable products.	MM.8 SR.34e

1751.7 (b)	Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a mar	MM.8 SR.32
1751.7 (c)	Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.	MM.8 SR.34f(1)
1751.7 (d)	Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.	MM.8 34f(2)
1751.8	In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.	MM.8 SR.28d

1760	In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/2001 10/2007), which are hereby incorporated by reference.	As Determined by California State Board of Pharmacy
	Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.	As Determined by California State Board of Pharmacy
1773 (a)	Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:	As Determined by California State Board of Pharmacy
1773 (a)1	Obey all laws and regulations substantially related to the practice of Pharmacy;	As Determined by California State Board of Pharmacy
1773 (a)2	Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;	As Determined by California State Board of Pharmacy
1773 (a)3	Submit to peer review if deemed necessary by the Board;	As Determined by California State Board of Pharmacy
1773 (a)4	Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;	As Determined by California State Board of Pharmacy
1773 (a)5	Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.	As Determined by California State Board of Pharmacy
1773 (a)6	Not supervise any registered interns nor perform any of the duties of a preceptor;	As Determined by California State Board of Pharmacy
1773 (a)7	The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.	As Determined by California State Board of Pharmacy

1773 (b)	If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;	As Determined by California State Board of Pharmacy
1773 (b)1	Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)2	Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)3	Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)4	If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.	As Determined by California State Board of Pharmacy
1773 (b)5	Complete an ethics course that meets the requirements of section 1773.5	As Determined by California State Board of Pharmacy
1773 (c)	When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.	As Determined by California State Board of Pharmacy
1773.5	When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.	As Determined by California State Board of Pharmacy

1773.5 (a)	The board will consider for approval an ethics course that at minimum satisfies the following requirements:	As Determined by California State Board of Pharmacy
1773.5 (a)1	Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.	As Determined by California State Board of Pharmacy
1773.5 (a)2	Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.	As Determined by California State Board of Pharmacy
1773.5 (a)3	Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.	As Determined by California State Board of Pharmacy
1773.5 (a)4	Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.	As Determined by California State Board of Pharmacy
1773.5 (a)5	Content. The course shall contain all of the following components:	As Determined by California State Board of Pharmacy
1773.5 (a)5(A)	A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.	As Determined by California State Board of Pharmacy
1773.5 (a)5(B)	A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.	As Determined by California State Board of Pharmacy
1773.5 (a)5(C)	An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.	As Determined by California State Board of Pharmacy
1773.5 (a)5(D)	Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.	As Determined by California State Board of Pharmacy

1773.5 (a)5(E)	Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.	As Determined by California State Board of Pharmacy
1773.5 (a)5(F)	A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.	As Determined by California State Board of Pharmacy
1773.5 (a)6	Class Size. A class shall not exceed a maximum of 12 participants.	As Determined by California State Board of Pharmacy
1773.5 (a)7	Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.	As Determined by California State Board of Pharmacy
1773.5 (a)8	Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.	As Determined by California State Board of Pharmacy
1773.5 (a)9	Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.	As Determined by California State Board of Pharmacy

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.

SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.

SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.

SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.

SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
- *the orders of the practitioner or practitioners responsible for the patient's care; and*
- *accepted standards of practice.*

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be

an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
    - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
    - *All non-controlled substances are to be locked when a patient care area is not staffed.*
    - *When not operational the operating use would not be considered secure and all drugs and biologicals are expected to be locked.*

Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the hospital will authorize the patient to have access to these medications. Such non-controlled medications may include (i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions, creams and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
    - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
    - *Labeling of medications*
    - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;*
    - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*

- *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;*
- *Availability of up-to-date medication information;*
- *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;*
- *Avoidance of dangerous abbreviations;*
- *Alert systems for look-like and sound-alike drug names;*
- *Use of facility approved pre-printed order sheets whenever possible.*
- *That orders to "resume previous orders" are prohibited;*
- *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- *The preparation, distribution, administration and proper disposal of hazardous medications;*
- *Drug recalls;*
- *That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- *Identification of when weight-based dosing for pediatric populations is required;*
- *Other relevant performance improvement activities*

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time, or part-time employee or employed on a consultative basis.

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

In a sampling of patient records, review and verify their medication orders (and the ordering process), medication administration records, and appropriate medication documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Review sample of medication administration records (MARs) to verify that they conform with practitioner's orders, the order is current and that the drug and dosage are correct and administered as ordered.

- *Verify the process for ensuring correct patient identification*
- *Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.*
- *Review the process followed when medications are not given on time and what action(s) are taken*

Verify that the hospital maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws..

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- *name and strength of the drug;*

- *lot and control number equivalent; and,*
- *expiration date.*

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

Verify the process for patient identification.

Review and verify that the labels of individual medications conform to State laws.

Review and verify that medications prescribed for a patient include:

- *Patient's full name;*
- *the prescriber's name;*
- *strength and quantity of the drug dispensed; and,*
- *appropriate accessory and cautionary statements are included as well as the expiration date .*

Review and verify that medications provided in floor stock include:

- *the name and strength of the drug;*
- *lot and control number of equivalent; and*
- *expiration date.*

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals

Review the transfusions and intravenous medications practices

- *Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices*
    - *Review the course content to ensure that the following information is included at a minimum:*
        - *Fluid and electrolyte balance*
        - *Blood components*
        - *Venipuncture techniques, returned demonstration and supervised practice*

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.

SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*

- *Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*

- *Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*

- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*

- *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.

SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.

SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.

SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

Interpretive Guidelines:

Elements that are to be included in any medication order (including all written, and verbal/telephone orders):

- *Name of patient;*
- *Age and weight of patient, when appropriate;*
- *Date and time of the order;*
- *Drug name;*
- *Dosage form (e.g., tablets, capsules, inhalants);*
- *Exact strength or concentration;*
- *Dose, frequency, and route;*
- *Quantity and/or duration;*
- *Indication for use when appropriate;*
- *Specific instructions for use; and*
- *Name of prescriber.*

Hospitals should establish policies and procedures that:

- *Describe limitations or prohibitions on use of verbal/telephone orders;*
- *Provide a mechanism to ensure validity/authenticity of the prescriber;*
- *List the elements required for inclusion in a complete verbal/telephone order ;*
- *Describe situations in when verbal/telephone orders may be used;*
- *List and define the individuals who may send and receive verbal/telephone orders; and,*
- *Provide guidelines for clear and effective communication of verbal/telephone orders.*

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within 48 hours.

Verify there process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

SR.1 The practitioner caring for the patient must determine the urgency of administration.

SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.

SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.

SR.4 All high-risk medications in this area shall be segregated and unavailable.

SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:

SR.5a potential drug-drug interactions;
SR.5b potential allergies or cross sensitivities;
SR.5c proper dose ranges; and,
SR.5d proper indications for administration.

SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.

SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*

- *Other contraindications*

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

  - *The practitioner caring for the patient must determine the urgency of administration;*
  - *The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law;*
  - *The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*

- *The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*
- *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
  - *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
  - *All high-risk medications in this area shall be segregated and unavailable;*
  - *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
    - *potential drug-drug interactions;*
    - *potential allergies or cross sensitivities;*
    - *proper dose ranges, and*
    - *proper indications for administration.*
  - *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
  - *The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

1. *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
2. *Physical signs and clinical symptoms relevant to the patient's medication therapy;*
3. *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.

SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

MS.8 STERILE COMPOUNDING (OPTIONAL)

(If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements are required to be met. The purpose these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.)

SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.

SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.

SR.3 A "reasonable quantity" of compounded drug product may be furnished to a to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where "reasonable quantity" is that amount of compounded drug product that:

SR.3a is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and

SR.3b is reasonable considering the intended use of the compounded medication; and

SR.3c for any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:

SR.4a Active ingredients to be used.
SR.4b Inactive ingredients to be used.
SR.4c Process and/or procedure used for preparation of the drug product.
SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.
SR.4e Post-compounding process or procedures required, as applicable.
SR.4f Dates of expiration/use by dates as required.

Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.

SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

SR.7 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.

SR.8 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "use by date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.

SR.10 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.

SR.11 For each compounded drug product, the pharmacy records shall include:

SR.11a The master formula record.
SR.11b The date the drug product was compounded.
SR.11c The name of the pharmacy personnel who compounded the drug product.

SR.11d The name of the pharmacist reviewing the final drug product.
SR.11eThe quantity of each component used in compounding the drug product.
SR.11f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from the requirements in this section are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
SR,11g The equipment used in compounding the drug product.
SR.11h A Pharmacy assigned reference or lot number for the compounded drug product.
SR.11i The expiration date of the final compounded drug product.
SR.11j The quantity or amount of drug product compounded.

SR.12 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three (3) years from the date the record was created or as otherwise required by State law/regulation.

SR.13 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).

SR.14 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

SR.15 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.

SR.16 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in the requirements of this section shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.

SR.17 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. The policy and procedure manual shall include the following:

SR.17a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.

SR.17b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

SR.17c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.

SR.17d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

SR.17e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

SR.18 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

SR.18a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.

SR.18b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.

SR.19 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products .

SR.19a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.

SR.20 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.

SR.20a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.

SR.20b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.

SR.20c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.

SR.21 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.

SR.22 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:

SR.22a Clean Room and Work Station Requirements.

SR.22b Construction of walls, ceilings and floors.

SR.22c Maintain appropriate ventilation of the preparation area.

SR.22d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.

SR.22e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

SR.22f A sink shall be in place and maintained within the compounding area of the Pharmacy.

SR.22g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.)

SR.23 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.

SR.24 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.

SR.24a for sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:

SR.24a(1) Training and competency evaluation of employees in sterile product procedures.
SR.24a(2) Monitoring of refrigerator and freezer temperatures.
SR.24a(3) Certification of the sterile compounding environment.
SR.24a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).
SR.24a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
SR.24a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

SR.25 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

SR.25a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
SR.25b Name and concentrations of ingredients contained in the sterile injectable product.
SR.25c Instructions for storage and handling
SR.25d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."

SR.26 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:

SR.26a Compounding, filling, and labeling of sterile injectable compounds.
SR.26b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
SR.26c Equipment and supplies used.
SR.26d Training of staff regarding the preparation of sterile injectable products.
SR.26e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).
SR.26f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products

SR.27 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:

SR.27a Competency evaluation
SR.27b Storage and handling of products and supplies.
SR.27c Storage and delivery of final products.
SR.27d Process validation of processes.
SR.27e Personnel access and movement of materials into and near the controlled area.
SR.27f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).

SR.27g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
SR.27h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
SR.27i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
SR.27j Sterilization.
SR.27k End-product evaluation and testing.

(Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested).

SR.28 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:

SR.28a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.

SR.28b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.

SR.28c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.

SR.28d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.

SR.29 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.

SR.30 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:

SR.30a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
SR.30b Clean room attire must be donned and removed outside the designated area.
SR.30c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
SR.30d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).

SR.31 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

SR.32 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.32a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

SR.32a(1) Use of aseptic preparation technique and procedures.
SR.32a(2) Appropriate use of personal protective attire and conduct in the controlled area.
SR.32a(3) Accuracy of pharmaceutical calculations and terminology.
SR.32a(4) Documentation of Sterile product compounding.
SR.32a(5) Appropriate use of sterilization techniques.
SR.32a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
SR.32a(7) Selection of containers, equipment, and closure system.
SR.32a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed.. Documentation of individual competency shall documented and retained in the Pharmacy for three (3) years.

SR.33 The Pharmacy shall have a process in place to the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.

SR.33a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.

SR.33b The same personnel, procedures, equipment, and materials are must be involved.

SR.34 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:

SR.34a Cleaning and sanitization of the parenteral medication preparation area.
SR.34b Storage of compounded sterile injectable products in the Pharmacy
SR.34c Periodic documentation of refrigerator temperatures.
SR.34d Corrective/Preventive actions to be taken in the event of a drug recall.
SR.34e Written justification of the indicated expiration dates for compounded sterile injectable products.
SR.34f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.34f(1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.34f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- *Altering the dosage form or delivery system of a drug*
- *Altering the strength of a drug*
- *Combining components or active ingredients*
- *Combining components or active ingredients*
- *Preparing a drug product from chemicals or bulk drug substances*

""Compounding" does not include:

- *does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.*

- *does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.*

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product.

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is 16 determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

Clean room: is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

> *ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."*
>
> *ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."*

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy

Verify that compounded drug products are only available in quantities as is necessary to ensure continuity of care for an identified population of patients

Validate there is a process in place for the supervision compounding is in place to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure there a written master formula record has been prepared

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding is maintained.

Review the written policies and procedures for:

- *compounding of drugs*
- *compounding sterile injectable products from one or more non-sterile ingredients*
- *preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products

Assess the designated area for the preparation of sterile injectable products

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

Code	Description	NIAHO℠ Standard
1735 (a)	"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:	IG - Definition
1735 (a)1	Altering the dosage form or delivery system of a drug	IG - Definition
1735 (a)2	Altering the strength of a drug	IG - Definition
1735 (a)3	Combining components or active ingredients	IG - Definition
1735 (a)4	Preparing a drug product from chemicals or bulk drug substances	IG - Definition
1735 (b)	"Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.	IG - Definition
1735 (c)	"Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.	IG - Definition
1735 (d)	The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7(Section 1735 et seq.).	IG - Definition
1735.1 (a)	"Integrity" means retention of potency until the expiration date noted on the label.	IG - Definition
1735.1 (b)	"Potency" means active ingredient strength within +/- 10% of the labeled amount.	IG - Definition
1735.1 (c)	"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.	IG - Definition
1735.1 (d)	"Strength" means amount of active ingredient per unit of a compounded drug product.	IG - Definition

1735.2 (a)	Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.	MM.8 SR.1
1735.2 (b)	A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.	MM.8 SR.2
1735.2 (c)	Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:	MM.8 SR.3
1735.2 (c)1	is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and	MM.8 SR.3a
1735.3 (c)2	is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and	MM.8 SR.3b
1735.2 (c)3	for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.	MM.8 SR.3c
1735.2 (d)	A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:	MM.8 SR.4
1735.2 (d)1	Active ingredients to be used.	MM.8 SR.4a
1735.2 (d)2	Inactive ingredients to be used.	MM.8 SR.4b
1735.2 (d)3	Process and/or procedure used to prepare the drug.	MM.8 SR.4c

1735.2 (d)4	Quality reviews required at each step in preparation of the drug.	MM.8 SR.4d
1735.2 (d)5	Post-compounding process or procedures required, if any.	MM.8 SR.4e
1735.2 (d)6	Expiration dating requirements.	MM.8 SR.4f
1735.2 (e)	Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.	MM.8 SR.11
1735.2 (f)	The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.	MM.8 SR.5
1735.2 (g)	All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.	MM.8 SR.7
1735.2 (h)	Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.	MM.8 SR.8
1735.2 (i)	The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.	MM.8 SR.5

1735.2 (j)	Prior to allowing any drug product to be compounded in a pharmacy, the pharmacistin-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.	MM.8 SR.10
1735.3 (a)	For each compounded drug product, the pharmacy records shall include:	MM.8 SR.11
1735.3 (a)1	The master formula record.	MM.8 SR.11a
1735.3 (a)2	The date the drug product was compounded.	MM.8 SR.11b
1735.3 (a)3	The identity of the pharmacy personnel who compounded the drug product.	MM.8 SR.11c
1735.3 (a)4	The identity of the pharmacist reviewing the final drug product.	MM.8 SR.11d
1735.3 (a)5	The quantity of each component used in compounding the drug product.	MM.8 SR.11e
1735.3 (a)6	The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.	MM.8 SR.11f
1735.3 (a)7	The equipment used in compounding the drug product.	MM.8 SR.11g

1735.3 (a)8	A pharmacy assigned reference or lot number for the compounded drug product.	MM.8 SR.11h
1735.3 (a)9	The expiration date of the final compounded drug product.	MM.8 SR.11i
1735.3 (a)10	The quantity or amount of drug product compounded.	MM.8 SR.11j
1735.3 (b)	Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.	MM.8 SR.12
1735.3 (c)	Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.	MM.8 SR.13
1735.3 (d)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.	MM.8 SR.12
1735.4 (a)	In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).	MM.8 SR.14
1735.4 (b)	A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.	MM.8 SR.15
1735.4 (c)	Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.	MM.8 SR.16

1735.5 (a)	Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.	MM.8 SR.17
1735.5 (b)	The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.	MM.8 SR.17
1735.5 (c)	The policy and procedure manual shall include the following:	MM.8 SR.17
1735.5 (c)1	Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.	MM.8 SR.17a
1735.5 (c)2	Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.	MM.8 SR.17b
1735.5 (c)3	The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.	MM.8 SR.17c
1735.5 (c)4	Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.	MM.8 SR.17d
1735.5 (c)5	Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.	MM.8 SR.17e
1735.6 (a)	Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.	MM.8 SR.18
1735.6 (b)	Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.	MM.8 SR.18a

1735.6 (c)	Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each	MM.8 SR.18b
	such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.	MM.8 SR.18b
1735.7 (a)	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.	MM.8 SR.19
1735.7 (b)	The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.	MM.8 SR.19a
1735.7 (c)	Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product.	MM.8 Sr.19a
1735.8 (a)	Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.	MM.8 SR.20
1735.8 (b)	The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.	MM.8 SR.20a
1735.8 (c)	The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.	MM.8 SR.20b

1735.8 (d)	The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.	MM.8 SR.20c
1751 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.	MM.8 SR.21
1751 (b)	Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:	MM.8 SR.22
1751 (b)1	Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22a
1751 (b)2	Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22b
1751 (b)3	Be ventilated in a manner in accordance with Section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations.	MM.8 SR.22c
1751 (b)4	Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.	MM.8 SR.22d
1751 (b)5	The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.	MM.8 SR.22e

1751 (b)6	A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations.	MM.8 SR.22f
1751 (b)7	There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.	MM.8 SR.22g
1751 (c)	Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.	MM.8 SR.23
1751.1 (a)	Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.	MM.8 SR.24
1751.1 (b)	In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:	MM.8 SR.24a
1751.1 (b)1	The training and competency evaluation of employees in sterile product procedures.	MM.8 SR.24a(1)
1751.1 (b)2	Refrigerator and freezer temperatures.	MM.8 SR.24a(2)
1751.1 (b)3	Certification of the sterile compounding environment.	MM.8 SR.24a(3)
1751.1 (b)4	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).	MM.8 SR.24a(4)
1751.1 (b)5	Inspection for expired or recalled pharmaceutical products or raw ingredients.	MM.8 SR.24a(5)
1751.1 (b)6	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.	MM.8 SR.24.a(6)
1751.1 (c)	Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.	MM.8 SR.24

1751.2	In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile products shall include the following information on the labels for those products:	MM.8 SR.25
1751.2 (a)	Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.	MM.8 SR.25a
1751.2 (b)	Name and concentrations of ingredients contained in the sterile injectable product.	MM.8 SR.25b
1751.2 (c)	Instructions for storage and handling.	MM.8 SR.25c
1751.2 (d)	All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly."	MM.8 SR.25d
1751.3 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:	MM.8 SR.26
1751.3 (a)1	Compounding, filling, and labeling of sterile injectable compounds.	MM.8 SR.26a
1751.3 (a)2	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.	MM.8 SR.26b
1751.3 (a)3	Equipment and supplies.	MM.8 SR.26c
1751.3 (a)4	Training of staff in the preparation of sterile injectable products.	MM.8 SR.26d
1751.3 (a)5	Procedures for handling cytotoxic agents.	MM.8 SR.26e
1751.3 (a)6	Quality assurance program.	MM.8 SR.26f
1751.3 (a)7	Record keeping requirements.	MM.8 SR.26
1751.3 (b)	The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.	MM.8 SR.1a

1751.3 (c)	Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.	MM.8 SR.27
1751.3 (d)	Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:	MM.8 SR.27
1751.3 (d)1	All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.	MM.8 SR.27
1751.3 (d)2	All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.	MM.8 SR.27
1751.3 (d)3	Policies and procedures must address at least the following:	MM.8 SR.27
1751.3 (d)3(A)	Competency evaluation.	MM.8 SR.27a
1751.3 (d)3(B)	Storage and handling of products and supplies.	MM.8 SR.27b
1751.3 (d)3©	Storage and delivery of final products.	MM.8 SR.27c
1751.3 (d)3(D)	Process validation.	MM.8 SR.27d
1751.3 (d)3(E)	Personnel access and movement of materials into and near the controlled area.	MM.8 SR.27e
1751.3 (d)3(F)	Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).	MM.8 SR.27f
1751.3 (d)3(G)	Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.	MM.8 SR.27g

1751.3 (d)3(H)	Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area..	MM.8 SR.27h
1751.3 (d)3(I)	For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.	MM.8 SR.27i
1751.3 (d)3(J)	Sterilization.	MM.8 SR.27j
1751.3 (d)3(K)	End-product evaluation and testing.	MM.8 SR.27k
1751.4 (a)	No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.	MM.8 SR.23
1751.4 (b)	During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.	MM.8 SR.28a
1751.4 (c)	All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.	MM.8 SR.28b
1751.4 (d)	Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.	MM.8 SR.28c

