



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE
MINUTES**

DATE: June 16, 2010

LOCATION: Bonderson Building
901 P Street, Hearing Room 102
Sacramento, CA 95814

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Public Member, Chair
Ramón Castellblanch, Public Member
Tappan Zee, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Ryan Brooks, Public Member
Deborah Veale, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

Chair Lippe called the meeting to order at 2:08 p.m.

1. **Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – New University of New England School of Pharmacy of Portland, Maine**

Chair Lippe provided that the University of New England School of Pharmacy is requesting board recognition of its program for purposes of issuing California intern pharmacist licenses to students attending their program, but who may spend some time and work in CA. He stated that precandidate status is a

provisional status awarded to a new school of pharmacy; however it is not "approved" status.

Executive Officer Virginia Herold provided that 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. In this case, she advised that the university may achieve candidate status by the end of June 2010.

No public comment was provided.

MOTION: Recommend to the board recognition of the University of New England, College of Pharmacy, Portland Maine.

M/S: Lippe/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

2. Discussion of Proposed Changes to the Intern Hours Requirements for California

Chair Lippe provided that 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.

Chair Lippe provided that 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. He stated that 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. Chair Lippe indicated that California pharmacy students typically earn these 600 "discretionary" hours for school-related experiential training (such as a clinical clerkship).

Chair Lippe provided that recently, board staff received a new proposal to modify the intern hour requirements. He stated that the proposal requests that the board change the current requirements to 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. Chair Lippe indicated that the proposal states that UCSF's current curriculum includes more than 1,000 hours of advanced pharmacy practice.

Dr. Ramón Castellblanch asked how this change for UCSF would impact other schools of pharmacy.

Assistant Executive Officer Anne Sodergren provided that several similar proposals have been brought before the committee over the past several years. She advised that this proposal would require a regulatory change.

Chair Lippe expressed concern that decreasing the hour requirement may have a detrimental impact to