1751.4 (e)	Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications, Certification records must be retained for at least three years.	MM.8 SR.29
1751.5 (a)	When preparing cytotoxic agents, gowns and gloves shall be worn.	MM.8 SR.30a
1751.5 (b)	When compounding sterile products from one or more non-sterile ingredients the following standards must be met:	MM.8 SR.30
1751.5 (b)1	Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.	MM.8 SR.30a
1751.5 (b)2	Cleanroom garb must be donned and removed outside the designated area.	MM.8 SR.30b
1751.5 (b)3	Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.	MM.8 SR.30c
1751.5 (b)4	Head and facial hair must be kept out of the critical area or be covered.	MM.8 SR.30d
1751.5 (b)5	Gloves made of low-shedding materials are required.	MM.8 SR.30a
1751.5 (c)	The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.	MM.8 SR.30
1751.6 (a)	Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.	MM.8 SR.31

1751.6 (b)	The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.	MM.8 SR.31
1751.6 (c)	Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.	MM.8 SR.32
1751.6 (d)	The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.	MM.8 SR.32
1751.6 (e)	Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:	MM.8 SR.32
1751.6 (e)1	The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:	MM.8 SR.32a
1751.6 (e)1(A)	Aseptic technique.	MM.8 SR.32a(1)
1751.6 (e)1(B)	Pharmaceutical calculations and terminology.	MM.8 SR.32a(3)
1751.6 (e)1(C)	Sterile product compounding documentation.	MM.8 SR.32a(4)
1751.6 (e)1(D)	Quality assurance procedures.	MM.8 SR.32a(8)
1751.6 (e)1(E)	Aseptic preparation procedures.	MM.8 SR.32a(1)
1751.6 (e)1(F)	Proper gowning and gloving technique.	MM.8 SR.32a(2)
1751.6 (e)1(G)	General conduct in the controlled area.	MM.8 SR.32a(2)
1751.6 (e)1(H)	Cleaning, sanitizing, and maintaining equipment used in the controlled area.	MM.8 SR.32a(6)
1751.6 (e)1(I)	Sterilization techniques.	MM.8 SR.32a(5)
1751.6 (e)1(J)	Container, equipment, and closure system selection.	MM.8 SR.32a(7)

	Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and	MM.8 SR.32
1751.6 (e)2	continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.	MM.8 SR.32
1751.7 (a)	Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:	MM.8 SR.32
1751.7 (a)1	Cleaning and sanitization of the parenteral medication preparation area.	MM.8 SR.34a
1751.7 (a)2	The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.	MM.8 SR.34b / SR.34c
1751.7 (a)3	Actions to be taken in the event of a drug recall.	MM.8 SR.34d
1751.7 (a)4	Written justification of the chosen expiration dates for compounded sterile injectable products.	MM.8 SR.34e

1751.7 (b)	Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a mar	MM.8 SR.32
1751.7 (c)	Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.	MM.8 SR.34f(1)
1751.7 (d)	Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.	MM.8 34f(2)
1751.8	In any pharmacy engaged in compounding sterile injectable drug products, there shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.	MM.8 SR.28d

1760	In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/2001 10/2007), which are hereby incorporated by reference.	As Determined by California State Board of Pharmacy
	Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.	As Determined by California State Board of Pharmacy
1773 (a)	Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:	As Determined by California State Board of Pharmacy
1773 (a)1	Obey all laws and regulations substantially related to the practice of Pharmacy;	As Determined by California State Board of Pharmacy
1773 (a)2	Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;	As Determined by California State Board of Pharmacy
1773 (a)3	Submit to peer review if deemed necessary by the Board;	As Determined by California State Board of Pharmacy
1773 (a)4	Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;	As Determined by California State Board of Pharmacy
1773 (a)5	Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.	As Determined by California State Board of Pharmacy
1773 (a)6	Not supervise any registered interns nor perform any of the duties of a preceptor;	As Determined by California State Board of Pharmacy
1773 (a)7	The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.	As Determined by California State Board of Pharmacy

1773 (b)	If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;	As Determined by California State Board of Pharmacy
1773 (b)1	Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)2	Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)3	Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;	As Determined by California State Board of Pharmacy
1773 (b)4	If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.	As Determined by California State Board of Pharmacy
1773 (b)5	Complete an ethics course that meets the requirements of section 1773.5	As Determined by California State Board of Pharmacy
1773 (c)	When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.	As Determined by California State Board of Pharmacy
1773.5	When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.	As Determined by California State Board of Pharmacy

1773.5 (a)	The board will consider for approval an ethics course that at minimum satisfies the following requirements:	As Determined by California State Board of Pharmacy
1773.5 (a)1	Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.	As Determined by California State Board of Pharmacy
1773.5 (a)2	Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.	As Determined by California State Board of Pharmacy
1773.5 (a)3	Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.	As Determined by California State Board of Pharmacy
1773.5 (a)4	Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.	As Determined by California State Board of Pharmacy
1773.5 (a)5	Content. The course shall contain all of the following components:	As Determined by California State Board of Pharmacy
1773.5 (a)5(A)	A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.	As Determined by California State Board of Pharmacy
1773.5 (a)5(B)	A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.	As Determined by California State Board of Pharmacy
1773.5 (a)5(C)	An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.	As Determined by California State Board of Pharmacy
1773.5 (a)5(D)	Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.	As Determined by California State Board of Pharmacy

1773.5 (a)5(E)	Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.	As Determined by California State Board of Pharmacy
1773.5 (a)5(F)	A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.	As Determined by California State Board of Pharmacy
1773.5 (a)6	Class Size. A class shall not exceed a maximum of 12 participants.	As Determined by California State Board of Pharmacy
1773.5 (a)7	Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.	As Determined by California State Board of Pharmacy
1773.5 (a)8	Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.	As Determined by California State Board of Pharmacy
1773.5 (a)9	Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.	As Determined by California State Board of Pharmacy

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-02

DATE: **October 3, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Approval of Deeming Authority of Det Norske Veritas Healthcare, Inc. for Hospitals

Memorandum Summary

This memorandum announces the Centers for Medicare & Medicaid Services' (CMS) decision to approve Det Norske Veritas Healthcare, Inc. (DNV Healthcare) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare program.

Section 1865(b) of the Social Security Act (the Act) permits providers and suppliers accredited by an approved national accrediting body to be *"deemed"* to meet Medicare Conditions for Coverage or Participation. To receive approval, accreditation organizations must demonstrate to CMS that their requirements meet or exceed the Medicare conditions.

CMS reviewed DNV Healthcare's application for approval of deeming authority for hospitals in accordance with 42 CFR 488.4 and 42 CFR 488.8. CMS' review included DNV Healthcare's survey and accrediting process as well as its health and safety standards. CMS' review found DNV Healthcare's accreditation program for hospitals to meet or exceed the Medicare Conditions of Participation (CoP).

CMS announced DNV Healthcare's approval as a deemed status accreditation program for hospitals in the September 29, 2008, ***Federal Register*** (see attachment A). This is an initial 4 year approval effective September 26, 2008 through September 26, 2012. Deeming authority for this program is limited to the Medicare CoPs and does not apply to ownership, enrollment, or other Medicare requirements. Attachment B contains talking points for use by Regional Office and State Agency staff.

This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association. DNV Healthcare's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital CoPs.

If you have any questions regarding this memorandum, please contact Cindy Melanson at 410-786-0310 or via E-mail at cindy.melanson@cms.hhs.gov.

Effective date: Immediately. The State agency should disseminate this information within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with relevant survey and certification staff, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamiliton

Attachments

cc: Survey and Certification Regional Office Management

CMS-2895-FN Approval of Det Norske Veritas Healthcare, Inc. for Deeming Authority for Hospitals

- This notice announces our decision to approve Det Norske Veritas Healthcare, Inc. (DNVHC) for recognition as a national accreditation program for hospitals seeking to participate in the Medicare or Medicaid programs.

- This is an initial 4-year approval effective September 26, 2008 through September 26, 2012.

- This approval provides hospitals with another accreditation option in addition to the Joint Commission and the American Osteopathic Association.

- DNVHC's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare hospital conditions of participation.

NIAHO℠ Accreditation Program
Accreditation Process
Revision 12

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DNV HEALTHCARE INC

NIAHO℠ ACCREDITATION PROGRAM

ACCREDITATION PROCESS

INTRODUCTION

The National Integrated Accreditation for Healthcare Organizations (NIAHO℠) is a program offered by DNV Healthcare Inc. (DNVHC) and is the first integrated accreditation program for hospitals in the United States. Integrated Accreditation utilizes two or more independent sets of standards in the same survey process to produce one set of outcomes.

The NIAHO℠ Hospital Accreditation Program integrates ISO 9001 Quality Management System requirements with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482) (CoPs). Healthcare systems that want to participate in the Medicare program must be found to be in compliance with the CoPs by the Centers for Medicare and Medicaid Services (CMS). CMS makes that determination by its own survey process through state agencies or by accepting the accreditation of a private national accreditation organization that has been approved by CMS to deem healthcare organizations in compliance with the CoPs.

DNVHC has been approved by CMS for deeming authority to determine healthcare organizations in compliance with the Conditions of Participation for Hospitals (CoPs) effective September 26, 2008. Compliance with the ISO 9001 standard must occur within three (3) years after the first deemed NIAHO℠ accreditation survey.

This Accreditation Process addresses healthcare organizations that are either applying for DNV Healthcare Inc. accreditation or are currently accredited by DNVHC. When a healthcare organization has applied for but not received DNVHC accreditation, it is referred to as an "Applicant Organization." When a healthcare organization is currently accredited by DNVHC, it is referred to as an "Accredited Organization. "

ACCREDITATION, MEDICARE DEEMED STATUS, AND ISO COMPLIANCE OR CERTIFICATION TIME FRAMES

A Medicare deemed status survey will consist of a survey for compliance with the NIAHO℠ accreditation standards <u>and</u> compliance with or Certification to the ISO 9001 Quality Management System within three years of initial NIAHO℠ accreditation. **Compliance** to ISO 9001 requirements must be done through DNVHC. **Certification** to ISO 9001 can be achieved either through DNVHC or by another Accredited Registrar as outlined in NIAHO℠ Standard QM.1, SR 1-3.

Continuing NIAHO℠ accreditation will require a successful annual survey that validates continuing compliance with NIAHO℠ Standards as well as continued ISO 9001 compliance or Certification following the ISO 9001 three-year grace period described in the above Introduction.

Once ISO 9001 compliance or Certification is achieved, continued compliance or Certification will depend on annual ISO Periodic Surveys (limited in scope to full ISO compliance or Certification Survey) and a full ISO compliance or Certification Survey done triennially. The triennial ISO compliance or Certification Survey as well as the annual ISO Periodic Surveys, done in intervening years, will take place concurrently with the annual NIAHO℠ Accreditation Survey.

Assuming the Applicant Organization elects to obtain NIAHO℠ Accreditation and ISO 9001 compliance or Certification at the same time, the schedule of Surveys will typically take place according to the following schedule:

Initial 3 Year Contract

- Year One: NIAHO℠ Accreditation Survey (informal ISO 9001 education will also take place)
- Year Two: NIAHO℠ Accreditation Survey and ISO 9001 Pre-Assessment Survey
- Year Three: NIAHO℠ Accreditation Survey and ISO 9001 Stage One (where is the hospital on their ISO journey and what is left to be done)

Second 3-Year Contract

- Year One: NIAHO℠ Accreditation Survey and ISO 9001 Stage 2 (Certification or Compliance)
- Year Two: NIAHO℠ Accreditation Survey and ISO Periodic Survey
- Year Three: NIAHO℠ Accreditation Survey and ISO 9001 Periodic Survey

Third 3-Year and All Subsequent Contracts

- Year One: NIAHO℠ Accreditation Survey and ISO 9001 Re-Certification or Continued Compliance)
- Year Two: NIAHO℠ Accreditation Survey and ISO Periodic Survey
- Year Three: NIAHO℠ Accreditation Survey and ISO 9001 Periodic Survey

Failure to obtain this ISO Compliance or Certification in this timeframe will result in Accreditation Jeopardy Status for the Accredited Organization.

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to a State Agency, CMS surveyor, or DNV Healthcare Inc, (DNVHC) staff, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The NIAHO℠ Accreditation Requirements and Interpretive Guidelines, and CMS State Operations Manual (SOM) provide the policies and procedures regarding NIAHO℠ survey activities.
- The ISO 9001 (Quality Management System [QMS]) and ISO 14001 (Environmental Management System [EMS]) and ISO 19011 (Guidelines for Quality and/or Environmental Management Systems Auditing as well as related NIAHO℠ Standards and Interpretive Guidelines provide the basis for the ISO survey activities

Surveyors assess the organization's compliance with the NIAHO℠ Standards for all services and locations in which the provider receives reimbursement for patient care services billed under its provider number. Surveyors assess the organization's compliance with the applicable ISO Standards for all services and locations included in the organization's scope statement.

All hospital surveys are unannounced. DNVHC will not provide hospitals with advance notice of the upcoming survey.

SURVEYS AND CLASSIFICATIONS
Annual NIAHO[SM] Accreditation Survey and ISO 9001 Compliance or Certification Survey

The length of the Accreditation/Compliance/Certification Survey and the number of survey team members are determined by the size and complexity of the Applicant Organization and will be determined in the application process. Regardless of the size and complexity of the Applicant Organization, the team will consist of at least two members, a nurse or physician and a Physical Environment Specialist. The following activities apply whether the survey is for a *combined* ISO *and* NIAHO[SM] or just ISO. In any of these survey scenarios the team shall include at least the following activities:

- Introduction to the Applicant Organization and discussion with the Applicant Organization's leadership, to include executive and medical staff leadership and board members;
- Document Review (3-6 hours, depending on size of the Applicant Organization);

The Team Leader will request that the following documents be produced no later than 3 hours after the request is made. If available, a hard copy of the documents requested is preferred. Computer access is also acceptable.

The Team Leader may use a worksheet to give to the facility for obtaining this information;

- Organizational Chart
- Organizational chart for nursing services
- A map/floor plan, indicating locations for patient care and treatment areas
- A list of current inpatients with each patient's room number, age, primary diagnosis, attending physician, admission date, and other significant information as it applies to that patient.
- Current Surgical Schedule
- Most recent ISO certification report unless provided by DNV
- Most recent healthcare accreditation report (if applicable)
- Bylaws of the Governing Body
- Minutes of the Governing Body
- Medical Staff Bylaws, Rules and Regulations
- Minutes of the Medical Executive Committee
- Organizational Plan for Patient Care/Scope of service for each department and patient care unit
- Minutes of the Quality Oversight/Management Review Committee – including Performance Improvement data for the previous 12 months
- Minutes from Environment of Care/Safety Committee
- Management plans for the physical environment and annual evaluations
- List of contracted services, companies and individuals- Surveyors will select a sample for review
- Nursing service plan of administrative authority/delineation of responsibilities for delivery of pt. care
- Infection Control Plan with risk assessment/hazard vulnerability analysis
- List of employees including name, title, unit, and hire date
- List of current patients who have had restraint or seclusion used during hospitalization
- List of patients discharged with the past 6 months who had restraint or seclusion used violent or self-destructive behavior during their hospitalization
- P&P: Autopsies
- P&P: Blood & Blood Product Administration
- P&P: History and Physical Examination
- P&P: Informed Consent
- P&P: Medication Security
- P&P: Moderate Sedation
- P&P: Patient Assessment (Nursing, respiratory, nutritional services, etc.)
- P&P: Pain Management
- P&P: Patient Care Planning/Interdisciplinary Treatment Plan
- P&P: Patient Grievance
- P&P: Procedural Verification Process (Practices ensuring the correct patient, site & procedure)

- P&P: Restraint or Seclusion
- P&P: Verbal/Telephone Orders

As applicable, to assess compliance with the ISO 9001 requirements the following documents will also be incorporated into this review process.

- Control of Documents;
- Control of Records;
- Control of Non-Conformity;
- Internal Reviews (Internal Audits);
- Corrective Action;
- Preventive Action;
- Quality Manual;
- Quality Policy;
- Quality Objectives;
- Management Reviews, and
- Various policies and procedures

- Leadership Interview following document review for clarification of any identified issues;
- Using Tracer Methodology, department/patient unit audits to include staff interviews and open medical record review as appropriate (both clinical and support departments)
  1. The department/units of the organization will be surveyed through the use of tracer methodology. Use of tracer methodology shall be the means by which the surveyors will select records and then follow the patient care and other process(es) to verify various aspects of the organization as they are applied against the NIAHO[SM] and ISO 9001 standards and organization policies.
  2. The organization can expect visits to multiple areas of the organization to include, but not limited to, patient care units, ancillary services, human resources/personnel office, medical staff office, purchasing, bio-med/clinical engineering and/or facilities management.
  3. The Tracer methodology process may identify performance issues as a result of reviewing an individual patient's case, in one or more steps in the process or perhaps the interfaces between steps that affect the care of the patient/family as well as staff and organization performance.
- Human Resources Interview to verify compliance with staff requirements
- Medical Staff credentialing session to verify compliance with Medical Staff requirements
- Building Tour (4-12 hours, dependent on Applicant Organization size);
- Interviews with individuals who oversee core processes (e.g. patient safety and infection control, etc.) and appropriate staff if deemed necessary by survey findings;
- Interviews with leadership, other management staff, physicians, and board members
- Interviews with patients
- Additional document review if deemed necessary by survey findings;
- Oral presentation of Preliminary Findings to Applicant Organization Leadership Team.

ACCREDITATION AND CERTIFICATION PROCESS

The Accreditation and Certification process begins when the Applicant Organization submits a completed DNV Healthcare Inc. Accreditation Application, to include an ISO 9001 Certification Application if DNVHC is to be the ISO Registrar. Upon receipt of a completed Application(s), DNVHC will review the information and provide a fee structure based on the Applicant Organization's complexity and services requested.

For new enrollees in the Medicare program and prior to issuance of a quote for an accreditation survey, the applicant organization must submit evidence of its 855A completeness notification by CMS. A survey may only be scheduled if the applicant organization has received their 855A enrollment completeness notification from CMS.

If the Applicant Organization requires a Business Associate Agreement, it must be submitted to DNVHC and executed prior to the on-site survey.

DNVHC shall identify a survey team to conduct the on-site survey and confirm acceptable dates when the survey may be conducted. As the survey is unannounced, the survey team and the dates will NOT be shared with the Applicant Organization.

Following the on-site accreditation survey the Applicant Organization will be made aware that the next survey (pending closure of any open issues) will occur any time from the ninth to the fifteenth month following the initial Accreditation Survey. The same timeframes will apply for subsequent NIAHO surveys conducted by DNVHC.

SURVEY LOCATIONS
For hospitals with either no or a small number of off-campus provider-based locations, the team will survey all departments, services, and locations that bill for services under the organization's provider number and included in the scope statement (as ISO required) and are considered part of the organization.

For organizations with many provider-based locations survey:

- All hospital departments and services at the primary organization campus and on the campuses of other remote locations of the hospital
- All satellite locations of the hospital
- All inpatient care locations of the hospital
- All out-patient surgery locations of the hospital
- All locations where complex out-patient care is provided by the hospital
- The surveyors will select a **sample** of each type of other services provided at additional provider-based locations.

CONTRACTED SERVICES
On any organization NIAHO survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on organization campuses or organization provider based locations should be surveyed as part of the organization for compliance with appropriate requirements.

SURVEY TEAM SIZE AND COMPOSITION
DNVHC decides the composition and size of the team. In general, a suggested survey team for a full survey of a mid-size (200 bed) hospital would typically include 3 surveyors who will be at the facility for 2 or more days. Each hospital survey team will include at least one RN or Physician with hospital survey experience and a Physical Environment Specialist as well as other surveyors who have the training and expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census and number of employees
- Complexity of services offered, including outpatient services
- Type of survey to be conducted
- Whether the facility has special care units or off-site clinics or locations;
- Whether the facility has a historical pattern of serious deficiencies or complaints

Prior to the on-site survey, DNVHC shall verify that all members of the survey team have confirmed that there is no present conflict of interest and they have in no manner assisted the Applicant Organization in preparation or otherwise served in the capacity as a consultant or as a former or current employee of the Applicant Organization. In the event a conflict of interest is apparent or suspected, DNVHC will remove any surveyor and replace that individual with another surveyor free of any conflict of interest.

TRAINING FOR SURVEYORS
Clinical, Physical Environment, and Generalist Surveyors must successfully complete the following:

- The DNVHC NIAHO℠ Surveyor Training
- The DNV Quality Lead Auditor or an equivalent course accredited by IRCA or RAB-QSA
- The DNV Risk-Based Certification methodology training
- Orientation to DNVHC policies, procedures and software requirements

Additionally, the Physical Environment Specialists must successfully complete the following:

- Successful completion of a NFPA (National Fire Protection Association) Life Safety Code training with an additional focus on hospital requirements.
- Alternatively, 5 years or more of experience within facilities management including safety programs, direct involvement in the environment where patient care services are provided and knowledge of the Life Safety Code will satisfy this requirement.

LEAD SURVEYOR (TEAM LEADER)

The survey is conducted under the leadership of a Lead Surveyor (Team Leader), designated by DNVHC staff. The Lead Surveyor (Team Leader) is responsible for assuring that all survey activities are completed within the specified time frames and in a manner consistent with this protocol and other DNVHC policies and procedures. Responsibilities of the Lead Surveyor (Team Leader) include:

- Acting as the spokesperson for the team on site
- Facilitating management of the survey
- Encouraging communication among team members
- Evaluating team progress and coordinating meetings with team members and hospital staff as needed
- Coordinating any ongoing conferences with organization leadership and providing feedback, as appropriate, to organization leadership on the status of the survey
- Facilitating Opening and Closing Meetings
- Coordination and preparation of Preliminary Survey Report, with active participation of all survey team members
- Submission of preliminary report to DNVHC

SURVEY PLAN PREPARATION

The objective of this activity is to analyze information about the organization in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the organization (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, scope statement, etc.) require additional surveyors to the team beyond those assigned based on average daily census, number of employees and complexity of the organization. Information obtained about the organization will also allow DNVHC to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated annually using the completed organization application)

  Currently accredited organizations will be required to provide information to DNVHC by completing an Annual Update to the application. The information contained within the Annual Update will identify:

  - Accurate contact information for the organization
  - Names of members of Senior Leadership
  - Any off-site locations that have been added since the prior survey
  - Volume information from the prior year of the annual survey
  - Any new services that have been added since the prior survey
  - Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc). (If applicable)

- If applicable review previous survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings

- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc).

- The annual survey will be unannounced.

SURVEY TEAM OFF-SITE SURVEY PREPARATION

The survey team should prepare for the survey offsite by sharing organization pertinent information so they are ready to begin the survey immediately upon entering the facility. This can best be accomplished electronically (from the Lead Surveyor (Team Leader) to other team members) with a follow-up conference call if necessary. The following should be included in this preliminary exchange and/or discussion:

- Organization demographics & services offered
- Layout of facility if available
- Survey schedule
- Timing of survey activities, including beginning and ending times
- Suggested lodging and transportation options
- Directions to facility

SURVEY TEAM ARRIVAL

The entire survey team should enter the organization together. Upon arrival, surveyors shall present their identification along with the announcement letter to the receptionist or other hospital representative upon entering the building.

The Lead Surveyor (Team Leader) will announce to the CEO or Executive in charge or organization contact, that a survey is being conducted. If the CEO (or executive in charge) is not onsite or available, the Lead Surveyor (Team Leader) will ask that they are notified that a survey is being conducted. The Survey Team will not delay the survey because the CEO or other hospital staff is/are not on site or available.

OPENING MEETING

- Explanation of the purpose, scope of the survey, and provide a schedule of survey activities to the organization (the schedule may be adjusted as necessary)
- Brief explanation of the survey process;
- Introduction of survey team members, including any additional surveyors who may join the team at a later time, the general area that each will be responsible for, and the various documents that they may request;
- Clarification of all organization areas and locations, departments, and patient care settings under the hospital provider number and/or scope statement that will be surveyed, including any contracted patient care activities or patient services located on organization campuses or organization provider based locations
- Discuss the location (e.g., conference room) where the team may meet privately during the survey
- A telephone and internet connection for team communications (or access to these services if needed), preferably in the team meeting location
- Determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey.
- Propose a preliminary date and time for the Closing Meeting.
- During the Opening Meeting, the Lead Surveyor (Team Leader) will request that the organization provide the survey team with the documents requested for Document Review as listed. The Lead Surveyor (Team Leader) will request that the documents be produced no later than 3 hours after the request is made.

INITIAL ON-SITE SURVEY TEAM MEETING

After the conclusion of the Opening Meeting, the survey team will meet in order to evaluate information gathered, and modify surveyor assignments, as necessary. The surveyors will not delay the continuation of the survey process waiting for information from the organization, but rather will adjust survey activities as necessary. During the on-site team meeting, team members should:

- Review the scope of hospital services
- Identify hospital locations to be surveyed, including any off-site locations
- Adjust surveyor assignments, as necessary, based on information provided
- Discuss issues such as change of ownership, adverse events, construction activities, and disasters, if they have been reported
- Make an initial patient sample selection (The patient list may not be available immediately after the opening meeting and the team may delay completing the initial patient sample selection a few hours as meets the needs of the survey team)

PATIENT SAMPLE SIZE AND SELECTION

To select the patient sample, the surveyors will review the patient list provided and select patients who represent a cross-section of the patient population and the services provided. Patient logs (ER, OB, OR, restraint, etc) may be

used in conjunction with the patient list to assure the sample is reflective of the scope of services provided by the organization.

Whenever possible and appropriate, select patients that are in the facility during the time of survey (i.e., open records). Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through record reviews with observations and patient and staff interviews. There may be situations where closed records are needed to supplement the open records reviewed (e.g., too few open records, complaint investigation, etc), surveyors will use their professional judgment in these situations and select a sample size that will enable them to make compliance determinations and verify consistency.

If it is necessary to remove a patient from the sample during the survey, (e.g., the patient refuses to participate in an interview), the surveyors will replace the patient with another who fits a similar profile. This will be done as soon as possible in the survey.

The number of clinical records selected for review will typically be based on the organization's Average Daily Census (ADC). A guiding principle when selecting clinical records is to consider 10% of the ADC as sufficient to determine compliance in most instances in a hospital with an ADC of 180 or more. For smaller hospitals the sample should not be fewer than 10 inpatient records, provided that the number of records is adequate to determine compliance with any given requirement.

Within the sample, the surveyors will select at least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc). In addition to the inpatient sample, the surveyors will select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations. The sample size may be expanded as needed to assess the organization's compliance with all applicable standards.

If a complaint is being investigated during the survey, the survey team will include patients who have been identified as part of the complaint in the sample. Issues or concerns identified through complaints may be an area of focus when selecting the patient sample.

SURVEYOR INFORMATION GATHERING AND INVESTIGATION

The objective of this activity is to determine the hospital's compliance with the requirements through observations, interviews, and document review.

- The surveyors will focus attention on actual and potential patient outcomes, as well as required processes.
- The surveyors will assess the care and services provided, including the appropriateness of the care and services within the context of the Standards.
- The surveyors will visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
- The surveyors will observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.

DURING THE SURVEY

Typically the survey team will be accompanied by assigned organization staff as the survey is conducted. However the surveyors have discretion whether to allow, or refuse to allow, organization staff to accompany the surveyors during a survey or a selected activity of the survey. Surveyors will make a decision whether to allow organization staff to accompany them based on the circumstances at the time of the survey activity.

The survey team will meet at least daily (typically each morning) with organization leadership in order to assess the status of the survey, progress of completion of assigned activities, areas of concern, and to identify areas for additional investigations. The meetings will include an update by each surveyor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the survey team and the organization staff will coordinate efforts to obtain additional information, if appropriate. The organization staff will have the opportunity to present additional information or to offer explanations concerning identified issues. Survey information will not be discussed unless the investigation process and data collection for the specific concerns is completed.

Additional team meetings can be called at any time during the survey to discuss crucial problems or issues. Any significant issues or significant adverse events must be brought to the Lead Surveyor's attention immediately.

Although non-consultative information may be provided upon request, the surveyor is not a consultant. However, it is common to educate the hospital staff on aspects of the requirements and their application to the hospital processes.

PATIENT CARE REVIEW
A comprehensive review of care and services received by patients in the sample will be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, the surveyors will observe sample patients receiving treatments (e.g., intravenous therapy, tube feedings, wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

SURVEYOR ASSESSMENTS
The team will observe the care environment to obtain information about how the care delivery system works and how the organization's departments work together to provide care. Surveyors will review services provided, conduct interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review the surveyor may also observe patient care, the environment, staff interactions with patients, safety hazards, infection control practices, or any other activity that affects patient care or staff performance.

During the survey, the surveyors will pay particular attention to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present as well as those that are not present that should be present;
- Integration of all services to determine that the facility is functioning as one integrated whole
- Whether quality improvement is a organization-wide activity, incorporating every service and activity of the organization
- Whether every organization department and activity reports to and receives reports from the organization's quality management oversight, facilitating the organization-wide quality management system.
- Awareness and the effectiveness of the hospital's quality management system
- Storage, security and confidentiality of medical records.

Surveyors will record notes of findings/issues and should document for objective evidence:

- The date and time of the observation(s)
- Location
- Patient identifiers
- Individuals present during the observation
- Activity being observed (e.g., therapy, treatment modality, etc).
- Document / Form names and/or numbers (if applicable)

The surveyor will try to have findings verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding an out-dated medication in the pharmacy, the surveyor will ask the pharmacist to verify that the drug is out-dated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

INTERVIEWS
Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews will be conducted throughout the survey. The surveyors will use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews, the surveyors will do the following:

- Maintain documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.
- The surveyors will conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interviews may include patient rights, advanced directives, and the facility's grievance/complaint procedure.
- Interviews with patients will be conducted in private and with the patient's prior permission.

- The surveyors will interview staff to gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview will be addressed in the staff interview in order to validate the patient's perception or to gather additional information.
- Telephone interviews will be conducted if necessary, but the preference is for in-person interviews.
- The surveyors will integrate the data from interviews with data gathered through observations and document reviews.

ORGANIZATION DOCUMENTATION

Documents reviewed by the survey team during the survey, in addition to the formal Document Review, may be both written and electronic and include the following:

- Patient's clinical records to validate information gained during the interviews as well as for evidence of advanced directives, discharge planning instructions, patient teaching etc. This review will provide a broad picture of the patient's care.
- Plans of care and discharge plans should be initiated immediately upon admission, and be modified as patient care needs change. As an example, the record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes.
- Although team members may have a specific area assigned during the survey, the team will avoid duplication of efforts during review of medical records and each surveyor will typically review the record as a whole instead of targeting the assigned area of concern.
- Surveyors should use open patient records rather than closed records whenever possible
- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the hospital at the time of the survey. (For example, if there are no obstetrical patients in the facility at the time of the survey, the surveyors will review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records.)
- In the review of closed clinical records, the surveyors will review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.
- Personnel files to determine if staff members have the appropriate educational and training, pre-employment requirements, competency/performance assessments, and are licensed if it is required;
- Physician and allied health credential files to determine if the facility complies with Standards requirements and State law and follows its own written policies for medical staff privileges and credentialing;
- Maintenance and calibration records to determine if equipment is periodically attested and/or calibrated to determine if it is in good working order and if environmental requirements have been met
- Staffing documents to determine if adequate numbers of staff are provided according to the number and acuity of patients
- Policy and Procedure Manuals
- Contracts, if applicable
- Organization activities minutes as requested

ANALYSIS OF FINDINGS

The objectives of this survey team meeting are to integrate findings, review and analyze all information collected from surveyor observations, interviews, and record reviews, and to determine whether or not the organization meets the appropriate Standard requirements. Each team member will review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team. Based on the team's decisions, additional activities may need to be initiated. The meeting will include the following: The surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. Decisions about deficiencies will be based on input from the team members but the final decision shall always be the responsibility of the Lead Surveyor (Team Leader).

- The team will document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of any facility Nonconformity.
- The team will ensure that their findings are supported by adequate documentation of surveyor observations, interviews and document reviews.

- Any additional documentation or evidence needed to support identified Nonconformities should be gathered prior to the Closing Meeting but at a minimum, prior to exiting the hospital.

When a deficient practice (Nonconformity) is determined to have taken place prior to the survey and the organization states that it has corrected the deficient practice/issue, the survey team will consider the following:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Has the organization implemented the corrective action(s)?
- Has the hospital taken a quality management approach to the corrective action to ensure monitoring, tracking and sustainability?
- The survey team will use their judgment to determine if any corrective action(s) taken by the organization prior to the survey is sufficient to correct the Nonconformity and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected **prior** to the survey, the survey team **will not cite** the Nonconformity.
- If a Nonconformity with any requirement is noted **during** the survey, even when the hospital corrects the Nonconformity during the survey, the Nonconformity shall be cited.

CLOSING MEETING

- The Lead Surveyor (Team Leader) is responsible for organization of the presentation of the closing meeting.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the closing, they should immediately contact the DNVHC office
- The facility determines which hospital staff will attend the closing meeting.
- The Lead Surveyor (Team Leader) will explain how the team will conduct the closing meeting and any associated ground rules.
- Ground rules will include waiting until the surveyor finishes discussing a given deficiency before accepting comments from facility staff.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference by which identity might be deduced
- The surveyor will present the findings of Noncompliance or Observation, explaining why the finding(s) is a violation. The surveyor will just present the facts.
- If immediate jeopardy is identified by the team, they will explain the significance and the need for immediate correction.
- The organization will have an opportunity to present new information after the closing meeting for consideration after the survey.
- The team will assure that all findings are discussed at the closing conference.
- If the closing conference was audio or video taped, the Lead Surveyor (Team Leader) must obtain a copy of the tape in its entirety before leaving the facility.

DISCONTINUATION OF THE CLOSING MEETING

It is DNVHC's policy to conduct a closing meeting at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct a closing meeting. For example:

- If the provider is represented by counsel (all participants in the closing meeting should identify themselves), surveyors may refuse to conduct the closing meeting if the attorney tries to turn it into an evidentiary hearing; or
- If the organization leadership creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of a closing meeting, surveyors may refuse to conduct or continue the

closing meeting. Under such circumstances, the Lead Surveyor (Team Leader) will stop the closing meeting and call the DNVHC offices immediately for further direction.

RECORDING THE CLOSING MEETING

If the organization wishes to audio tape the closing meeting, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the meeting. Video taping is also permitted if it is not disruptive to the meeting, and a copy is provided to the Lead Surveyor (Team Leader) at the conclusion of the meeting. It is at the sole discretion of the surveyor(s) to determine if video taping is permitted.

POST-SURVEY ACTIVITIES

- A Preliminary Report shall be completed by the Survey Team and issued to the accredited organization.
- DNVHC will forward the final survey report to the organization within 10 days of the last date of the survey.

SURVEY FINDING DEFINITIONS: NIAHO[SM]

Nonconformity (NC)- (Category 1)

- Objective evidence exists that a requirement has not been addressed (intent), a practice differs from the defined system (implementation), or the system is not effective (effectiveness).

- The absence of one or more required system elements or a situation which raises significant doubt that the services will meet specified requirements.

- A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to requirement of the standard.

- A category 2 non-conformity that is persistent (or not corrected as agreed by the customer) shall be up-graded to category 1, OR a situation, that, on the basis of available objective evidence, would have the capability to cause patient harm or does not meet a standard of care.

- Condition Level Finding- A Condition Level Finding is a Category 1 Nonconformity in which the customer is determined to be completely or substantially out of compliance with the standard. Such finding is made on a case-by-case basis in DNV Healthcare Inc.'s sole discretion. A Condition Level Finding will be identified as a Category 1 Nonconformity- Condition Level Finding. All Condition Level Findings will require a follow-up survey prior to the next annual survey.
    - For organizations as new enrollees in the Medicare Program, all Category 1 Nonconformities must be closed prior to issuance of the accreditation certificate. If there are any Condition Level Category 1 Nonconformities identified, the customer will be required to complete a full re-survey prior to issuance of an accreditation certificate.

For all other, Category 1 nonconformities, a follow-up survey may be required prior to the next annual survey as specified in 3.5.1 (below)

Nonconformity (NC)- (Category 2)

A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that services will meet requirements. Overall system requirement is defined, implemented and effective.

As applicable a finding as a Category 2 nonconformity may be:

- An isolated non-fulfillment of a standard requirement that is otherwise properly documented and implemented, or,

- Inconsistent practice compared to other areas of the customer, or,

- Significant enough to warrant the customer to take action to prevent future occurrence and/or has the potential for becoming a Category 1 nonconformity.

Customer Follow-up Required for Nonconformities

- A Corrective Action Plan (CAP) must be delivered to DNV Healthcare Inc. within ten (10) calendar days from date of the written report. The CAP must:
  - Identify the root cause that led to the nonconformity;
  - Identify the actions taken to correct the nonconformity in the affected areas and/or processes;
  - Identify other areas and/or processes (if applicable) that have the potential to be affected by the same nonconformity;
  - Identify the process or system changes that will be made to ensure that the nonconformity does not recur;
  - Identify the timeframe for the implementation of the corrective action measure(s);
  - Identify the time of the person responsible for implementing the corrective action measure(s) and,
  - Identify the performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

<u>DNV Healthcare Inc. follow-up with Customer for Nonconformities</u>

DNV Healthcare Inc. will acknowledge receipt of the CAP and state any deficiencies and additional requirements with timelines for submission OR declare acceptance of the submitted documentation.

The customer is expected to implement corrective action measure(s) within sixty (60) days. When this is not feasible DNV Healthcare will consider and evaluate the circumstances involved and approve a suitable timeframe to enable the customer to implement the corrective action measure(s). Although such instances for extending the timeframe will be evaluated on a case-by-case basis, it would be a rare occurrence that the extended timeframe for implementation of corrective action measure(s) to exceed six (6) months.

For Category 1 Nonconformities, within sixty (60) days of DNV Healthcare Inc. acceptance, the customer shall submit performance measure(s) data, findings, results of internal reviews (internal audits), or other supporting documentation, including timelines to verify implementation of the corrective action measure(s). If a Category 1 Nonconformity results in a Condition Level Finding, a follow-up survey prior to the next annual survey will also be required to determine compliance with the specific Category 1 Nonconformity.

For Category 2 Nonconformities, if the corrective action plan(s) requirements are met, validation of effective implementation of the agreed corrective action plan will take place at the next annual survey.

DNV Healthcare Inc. will respond to the customer regarding acceptance of the submitted documentation and identify any deficiencies and additional requirements with time lines for submission.

Failure to comply with the requirements of the CAP regarding nonconformities may also result in a Condition Level Finding. A Condition Level Finding could result in Jeopardy Status for the customer as described in Follow-up and Special Surveys (ICP-12-5-i5) and Jeopardy Status, Withdrawal of Accreditation, Disputes and Appeals (ICP-12-6-i4).

DNV Healthcare Inc., in its sole discretion, shall determine the need for a follow-up survey when compliance and implementation cannot be reasonably determined through written documentation of objective evidence.

The scope and extent of the follow-up survey will be determined based upon the complexity of the nonconformity and one or more surveyors will be assigned to the follow-up survey. When possible, members of the survey team that conducted the survey when the nonconformity was issued will be assigned. When this is not feasible, DNV Healthcare Inc. will assign a surveyor that is familiar with the process and has the qualifications to validate compliance.

NOTE- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, all Category 1 nonconformities must be removed prior to the awarding of accreditation. In addition, if any Category 1 nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

NIAHO℠ ACCREDITATION IN JEOPARDY (JEOPARDY STATUS)

NIAHO℠ Accreditation in Jeopardy (Jeopardy Status) may be invoked based on the following:

- Customer fails to submit a required Corrective Action Plan and/or related documentation or if established reasonable timelines in a Corrective Action Plan are not met
- Customer fails to maintain the ISO quality management system or be certified to ISO 9001 within 3 years of initial DNV Healthcare Inc following the first NIAHO℠ deemed survey.
- Customer violates terms of the signed accreditation agreement, including non-payment of fees or refusal of access.
  - Failure to respond adequately to nonconformities identified during the accreditation process.
  - Customer makes false public claims regarding its accreditation. (e.g., accreditation is used in a way that is unjustifiable or deceptive in advertising.)
  - Information from stakeholders that could affect the status of accreditation (e.g., non-compliance to regulatory/statutory requirements).
  - Individual is delivering patient care or providing services without a required valid license or certification or registration;
  - Preventable issues that pose Immediate Jeopardy (harm or injury to a patient); or,
  - Non-compliance with statutory and regulatory requirements of state and/or federal law.

The requirements that the Accredited Organization must meet to be removed from Jeopardy Status and the length of time an Accredited Organization may remain in Jeopardy Status before Accreditation and Certification are removed will be outlined for the Accredited Organization in the Jeopardy notification. Jeopardy Status notification will outline the length of time the Accredited Organization may remain in Jeopardy Status, but normally that timeframe will not exceed four (4) months. Any extension shall be based on a progressing Corrective Action Plan that has been validated by a Special Survey.

FINDINGS AND WRITTEN REPORT

- DNV Healthcare Inc. shall provide final written report(s), NIAHO℠ and/or ISO 9001, to the Applicant Organization within ten (10) days of the survey. The final written report(s) will contain all identified Nonconformities as well as Opportunities for Improvement relative to the NIAHO℠ standards and/or ISO requirements that were identified by the team during the performance of the survey.
- Following receipt of the final written report(s) the Applicant Organization will have ten (10) days from the date of the Survey report to appeal any Nonconformity findings relative to either NIAHO℠ standards or ISO requirements.
- The Applicant Organization will submit Corrective Action Plan(s) to address the nonconformities identified and return this to DNV Healthcare Inc. If the Corrective Action Plan(s) are approved, the report of nonconformities with the Corrective Action Plan(s) will be submitted to the Accreditation Committee.
- Based on successful survey findings and/or Action Plan follow-up as described above, this will be presented to the Accreditation Committee for their decision regarding the accreditation status of the applicant organization. If approved, the Applicant Organization will receive a three year DNV Healthcare Inc. NIAHO℠ Accreditation and, if appropriate, a three year Certification or Compliance for meeting the ISO 9001 Quality Management System requirements, subject to the approval of the Certification Body for ISO 9001.
- In order to maintain accreditation, the organization will be subject to annual surveys for assessment of continual compliance with the NIAHO℠ requirements and compliance with corrective action plan(s) from the prior survey.

APPEALS PROCEDURE

Appeals received by DNV Healthcare Inc. shall be:

- Registered in a log to record the progress to completion;
- Acknowledged by DNV Healthcare Inc. without undue delay; and,
- Reviewed and answered.

The appeal is not bound to a particular form or content. However, the appeal shall be submitted in writing stating the basis of the appeal and the relief being requested. The appeal can be faxed, e-mailed or sent by US mail to:

Darrel J. Scott, Senior Vice President, Regulatory & Legal Affairs
DNV Healthcare Inc.
463 Ohio Pike, Suite 203
Cincinnati, Ohio 45255
Fax: (513) 947-1250
Email: Darrel.Scott@dnv.com

The appellant shall be informed of the right to:

- Present its case in person
- Appeal to the President of DNV Healthcare Inc. if the appellant does not accept the decision of the Executive Vice President, Accreditation.

The following applies for all appeals:

The decision reached by the Executive Vice President, Accreditation or President shall be communicated to the appellant in writing

- If the appellant still remains dissatisfied with the decision of the Executive Vice President, Accreditation or President, the appellant is entitled to one (1) appeal to the Standards and Appeals Board.
- Any appellant notice that it will pursue a remedy beyond DNV Healthcare Inc. shall be reported to DNV Corporate Legal Affairs through the Vice President, Regulatory Affairs.
- The Executive Vice President of Accreditation and President, if appropriate, shall review the final outcome of all appeals to determine the need for any change in DNV Healthcare Inc. procedures.

FOLLOW-UP / SPECIAL SURVEY

A Follow-Up Survey will be performed when the following occur

- When compliance regarding a nonconformity has been issued, and cannot be reasonably determined to be corrected and implemented with contact with the organization written documentation of objective evidence;
- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, if any nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

A Special Survey will be performed when the following occur

- Either in response to a patient or patient family complaint to DNV Healthcare Inc.;
- Media coverage of issues and the issue(s) cannot be resolved through DNV Healthcare Inc. evaluation of data findings, internal audits, or other documentation as requested by DNV Healthcare;
- CMS informs DNV Healthcare Inc. of a concern based on information they may have received from another source,; or,
- When a situation within the definition of Immediate Jeopardy is identified.

In those instances where the leadership of the organization is aware of the incident or nonconformity, DNV Healthcare Inc. encourages the organization to contact DNV Healthcare Inc. at the time of the event to discuss a process for resolution or when feasible to respond to the respective nonconformity. The Special Survey will focus on the issues and associated processes surrounding the incident or nonconformity . These Special Surveys will be unannounced.

Any Follow-Up or Special Survey will be done at the expense of the organization. The costs will be based on those in the basic DNV Healthcare Inc. fee schedule in effect at the time of the Follow-Up or Special Survey. DNV Healthcare Inc. will forward a written Report to the organization within ten (10) days, outlining the requirements, timelines, and required follow-up for any Corrective Action Plan(s).

NIAHO^{SM} SURVEY REPORTS

DNVHC shall have a Lead Surveyor (Team Leader) evaluate all survey findings and provide a final report and any other appropriate information to the DNVHC Accreditation Committee. The DNVHC Accreditation Committee will make the final decision on granting or withholding DNVHC NIAHO^{SM} Accreditation. The final accreditation decision will be sent to the Applicant/Accredited Organization upon the organization's completion of the correction action plan(s) within the applicable timeframes and acceptance of the plan(s) by DNVHC. The Applicant/Accredited Organization shall have one opportunity to appeal the DNVHC. Accreditation Committee decision or any associated findings for a period of fifteen (15) days following the final decision date of the DNVHC Accreditation Committee. The DNVHC Accreditation Committee decision on the Applicant/Accredited Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

ISO 9001 CERTIFICATION/SURVEILLANCE AUDIT REPORTS

DNVHC shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on granting or withholding ISO 9001 Certification. The final Certification Status will be sent to the Organization within forty-five (45) days of the Survey. The Organization shall have the opportunity to appeal the Certification Body decision or any associated findings for a period of fifteen (15) days following the final decision date of the Certification Body. The Certification Body's decision on the Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

Once certified to ISO 9001, the organization will undergo annual periodic audits to maintain compliance or Certification. DNV Healthcare Inc. shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on continuing or determining the need to proceed with withdrawing ISO 9001 Certification if the audit findings warrant such action being taken. The organization will be notified of the decision of the Certification Body within forty-five (45) days. If a decision is made to proceed to withdraw the certification, the organization will be provided the appropriate information for remedying this and what subsequent actions that needs to be taken.

CHANGES IN ACCREDITATION REQUIREMENTS

DNVHC shall provide notice to DNVHC Accredited Organizations of any changes or additional requirements in the NIAHO^{SM} Accreditation Program. The notice shall contain a description of the change(s) or additional requirement(s), the effective date(s) of the change(s) or additional requirement(s) and the action(s) required of DNVHC Accredited Organizations to meet the changes.

DNVHC Accredited and Compliant or Certified Organizations will have the opportunity to comment on proposed change(s) or additional requirement(s) for a period of no less than thirty (30) days prior to the DNVHC effective date of the change(s) or additional requirements. Any changes as required by CMS to be made to the NIAHO^{SM} standards must be implemented immediately.

DNV HEALTHCARE INC. RESPONSE TO A COMPLAINT AGAINST AN APPLICANT OR ACCREDITED ORGANIZATION

DNVHC will respond to any written or verbal complaint received by DNVHC against an organization either accredited by DNVHC or scheduled for a survey to become accredited by DNVHC. A complaint may be received from the Centers for Medicare and Medicaid Services (CMS) or any other federal or state agency with oversight responsibility, a patient or patient family, payer, caregiver, or other interested party. Complaints will be prioritized as follows:

Immediate Jeopardy

- This complaint category is identified by the hospital's Noncompliance with one or more of the NIAHO requirements that has caused, or is likely to cause, serious injury, harm, impairment, or death of a patient or is an immediate threat to life.
- All Immediate Jeopardy complaints will result in an on-site Special Survey and investigation within two (2) working days of receipt of the information. A Special Survey for Immediate Jeopardy complaints will be

unannounced. Determination of Immediate Jeopardy may be identified as a result of complaint submitted to DNVHC or identified during an on-site survey.

Operational (Response Required)

- This complaint category is identified by the hospital's noncompliance with one or more of the NIAHO℠ requirements that have caused physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s). A Special Survey is usually not required but may be initiated if it is needed to determine if there was patient harm. If a Special Survey is not conducted, the complaint and resolution would be reviewed at the next survey.
- The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has caused harm of limited consequence and does not significantly impair the patient's mental, physical state for these types of complaints. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.

Operational (No Response Required)

- This complaint category is identified when the hospital is in Noncompliance with one or more of the NIAHO℠ requirements and has not resulted in any physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s).
- A Special Survey is usually not required but may be initiated if it is needed to determine to complexity and severity of the complaint.
- The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has not been determined and has caused harm of limited consequence and/or does not significantly impair the patient's mental, physical state for these types of complaints.
- The Vice-President for Regulatory and Legal Affairs will contact the organization and verify that the complaint has been addressed and resolved internally. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.
- No Action Required – If adequate information has been received about the complaint and the Vice-President for Regulatory and Legal Affairs has contacted the organization and determined that the complaint has been addressed and resolved internally, no further investigation is necessary.

INFORMATION SUPPLIED UPON REQUEST TO CMS OR STATE AGENCIES IN ACCORDANCE WITH DEEMING AUTHORITY OR OTHER REQUIREMENTS

- The following information will be supplied to CMS or any state agency that has regulatory oversight over the Applicant/Accredited Organization:
- Complaint information that includes the complaint and selected action(s) taken. If the resolution required a Special Survey and/or a Corrective Action Plan, related documentation will be supplied, including the eventual outcome;
- Notification of upcoming Surveys, including retrospective dates of unannounced Special Surveys;
- Survey Reports from Surveys;
- Corrective Action Plans and related documentation;
- Notification of an Accredited Organization entering Jeopardy Status, with Corrective Action Plan and timelines for resolution;
- Notification of removal of Accreditation and Certification following unsuccessful resolution of Jeopardy Status.

National Integrated Accreditation for Healthcare Organizations (NIAHO℠)

Accreditation Requirements

ISSUE 307-8.0

(Includes inadvertent omission of UR.1, SR.1(d))

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Use of NIAHO℠ Accreditation Requirements

Editor's Note

This Revision 8.0 includes an inadvertent omission of UR.1, SR.1(d). UR.1, SR.1(d) is included in the NIAHO℠ Interpretive Guidelines and Surveyor Guidance Revision 8.0 and the Crosswalk of the NIAHO℠ Accreditation Requirements and the Medicare Conditions of Participation.

Effective Date

These NIAHO℠ Accreditation Requirements, Issue 307-8.0 (Revision 8.0) have an Effective Date of 09-18-09.

National Professional Organizations- Standards of Practice

Standards of practice of the national professional organizations referenced in this NIAHO℠ Interpretive Guideline and Surveyor Guidance document are consultative and considered in the accreditation decision.

Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this NIAHO℠ Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHO℠ accreditation requirements.

NIAHO standards are based upon the Center for Medicare and Medicaid (CMS) Conditions of Participation. Hospitals participating in the Medicare and Medicaid program are expected to comply with current Conditions of Participation. When new or revised requirements are published hospitals are expected to demonstrate compliance in a time frame consistent with the effective date published by CMS in the Federal Register.

Life Safety Code®

The Life Safety Code® of the National Fire Protection Association referenced in this NIAHO℠ Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHO℠ accreditation requirements.

DEFINITIONS

AOA	American Osteopathic Association
AMA	American Medical Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CRNA	Certified Registered Nurse Anesthetist
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHA	Home Health Agency
HVAC	Heating Ventilating and Air Conditioning
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
Life Safety Code	Life Safety Code® of the National Fire Protection Association
LIP	Licensed Independent Practitioner
NFPA	National Fire Protection Association
NLN	National League for Nursing
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General, Department of Health and Human Services
PRN (prn)	Pro re nata, as the occasion arises, when necessary
QIO	Quality Improvement Organization
QMS	Quality Management System
Secretary	Secretary of the Department of Health and Human Services
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SR	Standard Requirement. Additional explanatory information under each major accreditation requirement in this Guide.

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the organization implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the organization are implemented, measured and monitored.

In addition to any other Quality Management System standard, the organization is required to comply with QM.1 at all times as a part of its Quality Management System. Until the organization achieves ISO 9001:2008 Certification, the organization shall follow at a minimum the ISO 9001:2008 methodology specified in QM.2, SR.3 (below).

SR.1 The organization must develop, implement and maintain an ongoing system for managing quality and patient safety.

SR.1(a) As a part of the Quality Management System for addressing performance improvement and patient safety, the organization must select projects or similar activities that focus attention on various processes, functions and areas of the organization.

SR.1(a)(1) The number and scope of these projects or similar activities will be conducted annually and be proportional to the scope and complexity of the organization's operations and services offered.

SR.1(a)(2) These projects or similar activities will be documented to include the rationale for selection and measurable progress achieved.

SR.1(a)(3) If the organization participates in a Quality Improvement Organization (QIO) cooperative project, the organization must demonstrate that information and supporting documentation is provided to the QIO. If the hospital does not participate in a QIO, the projects and activities are required to be of comparable effort.

SR.2 The organization must implement hospital-wide quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.

SR.3 The organization will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

SR.1 Compliance with the ISO 9001 standard must occur within three (3) years after the initial deemed NIAHO℠ accreditation. The Organization shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHO℠ accreditation survey or maintain Certification through an Accredited Registrar. Only certificates covered by an accreditation by an IAF MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The organization shall maintain ISO 9001 compliance or formal Certification in order remain eligible for NIAHO℠ Accreditation.

SR.1a Failure to demonstrate compliance or certification with the ISO 9001 standard within three (3) years after the NIAHO℠ accreditation that first occurs after DNVHC receives deeming authority from CMS shall result in NIAHO℠ Jeopardy Status.

SR.2 An Accredited Registrar recognized by the International Organization of Standardization shall meet the following minimum criteria:

SR.2a. shall be accredited for IAF Scope 38; and,
SR.2b. must have certified or conducted a pre-assessment at a minimum of twelve (12) hospitals.

SR.3 The organization will initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1 SR.1. At a minimum the organization must be able to demonstrate at the time of the NIAHO℠ Accreditation survey evidence of the following:

SR.3a Control of Documents: the organization's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;

SR.3b Control of Records: the organization ensures that suitable records are maintained for the CoP and NIAHO℠ requirements;

SR.3c Internal Surveys (Internal Audits) – the organization conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective;

SR.3d The organization has established measurable quality objectives and the results are analyzed addressed; and

SR.3f Appropriate information has been submitted to the oversight group for quality management as required in QM.6 SR.1 as well as top management for review and analysis during a management review process.

QM.3 QUALITY OUTLINE

The organization shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

QM.4 MANAGEMENT REPRESENTATIVE

A management representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the Quality Management System are implemented and maintained.

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any variation, deficiency or non-conformity identified by the organization shall be addressed by the organization. Appropriate corrective or preventive action will be determined, applied, and documented. Documentation of activities may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific Improvement Project analysis, etc. This documentation shall become a part of the Management Review performed at regular intervals, at a minimum of once annually.

QM.6 SYSTEM REQUIREMENTS

In establishing the Quality Management System, the organization shall be required to have the following as a part of this system:

SR.1 Interdisciplinary group to oversee the Quality Management System that includes at least the CEO, COO, Nurse Executive, Pharmacy, Risk Management, Safety Management, Privacy Officer, Quality Facilitator/Management Representative, and two members of the medical staff who must be doctors of medicine or osteopathy. This interdisciplinary group shall conduct Management Reviews;

SR.2 Written document defining the Quality Management System, to include all clinical and non-clinical services;

SR.3 Statement of the Quality Policy;

SR.4 Measurable Quality Objectives; and,

SR.5 Goal Measurement / Prioritization of activities based in some manner to:

SR.5a Focus on high-risk, problem-prone areas, processes or functions,

SR.5b Consider the incidence, prevalence and severity of problems in these areas, processes or functions,

SR.6c Affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The organization shall evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service. The monitoring shall include the use of internal reviews (audits) of each department or service at scheduled intervals, not to exceed one year and data related to these processes. Individual(s) not assigned to that department or service shall conduct the internal review (audit). Measurement, monitoring and analysis of processes throughout the organization require established measures that have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The organization must define the frequency and detail of the measurement. Those functions to be measured at a minimum must include the following:

SR.1 Threats to patient safety;

SR.2 Medication therapy/medication use; to include medication reconciliation and the use of dangerous abbreviations;

SR.3 Operative and invasive procedures; to include wrong site/wrong patient/wrong procedure surgery

SR.4 Anesthesia/moderate sedation;

SR.5 Blood and blood components

SR.6 Restraint use/seclusion;

SR.7 Effectiveness of pain management system;

SR.8 Infection control system, including nosocomial infections;

SR.9 Utilization Management System;

SR.10 Patient flow issues, to include reporting of patients held in the Emergency Department or the PACU in excess of eight hours.

SR.11 Customer satisfaction, both clinical and support areas;

SR.12 Discrepant pathology reports;

SR.13 Unanticipated deaths, non-sentinel event;

SR.14 Sentinel event/near miss and other medical errors;

SR.15 Other adverse events;

SR.16 Critical and/or pertinent processes, both clinical and supportive;

SR.17 Medical record delinquency; and,

SR.18 Physical Environment Management Systems

QM.8 PATIENT SAFETY SYSTEM

SR.1 The organization shall have a means for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.

SR.2 The organization's Patient Safety System shall be documented and shall address the following:

SR.2a. detection;
SR.2b. preventative and corrective action;
SR.2c. defined processes to reduce risk;
SR.2d. implementation of action plans;
SR.2e. on-going measurement to ensure action effectiveness;
SR.2f. management review of response and resource allocation to the results of patient adverse event and other analysis; and,
SR.2g. policy and practice of informing patients and/or their families about unexpected adverse events.

GOVERNING BODY (*GB*)

GB.1 LEGAL RESPONSIBILITY

The organization shall have an effective governing body legally responsible for the conduct of the organization as an institution. The governing body is responsible for all services provided in the organization including all contracted services. If an organization does not have an organized governing body, the persons legally responsible for the conduct of the organization must carry out the functions specified.

SR.1 The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials (to include the chief executive officer, chief financial officer, and nurse executive) are responsible and accountable for ensuring that the following:

SR1a. the organization is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;

SR1b. the organization is licensed by the appropriate State or local authority responsible for licensing hospitals;

SR1c. Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the organization, directly or under contract, and/or appointed through the formal medical staff appointment process; and,

SR1d. the personnel working in the organization are properly licensed or otherwise meet all applicable Federal, State and local laws.

GB.2 INSTITUTIONAL PLAN AND BUDGET

SR.1 The organization shall have an overall plan that includes an annual operating budget that contains all anticipated income and expenses and is prepared according to generally accepted accounting principles.

SR.2 The plan must provide for capital expenditures for at least a 3-year period including the year identified in SR.1 (above). The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or lesser amount established by the State in which the organization is located in accordance with Section 1122(g)(1) of the Social Security Act and is related to:

SR2a. acquisition of land;
SR2b. improvement of land, buildings and equipment, or
SR2c. replacement, modernization or expansion of buildings or equipment.

SR.3 The plan must be reviewed and updated annually.

SR.4 The plan must be prepared under the direction of the governing body and by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

SR.5. If required, the plan must be submitted for review in accordance with Section 1122 of the Social Security Act or, as applicable, to the appropriate health planning agency in the State.

GB.3 CONTRACTED SERVICES

SR.1 The governing body shall require annual management reviews of selected indicators to ensure that all contracted services (including all joint ventures or shared services) provide services that are safe and effective and that comply with all applicable NIAHO℠ requirements.

SR.2 The governing body is responsible for services furnished in the hospital whether or not they are furnished under contract. The organization must evaluate and select contracted services (including all joint ventures or shared services) (and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection will include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with all applicable NIAHO℠ requirements, and standards required for all contracted services.

SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.

CHIEF EXECUTIVE OFFICER (CE)

CE.1 QUALIFICATIONS

The governing body must appoint a chief executive officer who is qualified through education and experience to be responsible for managing the organization.

CE.2 RESPONSIBILITIES

The chief executive officer is responsible for operating the organization, according to the authority conferred by the governing body. The chief executive officer shall provide for the organization's compliance with applicable law and regulation, including State licensure laws.

MEDICAL STAFF (MS)

MS.1 ORGANIZED MEDICAL STAFF

The organization shall have an organized medical staff that is composed of fully licensed doctors of medicine or osteopathy. In accordance with State law, the medical staff may also include other practitioners.

MS.2 ELIGIBILITY

The governing body shall determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

MS.3 ACCOUNTABILITY

The medical staff shall be organized in a manner approved by and accountable to the governing body and shall be responsible for the quality of the medical care provided to patients.

MS.4 RESPONSIBILITY

The responsibility for organization and conduct of the medical staff must be assigned to an individual doctor of medicine or osteopathy or, when permitted by State law, a doctor of dental surgery or dental medicine.

MS.5 EXECUTIVE COMMITTEE

SR.1 The medical staff shall meet at regular intervals and minutes shall be maintained. If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.

SR.2 The chief executive officer and the nurse executive of the organization or designee shall attend each executive committee meeting on an ex-officio basis, with or without vote.

MS.6 MEDICAL STAFF PARTICIPATION

The medical staff shall participate in at least the following organization activities:

SR.1 Medication management oversight;

SR.2 Infection control oversight;

SR.3 Tissue review;

SR.4 Utilization review;

SR.5 Medical record review; and,

SR.6 Quality Management System.

SR.7 Reports and recommendations from these activities shall be prepared and shared with the medical executive committee and the governing body:

MS.7 MEDICAL STAFF BYLAWS

SR.1 The medical staff shall be appointed by the governing body and operate under bylaws, rules and regulations adopted and enforced by the medical staff and approved by the governing body.

SR.2 Changes to the medical staff bylaws, rules and regulations shall require approval of the medical staff and the governing body.

SR.3 The medical staff bylaws shall describe the organization of the medical staff and include a statement of the duties and privileges of each category of medical staff to ensure that acceptable standards are met for providing patient care for all diagnostic, medical, surgical and rehabilitative services.

SR.4 Medical staff bylaws shall include provisions for mechanisms for corrective action, including indications and procedures for automatic and summary suspension of medical staff membership or clinical privileges.

MS.8 APPOINTMENT

The medical staff bylaws shall describe the qualifications to be met by a candidate in order for the medical staff to recommend that the governing body appoint the candidate. Those qualifications shall include the following:

SR.1 Initial appointment to the medical staff:

SR.1a. primary source verification of licensure, education, specific training, experience, and current competence ;
SR.1b. current Federal Narcotics Registration Certificate (DEA) number;

SR.1c. two peer recommendations;

SR.1d. review of involvement in any professional liability action; and,

SR.1e. if available, review of individual performance data for variation from benchmark. Variation shall go to peer review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies.

SR.2 Reappointment to the medical staff:

SR.2a. primary source verification of licensure and current competence;

SR.2b. current DEA number;

SR.2c. review of involvement in any professional liability action; and,

SR.2d. review of individual performance data for variation from benchmark. Variation shall go to Peer Review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies.

MS.9 PERFORMANCE DATA

Practitioner specific performance data is required and must be rate-based with comparative peer or national data available for comparison. Areas to be measured are:

SR.1 Blood use: AABB transfusion criteria;

SR.2 Prescribing of medications: Prescribing errors and appropriateness of prescribing for Drug Use Evaluations;

SR.3 Surgical Case Review: appropriateness and outcomes for selected high-risk procedures;

SR.4 Specific department indicators that have been defined by the medical staff;

SR.5 Moderate Sedation Outcomes;

SR.6 Appropriateness of care for non-invasive specialties;

SR.7 Utilization data;

SR.8 Significant deviations from established standards of practice; and,

SR.9 Timely and legible completion of patients' medical records.

SR.10 Any variant should be analyzed for statistical significance.

MS.10 CONTINUING EDUCATION

All individuals with delineated clinical privileges shall participate in continuing education that is at least in part related to their clinical privileges.

SR.1 This documentation shall be considered in decisions about reappointment or renewal or revision of clinical privileges.

SR.2 Action on an individual's application for appointment /reappointment or initial or subsequent clinical privileges is withheld until the information is available and verified.

MS.11 GOVERNING BODY ROLE

SR.1 The governing body shall appoint members of the medical staff and approve clinical privileges after considering the recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

SR.2 The governing body may elect to delegate the authority to render initial appointment, reappointment, and renewal or modification of clinical privileges decisions to a committee of the governing body.

SR.3 The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

SR.4. A complete application shall be acted on within a reasonable period of time, as specified in the medical staff bylaws.

MS.12 CLINICAL PRIVILEGES

SR.1 The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.

SR.2 Appointment or reappointments to the medical staff and the granting, renewal, or revision of clinical privileges shall be made for a period defined by State law or if permitted by State law, not to exceed three years.

SR.3 All individuals who are permitted by the organization and by law to provide patient care services independently in the organization shall have delineated clinical privileges.

SR.4 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.

SR.5 The medical staff bylaws shall provide a mechanism for consideration of automatic suspension of clinical privileges in any of the following instances:

SR.5a. revocation/restriction of professional license;
SR.5b. revocation/suspension/probation of Federal Narcotics Registration Certificate (DEA);
SR.5c. failure to maintain the specified amount of professional liability insurance; or,
SR.5d. non-compliance with written medical record delinquency or deficiency requirements.

SR.6 The medical staff bylaws shall provide a mechanism for immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner's Medicare or Medicaid status.

SR.7 The medical staff bylaws shall contain fair hearing and appeal provisions for any adverse actions regarding the appointment, reappointment, suspension, reduction or revocation of privileges of any individual who has applied for or has been granted clinical privileges.

MS.13 TEMPORARY CLINICAL PRIVILEGES

When dictated by urgent patient care need or when an application is complete without any negative or adverse information before action by the medical staff or governing body, the chief executive officer or designee, may grant temporary clinical privileges:

SR.1 On the recommendation of the medical executive committee;

SR.2 For a period of time not to exceed thirty days. Temporary privileges may be extended for two separate 30-day intervals upon approval of the governing body.

SR.3 Criteria for granting temporary privileges:

SR.3a. verification of education (AMA/AOA Profile);
SR.3b. demonstration of current competence;
SR.3c. verification of State professional licenses;
SR.3d. receipt of professional references (including current competence); and,
SR.3e receipt of database profiles from AMA, AOA, NPDB, OIG Medicare/Medicaid Exclusions.

MS.14 CORRECTIVE OR REHABILITATION ACTION

The medical staff bylaws shall provide a mechanism for management of medical staff corrective or rehabilitative action. This documented action may result from unprofessional demeanor and conduct and/or this behavior is likely to be detrimental to patient safety or the delivery of quality care or is disruptive to organization operations. Any officer of the medical staff, the CEO, or any officer of the board may initiate this corrective or rehabilitative action.

MS.15 ADMISSION REQUIREMENTS

Patients are admitted to the organization only on the recommendation of a licensed practitioner permitted by the State to admit patients to the organization.

SR.1 The governing body shall ensure that every patient is under the care of a:

SR.1a. doctor of medicine or osteopathy who may delegate such care to other qualified health care professionals to the extent allowed by State law;

SR.1b. doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his/her license;

SR.1c. doctor of podiatric medicine, only with respect to functions authorized by State;

SR.1d. doctor of optometry who is legally authorized to practice optometry by the State;

SR.1e. chiropractor who is licensed by the State and legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; or

SR.1f. clinical psychologist (doctoral degree in psychology), but only with respect to clinical psychologist services as defined in 42 CFR §410.71 and only to the extent permitted by State law.

SR.2. The governing body shall ensure that:

SR.2a. a doctor of medicine or osteopathy is on duty or on call at all times; and,

SR.2b. a doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified in SR 1b-1f (above) as that scope of practice is defined by the medical staff and State law.

MS.16 MEDICAL RECORD MAINTENANCE

SR.1 The medical staff bylaws shall include the requirement for the preparation and maintenance of a complete and accurate medical record for each patient and policies and procedures for dealing with medical record delinquencies.

SR.2 The medical staff bylaws shall require that the medical staff have periodic meetings at regular intervals to review and analyze medical records of the patients for adequacy and quality of care.

MS.17 HISTORY AND PHYSICAL

SR.1 The medical staff bylaws shall include a requirement that a medical history and physical examination (HP) for each patient shall be done no more than 30 days before or twenty four (24) hours after an admission or registration, but prior to surgery or other procedure requiring anesthesia services and placed in the patient's medical record within twenty four (24) hours after admission. The HP must be in the medical record prior to any high-risk procedure.

SR.1a. An HP completed within 30 days prior to admission or registration shall include an entry in the medical record documenting an examination for any change in the patient's current medical condition completed by a doctor of medicine or osteopathy, oromaxillofacial surgeon or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

SR.1b. This examination and update of the patient's current medical condition shall be completed and placed in the medical record within twenty four (24) hours after admission or registration, but prior to surgery or other procedure requiring anesthesia services.

SR. 2 A doctor of medicine or osteopathy, oromaxillofacial surgeon shall do the HP described above. Alternatively, a physician's assistant or advance practice nurse may perform a history and physical if permitted by State law and scope of practice. The responsible physician must review and approve the history and physical as specified by the medical staff.

SR.3 The content of the HP examination and applicability shall be determined by the medical staff and may be done by the individuals described in SR. 2 and SR.3 (above). The content of the HP examination will be determined by an assessment of the patient's condition and any co-morbidities in relation to the reason for admission or surgery. This HP examination must be in the medical record prior to any high-risk procedure, surgery or other procedure requiring anesthesia services and within 24 hours of admission or registration as stated in MS.17, SR.1.

MS.18 CONSULTATION

The medical staff shall define in its bylaws the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required.

MS.19 AUTOPSY

SR 1. The medical staff shall attempt to secure autopsies in all cases of unusual deaths and those of medical-legal and educational interest.

SR 2. Mechanisms for documenting permission to perform an autopsy shall be defined.

SR 3. There shall be a system for notifying the medical staff and specifically the attending practitioner when an autopsy is being performed.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

SR.1 The organization must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care.

SR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each patient. A registered nurse or licensed practical nurse shall be on duty at all times except in facilities that have been granted a waiver in accordance with § 488.54(c), Federal law, rules or regulations.

SR.3 The nursing service must develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services must be provided or supervised by a registered nurse.

SR.4 There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other staff to provide nursing care to all patients as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.

SR.5 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.

SR.6 Non-employee licensed nurses who are working in the organization must adhere to the policies and procedures of the organization. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

NS.2 NURSE EXECUTIVE

SR.1 The nurse executive must be a licensed registered nurse with either a master degree, actively pursuing a master's degree or equivalent experience in comparable positions.

SR.2 The nurse executive is responsible for the operation of the service, including determining the types and numbers of staff necessary to provide nursing care for all patient care areas of the organization and standards of nursing practice.

NS.3 PLAN OF CARE

SR.1 Nursing staff shall develop and maintain a plan of care for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including pain assessment and interventions shall be included in the plan of care, as appropriate.

STAFFING MANAGEMENT (SM)

SM.1 LICENSURE OR CERTIFICATION

The organization shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification as required by the organization and Federal and State law. This written policy shall be strictly enforced and compliance data reported to Quality Management Oversight.

SM.2 PROFESSIONAL SCOPE

All staff, including contract staff, shall function within the limits of their scope of service as defined by their professional practice act, State law, and organization policy at all times. This written policy shall be strictly enforced and variations reported to Quality Management Oversight.

SM.3 DEPARTMENT SCOPE OF SERVICE

Each department, whether clinical or supportive, and each patient unit shall have a written scope of service that includes at least:

SR.1 The hours of operation;

SR.2 Patient populations served;

SR.3 Skill mix;

SR.4 Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,

SR.5 Description of assessment and reassessment practices, including timeframes.

SR.6 The organization shall consolidate these scopes of service, including these staffing requirements, into one organization-wide document.

SM.4 DETERMINING AND MODIFYING STAFFING

SR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.

SR.2 This validation shall be done at least monthly and reported to Quality Management Oversight.

SM.5 JOB DESCRIPTION

All staff, whether clinical or supportive, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

SM.6 ORIENTATION

All staff, whether clinical or supportive, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the organization. The orientation shall take place prior to the individual functioning independently in their job.

SM.7 STAFF EVALUATIONS

SR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators shall then be selected from this complete list of indicators for measurement as outlined below.

SR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through at least the following:

SR.2a variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
SR.2b high-risk, low volume procedures;
SR.2c new technology/equipment/processes;
SR.2d customer satisfaction feedback;
SR.2e scheduled training session outcomes;
SR.2f staff learning needs assessments that include variations identified through prior staff performance measurement;
SR.2g staff feedback;
SR.2h medical staff feedback; and,
SR.2i requirements of Federal or State law.

SR.3 Indicator measurement for contract staff may be modified based on organization outcomes and frequency of service of the individual. Modification of this measurement must take place no less than every calendar year and shall be justified by data analysis.

SR.4 The organization shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching, and mentoring.

SR.4a Re-measurement shall follow any intervention.
SR.4b The outcomes of this measurement shall be reported in the aggregate to Quality Management Oversight.

SR.5 The organization shall define a timeframe, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.

SR.6 The organization shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or organization policy. Compliance with this standard shall be reported to Quality Management Oversight.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.

SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.

SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.

SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.

SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

MM.3 SCHEDULED DRUGS

SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.

SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

MM.4 MEDICATION ORDERS

All medication orders shall:

SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.

SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.

SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.

SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

SR.1 The practitioner caring for the patient must determine the urgency of administration.

SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.

SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.

SR.4 All high-risk medications in this area shall be segregated and unavailable.

SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:

SR.5a potential drug-drug interactions;
SR.5b potential allergies or cross sensitivities;
SR.5c proper dose ranges; and,
SR.5d proper indications for administration.

SR.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.

SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

MM.6 OVERSIGHT GROUP

SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.

SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

SURGICAL SERVICES (SS)

SS.1 ORGANIZATION

SR.1 If the organization provides surgical services, the services shall be well organized, appropriate to the scope of the services offered, and provided in accordance with acceptable standards of practice. National standards of practice of AORN, CDC, APIC, ASA and other professional organizations are applicable to surgical services.

SR.2 If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

SR.3 Surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care, and must be consistent with needs and resources.

SS.2 STAFFING AND SUPERVISION

SR.1 The organization of the surgical services shall be supervised by either a registered nurse with appropriate experience, or by a doctor of medicine or osteopathy.

SR.2 Under the supervision of a registered nurse, the following personnel comprise the OR staff:

SR.2a registered nurses;
SR.2b licensed practical nurses; and,
SR.2c surgical technologists (operating room technicians).

SR.3 Qualified registered nurses shall perform circulating duties in the operating room. If a qualified registered nurse is present who is immediately available to respond to emergencies, licensed practical nurses and surgical technologists may assist in circulatory duties under the supervision of that registered nurse, if State law and medical staff policies and procedures permit.

SS.3 PRACTITIONER PRIVILEGES

SR.1 All practitioners performing surgery shall have surgical privileges established by the organization's department of surgery and medical staff and approved by the governing body. Surgical privileges shall correspond with the established competencies, technical skill and performance, as appropriate of each practitioner.

SR.2 A current roster of practitioners that specifies their surgical privileges shall be maintained by the department of surgery.

SR.3 Privileges for general surgery and surgical subspecialties defined with established criteria approved by the medical staff and in accordance with MS.12.

SS.4 HISTORY AND PHYSICAL

SR.1 Except in emergencies, there must be a complete history and physical in the medical record of every patient prior to surgery or procedure requiring anesthesia services.

SR.1a a complete history and physical examination must be completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration

SR.1b when the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

SR.2 If the history and physical has been dictated but not yet present in the patient's medical record, the practitioner who admitted the patient shall write a statement to that effect as well as an admission note in the medical record. Such circumstance is acceptable only in a medical emergency and is not applicable for a scheduled surgery.

SR.3 A properly executed informed consent form for the surgery shall be in the patient's medical record before surgery except in an extreme medical emergency.

SS.5 AVAILABLE EQUIPMENT

The following equipment shall be present and in operating condition in each surgical suite:

SR.1 Call-in system;

SR.2 Cardiac monitor;

SR.3 Resuscitator;

SR.4 Defibrillator;

SR.5 Suction equipment; and,

SR.6 Provisions for emergency airway intervention.

SS.6 OPERATING ROOM REGISTER

The operating room register shall be complete and current.

SS.7 POST-OPERATIVE CARE

SR.1 There shall be adequate provision for immediate post-operative care.

SR.2 Equipment, clinical staff, and plan of care provisions as well as criteria for discharge shall be developed and adopted by the medical staff and nurse executive designees.

SS.8 OPERATIVE REPORT

SR.1 An operative report describing techniques, findings, and tissues removed or altered shall be written or dictated and signed by the surgeon immediately following surgery.

SR.2 The operative report shall be dictated or written in its entirety before the patient is transferred to the next level of care (e.g. before the patient leaves the post anesthesia care area).

SS.9 IMMEDIATE POST-OPERATIVE NOTE

SR.1 An immediate postoperative note is required to be written if there is a dictation turn around delay. This shall include identification or description of:

SR.1a the surgeon and assistants;
SR.1b pre-op and post-op diagnosis;
SR.1c procedures performed;
SR.1d specimens removed;
SR.1e blood administered; and,
SR.1f any complications.
SR.1g type of anesthesia administered
SR.1h grafts or implants

SR.2 If information identified in the post-operative note is available in nursing documentation; it is acceptable if authenticated as accurate by the attending surgeon.

ANESTHESIA SERVICES (AS)

AS.1 ORGANIZATION

SR 1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the organization.

SR 2 Anesthesia services shall be appropriate to the scope of the services offered.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following:

SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist);

SR.2 A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

SR.3 A certified registered nurse anesthetist (CRNA) as defined in 42 CFR §410.69(b), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;

SR.4 For CRNAs to operate as licensed independent practitioners, the governor of the State must have received an exemption from CMS for that particular State; or

SR.5 An anesthesiologist's assistant as defined in 42 CFR §410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available if needed.

AS.3 POLICIES AND PROCEDURES

SR.1 Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities.

SR.2 The policies must ensure that the following are provided for each patient:

SR.2a a pre-anesthesia or pre-sedation evaluation, to include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and privileged to administer anesthesia/sedation, performed no more than 48 hours prior to surgery or procedure requiring anesthesia services;

SR.2b an intra-operative anesthesia/sedation record;

SR.2c for inpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia;

SR.2c(1) A post-anesthesia evaluation for anesthesia recovery is required and must be completed In accordance with State law and hospital policies and procedures approved by the medical staff and reflect current standards of care anytime general, regional, or monitored (this would include deep sedation/analgesia has been administered to the patient.

SR.2c(2) If the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged

SR.2d for outpatient surgery, a follow-up report as defined by the medical staff.

LABORATORY SERVICES (LS)

LS.1 ORGANIZATION

SR.1 The organization shall maintain, or have available, adequate laboratory services, either directly or through contractual services, to meet the needs of its patients.

SR.2 The organization shall ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with 42 CFR §493.

SR.3 The organization shall have the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day.

SR.4 A documented scope of laboratory services shall be available to the medical staff.

SR.5 The laboratory shall have policies and practices for proper receipt and reporting of tissue specimens.

SR.6 The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

LS.2 INFECTIOUS BLOOD AND PRODUCTS

Potential human immunodeficiency virus (HIV) or hepatitis C virus (HVC) *(as identified in 21 CFR 610.47)* infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the HIV or HCV on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, and the timing of seroconversion cannot be precisely estimated.

SR.1 If an organization regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products.

SR.2 The agreement shall require that the blood bank promptly notify the organization of the following:

SR.2a Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV or HCV on a later donation; and

SR.2b the results of the FDA licensed, more specific test or other follow-up testing recommended or required by the FDA completed within forty five (45) calendar days after the donor's repeatedly reactive screening test for HIV or HCV.

SR.2c Within 3 calendar days after the blood bank supplied blood and blood components collected from an infectious donor, whenever such records are available (as set forth at 21 CFR 610.48(b)(3)).

SR.2d quarantine of blood and blood products pending completion of testing: If the blood bank notifies the organization of the repeatedly reactive HIV or HCV screening test results, the organization shall determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

SR.3 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the organization may release the blood and blood products from quarantine.

SR.4. If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the organization shall dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify the transfusion recipients according to LS.3.

SR.5 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is indeterminate, the organization must destroy or label prior collections of blood and blood products held in quarantine (as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2)).

SR.6 The hospital must maintain adequate records which identify the source and disposition of all units of blood and blood components for no less than ten (10) years from the date of disposition in manner reflecting QM.2 SR.3b and are stored in such a manner they are available for prompt retrieval.

SR.6a The organization will have a plan in place to transfer these records to another hospital or other entity if the hospital ceases its operations for any reason. The organization will have allocated adequate funding to execute this plan when necessary.

LS.3 PATIENT NOTIFICATION

If the organization has administered potentially HIV or HCV infectious blood or blood products, either directly through its own blood bank or under an agreement, or released such blood or blood products to another entity or appropriate individual, the organization shall take the following actions:

SR.1 Promptly make at least three attempts to notify the patient, and/or patient's attending physician (the physician of record) or the physician who ordered the blood or blood product. (See LS.3 SR.7 regarding notification of legal representative when applicable)

SR.2 Request that the physician immediately notify the patient, or other individual of the need for HIV testing and counseling.

SR.3 If the physician is unavailable, declines to make the notification, or later informs the organization that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, legal representative or relative of the need for HIV or HCV testing and counseling.

SR.4 Document in the patient's medical record the notification or attempts to give the required notification.

SR.5 Timeframe for notification:

(*For donors tested on or after February 20, 2008 – for notifications resulting from donors tested on or after February 20, 2008 as set forth in 21 CFR 610.46 and 21 CFR 610.47*):

The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification for no less than twelve (12) weeks unless:

SR.5a the patient is located and notified; or

SR.5b the organization is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the organization's control that caused the notification timeframe to exceed twelve (12) weeks.

(F*or donors tested before February 20, 2008 – for notifications resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48(b) and (c)*:

SR.5c The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification and must complete the actions within one (1) year of the date on which the organization received notification from the blood bank.

Note: HCV notification requirements resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48 is set to expire on August 24, 2015.

SR.6 Content of notification: The notification shall include the following information:

SR.6a a basic explanation of the need for HIV or HCV testing and counseling;

SR.6b enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV or HCV testing and counseling; and,

SR.6c a list of programs or places where the patient can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

SR.7 Policies and Procedures: The organization shall establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records. A notification to legal representative or relative shall address the following:

SR.7a if the patient has been adjudged incompetent by a State court, the physician or organization shall notify a legal representative designated in accordance with State law;

SR.7b if the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or organization shall notify the patient or his/her legal representative or relative; and,

SR.7c if the patient is deceased, the physician or organization shall continue the notification process and inform the deceased patient's legal representative or relative.

SR.7d If the patient is a minor, the physician or organization must notify the patient's parents or legal guardian.

LS.4 GENERAL BLOOD SAFETY

For look-back activities only related to new blood safety issues that are identified after August 27, 2007, the organization must comply with FDA regulations as they pertain to blood safety issues in the following areas:

SR.1 Appropriate testing and quarantining of infectious blood and blood components.

SR.2 Notification and counseling of recipients that may have received infectious blood and blood components.

RESPIRATORY CARE SERVICES (RC)

RC.1 ORGANIZATION

SR.1 The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

SR.2 Respiratory care services provided at the organization shall be delivered in accordance with medical staff directives.

SR.3 There shall be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly.

SR.4 There shall be appropriate numbers of respiratory therapists, respiratory therapy technicians and other qualified personnel whose training meets the qualifications specified by the medical staff and State law.

RC.2 PHYSICIAN ORDER

An order from a doctor of medicine or osteopathy is required for the provision of respiratory treatments and interventions.

RC.3 POLICIES OR PROTOCOLS

Written policies or protocols shall specify:

SR.1 Which personnel are qualified to perform specific procedures; and,

SR.2 The amount of supervision required

RC.4 TESTS OUTSIDE THE LABORATORY

If blood gases or other laboratory tests are performed in the areas other than the lab, including the respiratory care unit, that area shall meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

MEDICAL IMAGING (MI)

MI.1 ORGANIZATION

SR.1 The organization shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements according to patient needs. The medical imaging services, particularly ionizing medical imaging procedures shall be free from hazards for patients and personnel.

SR.2 If therapeutic services are also provided, they shall meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements.

MI.2 RADIATION PROTECTION

SR.1 Proper radiation safety precautions shall be maintained, including adequate shielding for patients, staff, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

SR.2 Staff who work in radiation areas shall be monitored continually for the amount of radiation exposure by the use of exposure meters or badge dosimeters. This includes licensed independent practitioners who may be exposed to ionizing radiation during procedures.

SR.3 Any high radiation readings must be investigated and reported to Quality Management Oversight.

MI.3 EQUIPMENT

SR.1 Periodic inspection of equipment shall be performed, at least minimally according to manufacturer's recommendations. Hazards shall be identified and promptly corrected.

SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained.

MI.4 ORDER

Medical imaging services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners approved by the medical staff and the governing body and authorized to order the services.

MI.5 SUPERVISION

SR.1 A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing medical imaging services and shall interpret those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge.

SR.2 For purposes of this standard, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

MI.6 STAFF

Only staff designated as qualified by the medical staff, governing body, and State and/or Federal law may use the medical imaging equipment and perform medical imaging procedures.

MI.7 RECORDS

Records of medical imaging services must be maintained, in accordance with Nuclear Regulatory Commission requirements and any other applicable Federal and State law.

MI.8 INTERPRETATION AND RECORDS

SR.1 The radiologist or other practitioner who interprets radiology images and outcomes must sign the written reports of his/her interpretations.

SR.2 The organization must maintain the following for at least 5 years:

SR.2a copies of reports and printouts; and,
SR.2b films, scans, and other image records.

NUCLEAR MEDICINE SERVICES (NM)

NM.1 ORGANIZATION

SR.1 If the organization provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice as defined by the medical staff. The nuclear medicine services shall be free from hazards for patients and personnel.

SR.2 The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

SR.3 There shall be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

SR.4 The qualifications, training, functions, and responsibilities of nuclear medicine staff shall be specified by the service director and approved by the medical staff.

SR.5 Nuclear medicine services shall be ordered only by practitioners whose scope of Federal or State licensure and defined staff privileges allow such referrals.

NM.2 RADIOACTIVE MATERIALS

SR.1 Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the medical staff.

SR.2 The organization must maintain records of the receipt and disposition of radiopharmaceuticals.

SR.3 In-house preparation of radiopharmaceuticals shall be by or under the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

SR.4 If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

NM.3 EQUIPMENT AND SUPPLIES

SR.1 Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.

SR.2 The equipment must be maintained in safe operating condition and inspected, tested, and calibrated at least annually by qualified personnel.

SR.3 Documentation of equipment testing and preventative maintenance shall be maintained.

NM.4 INTERPRETATION

SR.1 The practitioner approved by the medical staff to interpret diagnostic procedures must sign the interpretation of these tests.

SR.2 The organization must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

SR.3 The organization must maintain copies of nuclear medicine reports for at least five (5) years.

REHABILITATION SERVICES (RS)

RS.1 ORGANIZATION

SR.1 If the organization provides rehabilitation, physical therapy, occupational therapy, audiology or speech pathology services, the service(s) shall be provided in a manner that ensures the patient's health and safety.

RS.2 MANAGEMENT AND SUPPORT

SR.1 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include:

SR.1a a director/manager who has the responsibility for the management, direction and accountability for ensuring services are carried throughout the organization;

SR.1b the director/manager shall have the qualifications, experience and/or training defined by the organization and appropriate for this position;

SR.1c staff who meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

RS.3 TREATMENT PLAN

The organization shall have a written treatment plan that is in accordance with the practitioner's orders who are authorized by the medical staff to order the services. The orders, treatment plan and results, notes and other related documentation shall be maintained in the patient's medical record.

SR.1 The treatment plan and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of § 409.17.

OBSTETRIC SERVICES (OB)

OB.1 COMPLIANCE

Obstetrical services will comply with recommendations of the American College of Obstetrics and Gynecology.

OB.2 ANESTHESIA SERVICES

SR.1 If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with the recommendations of the American Society of Anesthesiology.

SR.2 If a patient has received epidural analgesia, there will be a practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition.

EMERGENCY DEPARTMENT (ED)

ED.1 ORGANIZATION

SR. 1 The organization must meet the emergency needs of its patients in accordance with acceptable standards of practice.

SR.2 Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.

SR.3 The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered.

ED.2 STAFFING

SR.1 Adequate medical and nursing staff qualified in emergency care, as outlined in the written scope of service, must be present to meet the written emergency procedures and needs determined by the organization.

SR.2 A qualified registered nurse shall perform patient triage upon presentation to the emergency department.

ED.3 EMERGENCY SERVICES NOT PROVIDED

If emergency services are not provided at the organization, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

ED.4 OFF-CAMPUS DEPARTMENTS

The medical staff shall have written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided.

OUTPATIENT SERVICES (OS)

OS.1 ORGANIZATION

If the organization provides outpatient services, the services shall be appropriately organized and integrated with inpatient services.

OS.2 STAFFING

The organization shall assign an individual to be responsible for outpatient services and have appropriate professional and nonprofessional staff available.

OS.3 SCOPE OF SERVICE

A documented scope of service shall be available for each patient care site that includes core staffing for each site with associated staff responsibilities.

DIETARY SERVICES (DS)

DS.1 ORGANIZATION

SR.1 Dietary Services are organized processes that shall be carried out internally or through a contract with a nutrition management company that interacts on a regular basis with the medical staff on dietetic policies affecting patient care.

SR.2 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include a full-time person responsible for the management, direction and accountability for ensuring food and dietetic services are carried out daily throughout the organization. This full-time person shall have the qualifications, experience and training defined by the organization and appropriate for the position;

SR.3 The full-time person responsible for the management of Food and Dietetic Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the organization.

SR.4 The organization shall have a qualified dietitian in the organization who is available to address issues, concerns and patient care planning. This dietitian shall be employed by the organization on a full-time or part-time basis or contracted as a consultant for the organization and available as needed.

DS.2 SERVICES AND DIETS

Dietary Services shall be provided and menus/diets offered that meet the needs of the patients. The following criteria shall be applied:

SR.1 All menus/diets offered must meet the needs of the patients

SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; and,

SR.3 All nutritional needs of patients shall be met in accordance with recognized dietary practices that are consistent with the orders of the practitioner or practitioners responsive for the care of the patients.

DS.3 DIET MANUAL

SR.1 The organization shall maintain a written dietary manual that defines the current therapeutic diets used by the organization.

SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the medical staff.

SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The organization shall protect and promote each patient's rights. The organization shall inform, whenever possible, each patient and/or legal representative (as allowed under State law) of the patient's rights in advance of providing or discontinuing care and allow the patient to exercise his or her rights accordingly. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

SR.1 Beneficiary Notice of non-coverage and right to appeal premature discharge;

SR.2 Patient participation and means for making informed decisions regarding his/her plan of care;

SR.3 Information to the patient or family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of treatment or services deemed medically unnecessary or inappropriate;

SR.4 Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;

SR.5 Personal privacy;

SR.6 Provision of care in a safe setting;

SR.7 Freedom from all forms of abuse or harassment;

SR.8 Confidentiality of clinical records;

SR.9 Access information contained in his or her clinical records within a reasonable timeframe; and,

SR.9(a) The hospital must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.

SR.10 Procedure for submission of a written or verbal grievance. (See PR.5 Grievance Procedure)

SR.11 Pain Management

SR.12 Other rights defined within the Patient Rights requirements (PR.1 – PR.8)

PR.2 ADVANCE DIRECTIVE

The organization must allow the patient to formulate advance directives and to have organization staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

SR.1 The organization shall document in the patient's medical record whether or not the patient has executed an advance directive.

SR.2 The organization shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.

SR.3 The organization shall ensure compliance with State law regarding the provision of an advance directive.

SR.4 The organization shall provide education for staff regarding the advance directive.

SR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

PR.3 LANGUAGE AND COMMUNICATION

The organization shall inform the patient and/or legal representative of their rights in language or format that the patient and/or legal representative understand.

SR.1 Organization policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

PR.4 INFORMED CONSENT

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

PR.5 GRIEVANCE PROCEDURE

The organization shall develop and implement a formal grievance procedure for submission of a patient's written or verbal grievance to the hospital, approved by the governing body, that provides for the following:

SR.1 A list of whom to contact;

SR.2 The governing body responsibility for effective operation of the grievance process. The governing body must review and resolution of grievances or the written delegation of this function to an appropriate person or committee ;

SR.3 A process for timely referral of quality of care issues or premature discharge to the Utilization Review, Quality Management or Peer Review functions and Utilization and Quality Improvement Organizations (QIO), as appropriate; and,

SR.4 Specification of reasonable timeframes for review and response to grievances.

SR.5 Grievance resolutions must be in writing and directed to the patient. The grievance resolution shall include the following:

SR.5a organization contact person;
SR.5b steps taken to investigate;
SR.5c results of the grievance process; and,
SR.5d date of completion.

PR.6 RESTRAINT OR SECLUSION

All patients have the right to be free from physical or mental abuse, and corporal punishment.
All patients have the right to be free from restraint or seclusion, of any form, that is not medically necessary, or that is imposed by staff as a means of coercion, discipline, convenience, or retaliation. Each patient should be treated with respect and dignity.

SR.1 The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.

SR.1a A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

SR.1b A restraint includes a drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

SR.1c Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion

Seclusion may only be used for the management of violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

SR.2 The hospital will keep the patient safe and protect their rights when restraint or seclusion are applied.

SR.2a. The hospital will have policies and procedures designed to protect patient rights and dignity with regards to the use of restraint and seclusion, and ensure safety of the patient, staff and others. These policies and procedures guide staff in the safe use of restraint or seclusion, and incorporate all elements of the Federal and State regulations.

SR.2b. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.

SR.2c. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.

SR.2d. The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.

SR.2e. The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

SR.2f. Restraint and seclusion may not be used simultaneously, unless the patient is continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.2f(1) This monitoring must be in close proximity to the patient.
SR.2f(2) For the purposes of this provision, "continually" means ongoing without interruption

SR.3 Order for Restraint or Seclusion:

SR.3a. The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner (LIP) who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law.

SR.3b. An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;

SR.3c. An order for restraint or seclusion is never to be written as a standing order or on an as needed basis (PRN).

SR.3d. The attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.

SR.3e. Each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient.

SR.3e(1) Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1- hour for children under 9 years of age.
SR.3e(2) The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.

SR.3e(3) After 24 hours, and before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior a physician or other LIP (if allowed by State law) must see and assess the patient.

SR.3e(4)If the restraint or seclusion is discontinued prior to the expiration of the order, a new order must be obtained prior to re-initiation of the restraint or seclusion.

SR.3f. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy, at least each calendar day.

SR.4 One Hour Face-to-Face Evaluation

The condition of the patient must be continuously assessed, monitored, and reevaluated.

SR.4a. When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under PR.7 must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate:

SR.4a(1) The patient's immediate situation;
SR.4a(2) The patient's reaction to the intervention;
SR.4a(3) The patient's medical and behavioral condition; and,
SR.4a(4) The need to continue or terminate the restraint or seclusion.

SR.4b. If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation.

SR.5 Assessment, Monitoring, and Evaluation of the Restrained or Secluded Patient

SR.5a. The condition of patients in restraint or seclusion is monitored and assessed by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy, at least every 24 hours.

SR.5a(1) Hospital policies address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).

SR.5a(2) Hospital policies guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. (for example, every 15 minutes)

SR.5b. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

SR.5c. The LIP must evaluate the patient even if the patient is removed from restraint prior to the expiration of the order within 24 hours of the order initiation.

SR.5d. If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.5d(1) This monitoring must be in close proximity to the patient.
SR.5d(2) For the purposes of this provision, "continually" means ongoing without interruption

SR.6. Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

SR.6a(1) A description of the patient's behavior and the intervention used;

SR.6a(2) Alternatives or other less restrictive interventions attempted (as applicable);

SR.6a(3) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,

SR.6a(4) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention

SR.6a(5) The 1-hour face- to-face medical and behavioral evaluation and assessment findings if restraint or seclusion is used to manage violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;

SR.6a(6) Monitoring and assessment activities

SR.6a(7) Written modification to the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.

SR.6a(8) The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.

SR.6a(9) Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.

SR.6b. In addition, staff must document in the patient's medical record the date and time any death associated with restraint or seclusion use was reported to CMS. (see section on Report of Death)

SR.7 Quality Monitoring

SR.7a. The use of restraint and seclusion is to be monitored and evaluated on a continual basis as part of the organization's Quality Management System. (See also QM.7.SR.6)

SR.7b Evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed by the treatment team.

SR.7c Aggregate data regarding the use of restraint must be collected and analyzed for the identification of patterns and trends. Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

PR.7 RESTRAINT OR SECLUSION: STAFF TRAINING REQUIREMENTS

The patient has the right to safe implementation of restraint or seclusion by trained staff.

SR.1 Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion

SR.1a. Training must occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.

SR.2 The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

SR.2a. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;

SR.2b. The use of non-physical intervention skills, including de-escalation and dealing with aggressive behavior;

SR.2c. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition;

SR.2d. The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

SR.2e. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;

SR.2f. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and;

SR.2g. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including recertification requirements.

SR.3 At a minimum, physicians and other LIP's authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of the hospital policy regarding the use of restraint or seclusion.

SR.3a. Physician and other LIP training requirements must be specified in hospital policy

SR.4 Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

SR.5 The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed

PR.8 RESTRAINT OR SECLUSION: REPORT OF DEATH

SR.1 Hospitals must report deaths associated with the use of restraint or seclusion directly to CMS in accordance with 42 CFR 482.13(g), the Conditions of Participation, and the State Operations Manual.

SR.2 Staff must document in the patient's medical record the date and time the death was reported to CMS.

INFECTION CONTROL (IC)

IC.1 INFECTION CONTROL SYSTEM

SR.1 The organization shall have a process in place, as required and/or recommended by the Centers for Disease Control (CDC) and related professional organizations, to maintain a sanitary environment for organization patients, staff, and others. This process shall provide the means for avoiding and transmitting infections and communicable diseases.

SR.2 The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization.

SR.3 The Infection Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight.

SR.4 The documented process shall define the following:

SR.4a there shall be a designated Infection Control Officer that has the appropriate qualifications and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases;

SR.4b any designated practitioner shall have completed a course in basic surveillance by a recognized body. If in the role five (5) years or longer there must be evidence of pertinent continuing education related to infection control, minimally every two (2) years;

SR.4c the process for identifying, reporting, investigating and controlling infections and communicable diseases; and,

SR.4d the maintaining and control of records to account for incidents related to infections and communicable diseases.

SR.5 Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.

SR.6 The organization, through its chief executive officer, medical staff and nurse executive shall ensure that the Infection Control System and associated activities adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues and provide adequate resources to accomplish the associated activities of the infection control program,

SR.7 Significant infection control data/information shall be disseminated no less than quarterly to the organization oversight group responsible for the infection control function.

SR.8 Surveillance methodology shall be appropriate for the population(s) served and approved no less than annually by the Infection Control oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illnesses

MEDICAL RECORDS SERVICE (MR)

MR.1 ORGANIZATION

SR.1 Administrative responsibility for medical records shall rest with the medical record service of the organization.

SR.2 The organization shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

MR.2 COMPLETE MEDICAL RECORD

SR.1 The organization shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.

SR.2 The organization shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.

SR.3 Authenticity and security of all record entries shall be safeguarded.

MR.3 RETENTION

SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years.

SR.2 The coding and indexing system shall be designed in such a way that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

MR.4 CONFIDENTIALITY

SR.1 Confidentiality of patient records shall be assured.

SR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.

SR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.

SR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

MR.5 RECORD CONTENT

SR.1 The medical record shall contain information to:

SR.1a justify admission and continued hospitalization;
SR.1b support the diagnosis; and,
SR.1c describe the patient's progress and response to medications and services

SR.2 All entries shall be:

SR.2a legible, complete, dated and timed; and,

SR.2b authenticated by the person responsible for providing or evaluating the services provided consistent with hospital policy.

SR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

SR.4 All orders must be dated, timed and authenticated promptly by the prescribing practitioner.

SR.5 Verbal orders must be in accordance with Federal and State law and authenticated within forty (48) hours or earlier if required by State law.

SR.5(1) Telephone or verbal orders are to be used infrequently and when used must be accepted only by Personnel authorized by the medical staff and in accordance with Federal and State law.

SR.5(2) Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

SR.5(3) For the limited time period defined in 42 CFR §482.24(c)(1)(ii), all such orders may be dated, timed and authenticated by another practitioner who is responsible for the patient's care as specified in 42 CFR §482.12(c) and who is authorized to write orders in accordance with hospital policy and State law.

MR.6 IDENTIFICATION OF AUTHORS

The organization shall have a system to identify the author of each entry into the medical record.

MR.7 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

SR.1 Evidence of a physical examination, including a health history, must performed no more than thirty (30) days prior to admission or within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services:

SR.1a the history and physical completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services; and placed in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

SR.1b when the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

SR.2 Admitting diagnosis,

SR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,

SR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,

SR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,

SR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition,

SR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,

SR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge

DISCHARGE PLANNING (DC)

DC.1 WRITTEN POLICIES

SR.1 Written policies shall be in place to establish a system for discharge planning that applies to all patients.

SR.2 At an early stage of hospitalization, all patients who are at risk for negative outcomes without adequate discharge planning shall be identified and a plan developed to account for the patient's needs.

SR.3 A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge planning evaluation for or upon the request of:

SR.3a the patients identified in the above paragraph;
SR.3b any patients upon their request;
SR.3c a person acting on the patient's behalf; or,
SR.3d the patient's physician.

DC.2 DISCHARGE PLANNING EVALUATION

SR.1 The discharge planning evaluation shall include:

SR.1a an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services; and,
SR.1b an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the organization.
SR.1c A means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services, and must, when possible, respect patient and family preferences when they are expressed.

SR.2 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.

SR.3 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.

SR.4 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan and associated educational materials.

DC.3 PLAN IMPLEMENTATION

SR.1 The initial implementation of the patient's discharge plan shall be performed by the organization.

SR.2 Patients shall be transferred or referred with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed.

SR.3 When the discharge planning evaluation determines a referral is medically appropriate, the organization shall give the patient a list of Medicare-participating providers (including those qualified to receive the patient from the patient's managed care organization where applicable) that are available and serve the geographical area where the patient resides. The organization shall document in the medical record that the patient (or authorized representative) received a copy of the list and was advised of his/her freedom of choice.

SR.3a The organization must respect the choice of the patient or authorized representative except in unusual circumstances. The organization may not lead, direct, specify or otherwise limit the selection of qualified Medicare-participating providers.

SR.3b The organization must identify in writing any Medicare-participating providers to which the patient is referred in which the organization has a disclosable financial interest and any Medicare-participating providers that has a disclosable financial interest in the organization. Disclosable financial interests are defined by 42 CFR §420, Subpart C.

SR.4 When the organization must transfer or refer patients, the necessary medical information and other supporting documentation must be provided to appropriate facilities, agencies or outpatient services as needed, for follow-up or ancillary care.

DC.4 EVALUATION

SR.1 The discharge plan shall be periodically reevaluated on an on-going basis to provide for changes in the patient's condition or circumstances. The reassessment must include a review of the discharge plans to ensure that they are responsive to discharge needs.

SR.2 As needed, the patient and family members or interested persons shall be educated to prepare them for post-hospital care.

UTILIZATION REVIEW (UR)

UR.1 DOCUMENTED PLAN

The organization shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients, particularly those patients entitled to benefits under both Medicare and Medicaid. The plan shall include:

SR.1 Responsibilities and authority for those involved in utilization review activities in a Utilization Review (UR) Committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners as defined in MS.15 (SR.1)

SR.1(a) A staff committee of the institution; or

SR.1(b) A group outside the institution established by the local medical society and some or all of the hospitals in the locality; or

SR.1(c) Established in a manner approved by CMS.

SR.1(d) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as such that;

SR.1(d)(1) The committee or group's reviews may not be conducted by any individual who ;

SR.1(d)(1)(a) Has a direct financial interest (for example, an ownership interest) in the hospital; or

SR.1(d)(1)(b) Was professionally involved in the care of the patient whose case is being reviewed.

SR.2 Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

SR.3 Provision for avoidance of conflict by prohibiting any individual with any financial or professional involvement in the case from participating in the review. This shall be strictly enforced.

SR.4 Review of:

SR.4a. medical necessity of admissions and extended stays;
SR.4b. appropriateness of setting; and,
SR.4c. medical necessity of professional services.

UR.2 SAMPLING

The review may be done before, at or after admission and may be conducted by sampling. The review shall include medical necessity for the following:

SR.1 Admissions;

SR.2 Length of stay; and,

SR.3 Professional services furnished, including medications.

UR.3 MEDICAL NECESSITY DETERMINATION

SR.1 The committee must review professional services, to determine medical necessity and to promote the most efficient use of available health facilities and services.

SR.2 The determination that an admission or continued stay is not medically necessary may be made by two members of the Quality Management Oversight group after the practitioner(s) caring for the patient has (have) been notified and given an opportunity to present his/her views.

SR.2a Practitioner(s), the organization and the patient must receive written notification of a decision that admission or continued stay is determined to be not medically necessary.
SR.2b The notification must be given no later than two (2) days after such decision is made.

UR.4 EXTENDED STAY REVIEW

The utilization review plan must include a process to periodically review all patients who receive services during a continuous period of extended duration.

SR.1 For organizations paid under the prospective payment system, all patients whose length of stay is considered an outlier must be reviewed.

SR.2 All reviews must be conducted no later than seven (7) days after the day required in the utilization review plan.

PHYSICAL ENVIRONMENT (PE)

PE.1 FACILITY

The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special organization services appropriate to the needs of the community.

SR.1 The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.

SR.,2 The hospital must maintain adequate facilities for its services.

SR.2 (a) Diagnostic and therapeutic facilities must be located for the safety of patients.

SR.2. (b) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

SR.2 (c) The extent and complexity of facilities must be determined by the services offered.

SR.3 The organization shall have a process in place, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization's patients, staff, and others.

SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the organization.

SR.5 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.

SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.

SR.7 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues.

SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

PE.2 LIFE SAFETY MANAGEMENT SYSTEM

SR.1 The organization shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association.

SR.1a Effective March 13, 2006 a hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf, Chapter 19.3.6.3.2, exception number 2.

SR.1b. A hospital has until March 31, 2006, to replace 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources, Chapter 19.2.9, Emergency Lighting.

SR.2 Any hospital that on November 26,1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code®, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Life Safety Code®.

SR.3 After consideration of the State survey agency findings, CMS may waive specific provisions of the Life Safety Code®, which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

SR.3a The provisions of the Life Safety Code® do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protect patients.

SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):

The organization shall establish a Life Safety Management System that provides for written fire control processes that contain provisions for:

SR.4a. Use of alarms

SR.4b. Transmission of alarm to fire department

SR.4c. Response to alarms

SR.4d. Isolation of fire

SR.4e. Evacuation of immediate area

SR.4f. Evacuation of smoke compartment

SR.4g. Preparation of floors and building for evacuation

SR.4h. Extinguishment of fire

SR.5 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.

SR.6 Health care occupancies shall conduct unannounced fire drills regularly, but not less than one (1) drill per shift per building each calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. (NFPA 101-2000, 18.7.1.2. & 19.7.1.2). False alarms may be used (up to 50% of total drills) if all elements of the fire plan are exercised.

Business occupancies shall conduct at least one unannounced fire drill annually per shift.

SR.6a. Fire drills must be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2, SR.4

SR.6a.(i) At least annually, the organization shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.

SR.7 The Life Safety Management System shall address applicable Interim Alterative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired , or deficiencies deficient are created or occur. Thorough documentation is required.

SR.7a. All alternative life safe measures must be approved by the authority having local jurisdiction

SR.8 Life Safety Management System shall require that Life Safety systems (e.g., fire alarm suppression, notification, and detection equipment) shall be is tested and inspected (including portable systems).

SR.9 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.

SR.10 The Life Safety Management System shall require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

SR.11 Construction, Repair, and Improvement operations shall involve the following activities:

SR.12.a During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 2006 edition, published by the American Institute of Architects shall be consulted for designing purposes.

SR.12. b The organization shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).

SR.12. c In occupied areas where construction, repairs, or improvement operations occur, all required means of egress and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.

NFPA 241-1996, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.

SR.12. d All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2000 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

PE.3 SAFETY MANAGEMENT SYSTEM

SR.1 The organization shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients.

SR.2 The Safety Management System shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.

SR.3 The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

SR.4 The Safety Management System shall require that the organization maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

SR.5 The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.

SR.6 The Safety Management System shall address safety recalls and alerts.

PE.4 SECURITY MANAGEMENT SYSTEM

SR.1 The organization shall develop a Security Management System that provides for a secure environment.

SR.2 The Security Management System shall provide for identification of patients, employees and others.

SR.3 The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.

SR.4 The Security Management System shall establish emergency security procedures to include all hazard events

SR.5 The Security Management System shall require vehicular access to emergency service areas.

SR.6 The Security Management System shall require a process for reporting and investigating security related issues.

PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT SYSTEM

SR.1 The organization shall provide a Hazmat Management System to manage hazardous materials and waste.

SR.2 The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.

SR.3 The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.

SR.4 The organization monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.

SR.5 Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if:

SR.5a. Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

SR.5b. The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

SR.5c. The dispensers are installed in a manner that adequately protects against inappropriate access

SR.5d. The dispensers are maintained in accordance with dispenser manufacturer guidelines.

SR.5e. If dispensers are stored in corridors, the corridor must be a minimum of 72 inches.

SR.5f. The maximum individual dispenser fluid capacity shall be:

- 1.2 liters (0.3 gallons) for dispensers in rooms, corridors, and areas open to corridors.
- 2.0 liters (0.5 gallons) for dispensers in suites of rooms.

SR.5g. The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.

SR.5h. Not more than an aggregate 37.8 liters (10 gallons) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.

SR.5i. Storage of quantities greater than 18.9 liters (5 gallons) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code.*

SR.5j. The dispensers shall not be installed over or directly adjacent to an ignition source.

SR.5k. In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

SR.5l. Where minimum corridor width is 72 inches (1830 mm), projections of maximum 6 inches (152 mm) from the corridor wall, above the handrail, shall be permitted for the installation of hand-rub dispensing units.

SR.6 In anesthetizing locations, which use alcohol-based skin preparations, have implemented effective fire risk reductions measures which include:

SR.6a. The use of unit dose skin prep solutions

SR.6b. Application of skin prep follows manufacture/supplier instructions and warnings.

SR.6c. Sterile towels are used to absorb drips and runs during the application and then removed from the anesthetizing location prior to draping

SR.6d. Verifying that all of the above has occurred prior to initiating the surgical procedure.

SR.7 Verify that nonflammable medical gas located outside of an enclosure, in use for patients, does not exceed 300 cubic feet per smoke compartment.

PE.6 EMERGENCY MANAGEMENT SYSTEM

SR.1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.

SR.2 The organization shall meet the requirements set forth in NFPA 99, Chapter 12, Emergency Management.

SR.3 The Emergency Management System shall require that the organization conduct a hazard vulnerability analysis to identify potential emergencies in the organization and the community.

SR.4 The Emergency Management System shall establish an emergency process to address the potential hazards to the organization and the community. The hospital shall conduct an organization-wide emergency management exercise, including the triage and disposition of patients. The organization-wide emergency management exercises, including the triage and disposition of patients, shall be conducted no less frequently than twice per year

SR.4a. Emergency management exercises shall test the most threatening hazard(s) identified in the HVA and tax the resources of the organization.

SR.4b. At least every other emergency management exercise shall be conducted with the community to evaluate surge capacity, the integration of Incident Command and intraoperability of communications.

SR.4c The organization shall formulate an After Action Report of all emergency management exercises to identifying opportunities for improvements and revise its emergency management plan according to the identified opportunities for improvement.

SR.5 The Emergency Management System processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.

SR.6 The Emergency Management System shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organizational, community, or regional crisis.

SR.7 The organization shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.

SR.2 The Medical Equipment Management System shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for of demonstration or rental or physician owned equipment.

SR.3. The Medical Equipment Management System shall address criteria for the selection of equipment.

SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).

SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.

SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.

SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

PE.8 UTILITY MANAGEMENT SYSTEM

SR.1 The organization shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for organization-acquired illnesses.

SR.2 The Utility Management System shall provide for a process to evaluate critical operating components.

SR.3 The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.

SR.4 The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).

SR.5 The Utility Management System shall provide for emergency processes for utility system failures or disruptions.

SR.6 The Utility Management System shall provide for reliable emergency power sources with appropriate maintenance as required.

SR.7 The Utility Management System shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.

SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the organization (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.

Emergency lighting standards shall comply with Section 7.9 of Life Safety Code, 101-2000, and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

SR.9 There shall be facilities for emergency gas and water supply.

SR.10 All relevant utility systems shall be maintained inspected, and, tested,

ORGAN, TISSUE AND EYE PROCUREMENT (TO)

TO.1 PROCESS

SR.1 The organization shall have a process in place for the procurement of organs, tissue, and eyes. The organization shall have an agreement with at least one tissue bank and one eye bank.

TO.2 ORGAN PROCUREMENT ORGANIZATION (OPO) WRITTEN AGREEMENT

The organization shall have a written agreement an OPO designated under 42 CFR §486. Per SR.1 through SR.5 (below), this agreement shall:

SR.1 Contain procurement protocols that have been approved by the organization's governing body and medical staff,

SR.2 Ensure that timely notification is provided to the OPO or a third party designated by the OPO for all individuals whose death is imminent or who have died in the hospital,

SR.3 Ensure communication of the policy for organ, tissue and eye procurement to all appropriate area of the organization, in addition to any revisions or modifications under a controlled document,

SR.4 Acknowledge that it is the OPO's responsibility for the determination of medical suitability for organ donation, and, in the absence of alternative arrangements by the organization, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the organization for this purpose.

SR.5 Ensure, in collaboration with the designated OPO, that the family or each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. If a designated requestor is responsible for initiating this request, this individual must have completed a course offered or approved by the OPO that has been designed in conjunction with the tissue and eye bank

community in the methodology for approaching potential donor families and requesting organ or tissue donation.

SR.6 Ensure that it works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining

potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

TO.3 ALTERNATIVE AGREEMENT

In the event the organization has an alternative agreement with a tissue and/or eye bank, this agreement shall:

SR.1 Specify the criteria for referral of all individuals who have died in the organization, and,

SR.2 Acknowledge the OPO's responsibility for the determination of medical suitability in lieu of any alternative arrangement with a different tissue and/or eye bank

TO.4 RESPECT FOR PATIENT RIGHTS

The organ, tissue and eye procurement policies, procedures and practices shall demonstrate the respect for individual patient and family rights that reflect their views, religious beliefs and other special circumstances that have been communicated by the patient and/or family to the organization personnel.

TO.5 DOCUMENTATION

Documents and records of organ procurement will be maintained in the manner directed by the OPO.

TO.6 ORGAN TRANSPLANTATION

If the organization performs organ transplantation, the organization shall:

SR.1 Be a member in the Organ Procurement and Transplantation Network (OPTN), which is established and operated in accordance with section 372 of the Public Service Act (42. U.S.C 274) and abide by its rules,

SR.2 Define the term "organ" as to what transplantation is done. The consistency in terms shall apply to a kidney, liver, heart, lung or pancreas, and,

SR.3 Provide data related to the performance of organ transplantation as requested by the OPTN, the Scientific Registry of Transplant Recipients and the OPO. The organization shall be required to provide this data to CMS as requested by the Secretary.

TO.7 TRANSPLANT CANDIDATES

SR.1 The organization shall ensure the appropriate candidates for receipt of transplanted organs have been screened, matched and medically cleared prior to receipt of any organs.

SR.2 Candidate information shall be documented, accurate and available at the time of the organ transplantation.

SR.3 Authority for transplantation shall be co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

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DNV ACCREDITATION PROGRAM
FREQUENTLY ASKED QUESTIONS
JANUARY 11, 2010

Who is DNV Healthcare Inc?

DNV Healthcare Inc. (DNVHC) is an operating company of Det Norske Veritas (DNV). DNVHC has corporate offices in Houston, Texas and Cincinnati, Ohio. DNV is an international, independent, self-supported, tax-paying foundation that has more than 300 offices in over 100 countries and more than 9,000 employees. Established in 1864 in Oslo, Norway, DNV operates 15 offices in the United States and has been in this country since 1898. The corporate purpose of DNV is safeguarding life, property, and the environment. DNV has a worldwide reputation for quality and integrity in certification, standards development and risk management in a wide range of industries, including extensive international healthcare experience. On September 26, 2008 the US Centers for Medicare and Medicaid (CMS) approved DNVHC by granting it deeming authority for hospitals. Any hospital accredited by DNVHC after that date is deemed to be in compliance with the Medicare Conditions of Participation (CoPs).

Who manages DNVHC?

DNVHC is managed by a dedicated group of degreed professionals, each with many years of experience in their respective field of healthcare management, clinical services, health law, ISO certification and engineering. The accreditation management team has extensive healthcare operational experience in the U.S. and understands the dynamics of a complex healthcare organization.

What does NIAHO℠ stand for?

NIAHO℠ is the acronym for the National Integrated Accreditation for Healthcare Organizations. NIAHO℠ is the name of DNVHC's hospital accreditation program. The NIAHO℠ standards integrate requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standard for the formation and implementation of the Quality Management System. ISO 9001 is the infrastructure of quality that infiltrates every aspect of your organization – it enables an organization to reach maximum effectiveness and efficiency in its processes that leads to improved outcomes, both clinically and financially. These two sets of standards form the basis of DNVHC's revolutionary Integrated Accreditation concept in NIAHO℠.

Does the hospital have to be ISO compliant before it can receive DNV accreditation?

No. You can be accredited by DNV immediately after the first survey without being in compliance with ISO 9001. In fact, unless the hospital is currently involved with ISO, it is not expected to be in ISO 9001 compliance at the time of the first survey. The hospital has three years to become compliant with ISO 9001 after the first DNV survey. After submitting an acceptable Corrective Action Plan, if needed, and upon approval by the Accreditation Committee, DNV's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is

determined by CMS. The hospital then has up to three years to become ISO 9001 compliant. The first survey has two goals- conduct a CMS deemed-status accreditation survey for Medicare certification and introduce the hospital to the ISO 9001 Standard. The second year accreditation survey includes an ISO 9001 preassessment. These two activities are conducted by one survey team during the initial survey. It should be noted that most hospitals currently accredited by DNV have become ISO 9001 compliant without adding any additional staff.

Can the hospital immediately switch its accreditation to DNVHC without interruption in Medicare reimbursement?

Yes. If a hospital wants to switch its accreditation to DNVHC, it can notify its current accreditation organization (AO) as soon as it has made its decision. Hopefully, the hospital and the AO will work out a plan for an orderly transition. If the hospital and AO cannot agree and the AO immediately withdraws its accreditation, the hospital's Medicare provider agreement is not affected. The current AO will notify the CMS Central Office (CO) and applicable Regional Office (RO) that it has withdrawn its accreditation and the effective date.

If the hospital's termination by one AO is concurrent with the new recommendation for accredited, deemed status by DNVHC, then it may remain under DNVHC rather than State Survey Agency (SA) jurisdiction.

If the hospital's termination by its current AO is not concurrent with a new recommendation for accredited, deemed status by DNVHC, the hospital is placed under SA jurisdiction until such time as a new recommendation for accredited, deemed status by DNVHC is received and approved by the CMS CO and appropriate RO. The hospital's accredited, deemed status is then reestablished and the hospital is placed under DNVHC for ongoing monitoring and oversight. During the transition from the hospital's current AO to DNVHC or, if the transition is not concurrent, from the hospital's current AO to the SA then to DNVHC, **there is no interruption in the Medicare provider agreement, and thus, no break in Medicare reimbursement.**

What is ISO 9001?

The ISO 9001 Standard was first published in 1987 and was recently revised in 2008 to address the issues encountered by facilities in the service industries, including healthcare. ISO changes the standards no more frequently than every six years. This allows the hospitals to stabilize their processes and ensure effectiveness instead of forcing the hospitals to chase a constantly moving target of changing standards.

How is the NIAHO℠ survey performed and when does DNVHC's accreditation become effective in terms of Medicare and Medicaid reimbursement?

The NIAHO℠ and ISO surveys are done together through Tracer Methodology as well as staff and patient interviews. While surveying the hospital to the CoP criteria, DNVHC surveyors also ensure the applicability of the ISO 9001 standard. Tracer Methodology has been a staple of ISO 9001 surveys since ISO 9001's inception in 1987. All areas of the hospital are surveyed, both clinical and non-clinical. Tracer Methodology is a tool to identify and document effective processes.

DNVHC surveyors are recruited from the hospital and related sectors and trained extensively in the classroom and in the field by DNV in NIAHO℠ and the ISO 9001 Standard.

There are always at least two surveyors on site (two for small hospitals and three to five for larger hospitals). There will always be either a physician or registered nurse and a physical environment (PE) specialist on site. A Generalist will also be a part of the team for larger hospitals. The PE specialist is a fully functioning team member and will be there throughout the entire survey. All teams include surveyors with extensive healthcare clinical and management background.

Once the survey is completed the hospital will receive a preliminary report from the survey team. The hospital will receive a final report from DNVHC within ten days. The hospital will then have ten days to submit its Corrective Action Plan with timelines for implementation. Once the Corrective Action Plan has been approved, the documentation is submitted to the Accreditation Committee for the final accreditation decision. Upon approval by the Accreditation Committee, DNV's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is determined by CMS.

How long does a hospital have to become compliant with the ISO 9001 Standard?

The NIAHO℠ standards allow up to three years from the initial NIAHO℠ survey to become ISO 9001 compliant. Our experience shows, however, hospitals can begin to realize positive outcomes in the first year.

If a hospital is currently accredited by TJC or AOA or has received a State survey, it is basically 65-75% of the way to ISO 9001 compliance. The hospitals we have surveyed that have implemented ISO have taken 3-6 months for ISO implementations. The schedule we follow is outlined below. These are **annual** on-site visits.

- Year One – NIAHO℠ Accreditation and Introduction to ISO 9001
- Year Two – NIAHO℠ Accreditation and ISO 9001 Pre-assessment Survey (The pre-assessment is an analysis to show the hospital where it is currently compliant with ISO and any gaps that need to be addressed to become ISO 9001 compliant.)
- Year Three- NIAHO℠ Accreditation and Stage One ISO 9001 Surveys (Stage One is designed to confirm hospital readiness for an ISO 9001 compliance/certification audit.)

Year Four- NIAHO℠ Accreditation and ISO 9001 Compliance/Certification Audit.

Years Five- NIAHO℠ Accreditation and ISO 9001 periodic audit.

Year Six- NIAHO℠ Accreditation and ISO 9001 periodic audit.

The first contract for accreditation services is a three year contract (see above) in order to confirm the hospital's readiness for an ISO 9001 Compliance/Certification Audit, unless the hospital is already certified to ISO 9001. Existing hospital certification to ISO 9001 is typically not the case. ISO 9001 compliance/certification is determined in Year Four. Hospitals that want to move forward with the ISO 9001 process at an accelerated rate will be able to work with DNV to develop a strategy that meets their particular needs and allows them to achieve their objectives within an agreed time frame.

The next and subsequent three-year contracts would be identical to Years Four, Five and Six.

In terms of CMS deeming authority, DNVHC can accredit any part of the organization that is included under the hospital CCN Number (formerly Medicare Provider Number). However, even if some parts of the organization are not surveyed for accreditation, these functions can still be audited for compliance/ certification to ISO 9001. DNVHC encourages this because it drives consistency and best practices throughout the organization.

How often do the NIAHO℠ standards change?

There are two types of changes to the NIAHO℠ standards - mandatory and discretionary:

Mandatory- DNVHC is required to change NIAHO℠ standards to conform to any CMS change in the Medicare CoPs. DNVHC is required to implement these changes in NIAHO℠ standards within thirty (30) days of the new CoP effective date.

Discretionary- DNVHC may add, remove or amend any NIAHO℠ standard that is not required by the CoPs. Discretionary changes will clarify existing standards and incorporate practices, principles and processes that will enhance the NIAHO℠ accreditation program. Such changes will be implemented only if they can be expected to improve the overall quality and safety of patient care. Discretionary changes will occur through a dynamic review process that will involve input from the field, comments from applicable agencies and organizations and review by the DNVHC accreditation management team. Any discretionary change to the NIAHO℠ standards must be approved by the DNVHC Standards and Appeals Board (SAB). The SAB is comprised of representatives active in medicine, nursing and hospital management. Since ISO 9001 is already designed to encourage and accommodate contemporary best practices, discretionary changes should be infrequent.

How long have hospitals been surveyed to the NIAHO℠ standards?

The NIAHO℠ application process to CMS took approximately four years. CMS requires that an applicant organization for deeming authority continue its survey program throughout the submission process. DNVHC worked with many hospitals throughout the United States to develop standards, field train surveyors and submit to the entire NIAHO℠ hospital program. This participation has occurred despite the need to maintain TJC accreditation (or other) accreditation because these hospitals were looking for an alternative accreditation. As a result the NIAHO℠ standards and survey process have been in place continuously for five years.

What are the training and qualifications of DNVHC surveyors?

There are three classifications of DNVHC surveyors: Clinical Surveyors, Generalist Surveyors, and Physical Environment (PE) Specialists. The Clinical Surveyor is either a physician or a registered nurse; the Generalist Surveyors may have a clinical (not a physician or registered nurse) or nonclinical hospital background. The PE Specialists come with a facilities and safety background.

All DNVHC surveyors must successfully complete NIAHO℠ Surveyor didactic training and separate ISO 9001 Lead Auditor didactic training. The PE Specialists receive further training in the NFPA Life Safety

Code. Following the classroom, each surveyor completes a sufficient number of surveys in a student role until their trainer validates that the surveyor is ready to perform as a Team Member.

In addition to the surveyor background and competency, all surveyors are evaluated in terms of their interpersonal skills. Surveyors must possess sufficient interpersonal skills to translate into a collegial, non-confrontational survey. The surveyors clearly understand that anything less is unacceptable.

All surveyors must complete 45 hours of continuing education in their discipline within every three year period. Additionally all surveyors must participate in annual surveyor training as well as other courses offered throughout the year by DNV and DNVHC staff.

The NIAHO℠ standards require either ISO Certification or ISO Compliance. What is the difference between ISO Certification and ISO Compliance?

The NIAHO℠ standards require that a hospital become **Compliant** with ISO 9001 within three years of the first NIAHO℠ survey but **Certification** to ISO 9001 is an option that the hospital may select.

Compliance means that the hospital has implemented all requirements of ISO 9001 and is **compliant** with the ISO 9001 standard. The hospital will receive **one** Certificate for NIAHO℠ accreditation that includes confirmation that the hospital is also compliant with the ISO 9001 standards.

In a competitive marketplace, a hospital may want to further publicize its ISO compliance by displaying the separate internationally-recognized ISO 9001 certificate. When a hospital is ISO certified, it will receive **two** certificates, one for NIAHO℠ Accreditation and another certificate for ISO 9001 Certification.

Certification involves significant additional DNVHC documentation apart from CMS requirements. Issuance of a separate ISO certificate requires this additional documentation to be prepared by DNVHC and sent to a separate ISO Certification Body to provide the international ISO recognition. This additional work by DNVHC requires an additional charge to the hospital of $3,500. If Certification is requested by the hospital, the ISO Certification Body will determine the number of survey days required for the survey. If Compliance only is selected, DNVHC will have more latitude in determining the number of survey days. Since survey days drive the cost, DNVHC would have more latitude in determining costs.

In either case, the hospital will have to be fully compliant with the ISO 9001 standards within three years. There is no difference in meeting the ISO 9001 requirements whether it is a Compliance Survey or a Certification Survey. The only difference is in the cost of the internationally-recognized ISO certificate. It is a decision for the hospital to make based on its market.

Does DNVHC provide any resources for ISO 9001 and/or NIAHO℠ implementation?

Yes. DNVHC offers an ISO 9001/NIAHO℠ Implementation course. This one-week course is offered at various times throughout the country. Check www.dnvaccreditation.com for dates and fees. This course can also be offered on-site to an individual organization for a fee and expenses. Call the DNVHC toll-free number (866-523-6842) for more information.

DNVHC also publishes a roster of consultants who have successfully completed the DNVHC NIAHO℠ Accreditation Standards course and the specific ISO 9001 Lead Auditor course approved by DNVHC for healthcare organizations.

DNVHC maintains and publishes this roster solely as a convenience to the healthcare public for organizations that are interested in pursing or maintaining DNVHC accreditation and/or becoming ISO 9001 compliant. DNVHC has no financial relationship with these persons when they are providing these services. DNVHC does not endorse, approve or recommend any person listed on the roster.

The roster is available on website www.dnvaccreditation.com under the Resources tab.

What other training does DNVHC offer to the hospital field?

DNVHC offers free 90 minute webinars from time to time. Additionally, DNVHC offers full- day and week-long training programs in NIAHO℠ and ISO 9001 in locations across the country as demand requires. There is a charge for these programs. See www.dnvaccreditation.com for information when these webinars and programs are offered.

DNVHC is also willing to come on-site to individual organizations for a fee and expenses. Call DNVHC for more information.

DNVHC also has a unique program for its customers. DNVHC will train one individual in the organization to the NIAHO℠ and ISO 9001 Standards. DNVHC does not pay these individuals a salary or reimburse their expenses during training, nor do we charge for the training or related literature and training tools. The ISO 9001 Lead Auditor training involves 5 days and the NIAHO℠ training takes 4 days, both weeks in our Cincinnati offices.

The hospital must agree to allow the staff member to survey up to two times per year (if needed by DNVHC) as a fully qualified surveyor and a full member of the survey team – obviously not in their market area. It typically takes 2-3 surveys after training for the staff member to become comfortable with being a full team member. Once the staff member successfully completes the didactic training (usually in Cincinnati, Houston or Atlanta), all travel expenses of surveying are paid by DNVHC and salary remains the hospital's responsibility.

DNVHC's training and use of hospital-based surveyors is based on availability and need.

These staff members would receive all changes and documentation that any other surveyor for DNVHC receives and will always be current with CMS changes in requirements as well as NIAHO℠ and ISO 9001 changes or modifications and survey nuances. While the hospital will receive all standards updates, these staff members would be on all surveyor conference calls,

emails, or other training and/or communication. This is DNVHC's commitment to a totally transparent survey process.

If a hospital changes its mind about DNV accreditation, can the hospital terminate the contract?

Contracts are quoted in multiyear cycles to maintain accreditation and ISO continuity. If a hospital does not want to continue DNVHC accreditation, it may terminate its contract at any time with a 60-day written notice.

How do the number of findings during a survey affect the hospital's accreditation decision?

The number of findings during a survey has no effect on accreditation. There is no tipping point of findings such that one more finding will lead to non-accreditation. Continual improvement and adherence to the Corrective Action Plan is the key to DNVHC Accreditation.

(More detailed information pertaining to Nonconformities can be obtained in the *Accreditation Process* document that can be downloaded at no charge on the www.dnvaccreditation.com website.)

Do the NIAHO℠ standards contain patient safety goals?

DNVHC supports the initiatives that hospitals have developed and implemented to guide safe patient care practices. We also support and foster innovations through development of hospital best practices, but clearly understand that some practices do not suit all organizations. DNVHC does not dismiss the notion that patient safety goals can be effective and many organizations may want to consider these "goals" in place of their current practices. However, we also realize that there are different avenues for achieving positive patient safety outcomes and the hospitals know their patient populations and resources best. The decision-makers in each individual hospital are certainly well-trained, qualified, and best equipped address these issues. DNVHC will look at the outcomes to validate problem resolution.

DNVHC has two major goals – to assess compliance and educate hospitals in best practices. Hospitals can use innovation to develop new methods for producing positive results, but not by DNVHC forcing one practice over another when good outcomes are being achieved. At the same time, we hold hospitals accountable to ensure that processes are planned, managed, measured, documented and continually improved.

Does the DNV parent company in Oslo make accreditation decisions?

No. All accreditation decisions are made by DNVHC in the U.S. If a hospital is dissatisfied with an accreditation decision, it may appeal to the Standards and Appeals Board (SAB). The SAB is an independent body chartered by the DNVHC board of directors to hear accreditation appeals. All SAB members are Americans. They have extensive training and experience in the U.S. healthcare system and are eminently qualified in their respective fields of medicine, nursing and hospital management. The decision of the SAB is final.

What is the cost of purchasing the NIAHO℠ standards?

- There is no charge for the NIAHO℠ Standards, Interpretive Guidelines, or Accreditation Process for non-commercial use. These can all be downloaded at www.dnvaccreditation.com.
- The ISO 9001standards can be purchased at www.iso.ch or www.asq.com.
- Another excellent source for ISO in healthcare is a publication from Australia. It may be purchased at http://www.saiglobal.com/shop/Script/Details.asp?DocN=AS318210814901. It is the Australia Standards Guide and the purchase information is: HB 90.8-2000: Healthcare Services – Guide to ISO 9001.

What are the costs associated with a NIAHO℠ accreditation?

The cost of the survey is based on the number of surveyors and the length of the survey. Survey team size and number of survey days are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census (ADC) and **number of FTEs**
- Complexity of services offered, including outpatient services
- Type of survey to be conducted
- Whether the facility has special care units or off-site clinics or locations and the distance from the main campus

Contracts are typically for three years. However, a hospital can it may terminate its contract at any time with a 60-day written notice. The attached Appendix contains several scenarios that outline approximate costs based on the size and complexity of the hospital. Please understand that the number of off-sites and the distance from the hospital may have an impact on the number of surveyor days. For purposes of these scenarios, 3-4 off-sites are assumed to be present and within 20 miles of the hospital.

It is important to remember that the hospital will receive an on-site visit **every year** (e.g., in three years the hospital would have **three on-site surveys** instead of one survey every three years). Current DNVHC hospitals view this as a significant benefit.

Please note the higher number of on-site survey days the hospital will receive with DNVHC as compared to the number of on-site survey days that the hospital has been receiving in its current accreditation program. **It is the increase in survey days that will reduce (and in most cases eliminate) the ramp-up costs that the hospital currently incurs.**

Quotations for annual surveys include all fees and expenses. There is no charge for the NIAHO℠ Requirements and Interpretive Guidelines for non-commercial use and you may contact us for standards interpretation or other questions by email or telephone on an unlimited basis at no charge. There are no hidden charges.

The attached Appendix depicts a fee schedule for various sized hospitals. The schedules include the time and fee structure for the first 3-year cycle and subsequent 3-year cycles, based on average daily census (ADC) and number of FTEs. **The number of FTEs is the single most important factor when determining costs. It is essential that the hospital FTE count on the DNVHC Application for Accreditation is completely accurate.**

Are there indirect costs associated with DNVHC accreditation?

No. Quotations include all fees and expenses. There are no annual charges, consulting costs, additional staff or other expenses necessary to maintain the NIAHO℠ accreditation program or the ISO 9001 quality management system. TJC hospitals can spend thousands of dollars each with TJC's affiliate, Joint Commission Resources (JCR) preparing for a TJC survey. This does not count the indirect internal costs hospitals may spend ramping up for a TJC survey. JCR sells consulting and publications to hospitals to help them prepare and maintain TJC accreditation and keep abreast of ever-changing TJC standards. JCR had revenue in excess of $48 million in 2007 (latest available). **There are no ramp-up or maintenance costs for DNVHC accreditation.** Hospitals are just using existing staff to do different things. **There is no need to incur the expense of preparing for and undergoing "mock surveys" to prepare for DNVHC accreditation. For many hospitals, this can equal the cost of actual accreditation.**

Are the costs computed differently for Hospital Systems?

Yes. An economy of scale is built into the ISO formula that determines the number of survey days. A Hospital System (HS) can be surveyed in one of two ways. The HS can implement one Quality Management System (QMS) using the principles of ISO 9001, or the individual hospitals in the HS can each implement their own QMS.

If the HS selects a single QMS the corporate office would oversee the QMS and the principles would reach through all the HS hospitals, assuring consistency and best practice across all hospitals. Because it is a single QMS, the ISO table dictating survey days compresses as the number of employees increases; therefore, the cost of the contract is significantly less if the HS implements a single Quality Management across the organization because the survey days are reduced.

If the HS decides to have individual Quality Management Systems, DNVHC would be required to validate compliance with each individual QMS within the system and that involves many more days, resulting in higher costs.

DNVHC recommends that the HS select the single QMS to maximize the opportunity to bring consistency and known best practice across the organization. In either scenario, all hospitals in the HS would receive an on-site survey each year.

Any other questions? Contact:

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Appendix A: Time and Fee Schedule Examples

The following examples are for reference only; actual costs will be based on the hospital's size and complexity as outlined in the individual hospital's Application for Accreditation.

Ex.	Average Daily Census (ADC)	Employees (FTEs)	Average **Survey** Days on Site **Each** Year	Average Number of **Surveyors** On **Annual** Survey	Average **Surveyor** Days On-Site **Each** Year	Average **Annual** Cost	Hospital's Current Accreditation Fees (to be completed by hospital)		
							Number of Days On Site In 3-Year Period	Direct Cost (annual fee + survey every 3 years)	Indirect Costs (consulting, standards and publications, mock surveys)
1	10	85	1 - 2	2	2.5	$7.800			
2	30	210	1.5 - 2	2	3.5	$11,800			
3	75	375	2	2-3	4.5	$15,100			
4	125	625	2 – 2.5	2-3	5	$17,000			
5	180	900	2.5 - 3	2-3	6.5	$21,000			
6	250	1250	3	2-3	7	$23, 100			
7	350	1760	3 – 3.5	3	8	$27,000			
8	450	2250	3 – 3.5	3-4	9	$29,500			
9	650	3250	3 - 4	3-4	10	$33,000			

The above DNVHC fees are all-inclusive. These fees include all travel expenses, NIAHO℠ standards and related documents and include an on-site visit every year.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Licensing Statistics**

Following are the licensing statistics reflecting data from July 1, 2009 through May 31, 2010. The board continues to experience significant in a number of areas in licensing, most notably in pharmacy technicians. Provided below are some of the most significant increases.

Applications Received:

Pharmacy Technicians	10%
Sterile Compounding	13%
Hospitals	61%
Wholesalers	21%

Licenses Issued:

Pharmacy Technicians	25%
Wholesalers	21%

The fiscal year totals will be provided during the July Board Meeting along with a three year comparison.

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	185	287	132	134	90	128	29	105	161	195	343		1789
Pharmacist (initial licensing applications)	280	134	161	155	125	69	93	90	79	51	23		1260
Intern pharmacist	61	479	331	327	57	65	27	81	158	99	106		1791
Pharmacy technician	962	887	1036	1021	677	1018	202	845	1256	1005	1089		9998
Pharmacy	29	23	30**	28	18	22	19	26	25	100	101		391
Sterile Compounding	6	2	1	5	2	1	2	25	7	6	10		67
Clinics	6	6	13	8	3	10	5	8	2	10	19		90
Hospitals	0	0	0	0	0	0	1	0	0	16	14		31
Nonresident Pharmacy	3	6	3	5	6	1	8	3	20	14	9		78
Licensed Correctional Facility	0	0	0	0	0	0	2	0	0	0	0		2
Hypodermic Needle and Syringes	1	3	2	0	2	2	2	0	0	0	0		12
Nonresident Wholesalers	6	15	6	9	4	11	2	2	9	18	25		107
Wholesalers	5	7	6	15	5	6	6	1	7	10	19		87
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0		0
Designated Representatives	34	57	36	74	36	32	22	45	47	36	42		461
Issued													
Pharmacist	243	308	139	189	94	101	87	93	53	83	21		1411
Intern pharmacist	39	277	323	476	102	119	44	19	73	184	109		1765
Pharmacy technician	751	788	764	722	416	1407	889	704	1017	1016	1067		9541
Pharmacy	35	24	36	24	7	12	25	13	33	33	16		258
Sterile Compounding	9	2	7	1	0	0	0	2	1	4	4		30
Clinics	5	4	11	1	10	4	8	0	9	3	1		56
Hospitals	6	1	5	2	0	0	4	0	0	2	0		20
Nonresident Pharmacy	10	3	1	1	7	5	3	2	10	3	10		55
Licensed Correctional Facility	1	0	0	0	0	0	1	0	1	0	0		3
Hypodermic Needle and Syringes	1	5	1	3	2	1	1	1	2	0	1		18
Nonresident Wholesalers	10	13	16	4	9	2	11	3	6	3	8		85
Wholesalers	8	7	15	4	3	2	3	0	5	0	5		52
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	1	0	0	0	0		1
Designated Representatives	45	26	40	44	11	26	31	8	56	41	57		385

*u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Pending													
Pharmacist Examination	241	283	192	217	196	141	172	139	845	563	808		808
Intern pharmacist	278	496	488	320	159	226	201	235	270	248	270		270
Pharmacy technician	1894	1888	1837	1969	1451	2704	2121	2050	3262	3209	3119		3119
Pharmacy	58	54	49	42	47	65	52	53	57	70	72		72
Sterile Compounding	18	18	13	12	16	19	19	17	25	32	27		27
Clinics	30	28	24	37	36	32	27	30	29	32	46		46
Hospitals	19	16	12	14	14	9	9	9	11	9	9		9
Nonresident Pharmacy	34	32	33	39	36	38	36	37	42	50	40		40
Licensed Correctional Facility	0	0	0	0	0	0	1	1	0	0	0		0
Hypodermic Needle and Syringes	19	10	11	12	10	10	6	4	5	15	13		13
Nonresident Wholesalers	92	79	72	79	73	79	70	66	70	90	77		77
Wholesalers	43	35	20	23	31	36	34	36	43	48	43		43
Veterinary Food-Animal Drug Retailer	1	1	1	2	2	2	0	0	0	0	0		0
Designated Representatives	132	88	128	119	159	167	163	168	197	211	166		166
Change of Pharmacist-in-Charge* **													
Received	189	159	130	182	119	134	160	43	36	128	138		1418
Processed	151	91	75	132	40	109	42	112	133	46	112		1043
Pending	38	106	161	211	290	315	433	364	267	349	375		375
Change of Exemptee-in-Charge* **													
Received	37	22	19	14	12	14	9	6	5	9	14		161
Processed	6	7	0	13	1	9	12	0	10	0	0		58
Pending	31	46	65	66	77	82	79	85	80	89	103		103
Change of Permits													
Received	347	103	74	100	39	50	46	49	43	37	69		957
Processed	37	1	311	57	90	67	126	9	46	0	2		746
Pending	310	412	175	218	167	150	70	110	107	144	211		211
Discontinuance of Business* **													
Received	42	33	35	42	37	35	12	21	0	15	13		285
Processed	35	12	18	21	19	14	8	1	14	17	2		161
Pending	7	28	45	66	84	105	109	129	115	113	124		124

*u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010

Board of Pharmacy Licensing Statistics - Fiscal Year 2009/10

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1213	2757	2836	1640	839	1687	1640	1340	1446	1143			16541
Pharmacy technician	1632	3740	4021	1716	527	2181	2059	2053	2224	1810			21963
Pharmacy	182	484	641	991	377	460	395	442	863	1134			5969
Sterile Compounding	21	49	74	17	24	23	21	3	14	24			270
Clinics	76	131	187	70	55	80	100	87	61	86			933
Nonresident Pharmacy	34	31	53	14	23	17	21	21	36	27			277
Licensed Correctional Facility	0	1	27	0	6	0	0	0	0	0			34
Hypodermic Needle and Syringes	10	23	41	37	16	26	22	11	23	14			223
Nonresident Wholesalers	32	54	64	40	27	33	38	37	49	43			417
Wholesalers	32	71	71	30	20	41	37	20	35	39			396
Veterinary Food-Animal Drug Retailer	2	4	2	1	5	4	4	5	1	1			29
Designated Representative	149	306	320	192	145	139	135	116	246	219			1967

*u/a denotes unavailable
** denotes corrected
*** denotes change in method of collecting date effective 03/2010

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **June 9, 2010**

To: **Licensing Committee**

Subject: **Strategic Plan Update 2010-11**

At the July Board Meeting, the board will update its 2010-11Strategic Plan. The board truly manages its operations by its strategic plan. All activities undertaken by the board are reported in the plan -- in the component committee reports provided quarterly to the board (in the board packets).

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

The revision is done by each strategic committee by reviewing its portion of the strategic plan, making recommendations and then recommendations to the full board for review and approval at the board meeting.

The Licensing Committee's strategic goals, objectives and tasks are being updated and will be provided at the meeting. The committee needs to review the plan to ensure its activities are current and reflect projects underway.

Licensing unit managers reviewed the plan in advance of this meeting and are recommending inclusion of the following tasks:

- Initiate changes to improve internal processing of application process.
- Initiate internal and external processing of pharmacy technician applications
- Implement Fingerprint Requirement for Pharmacist Renewal. (Regulation recently approved by OAL.)
- Initiate internal and external processing of site licensing applications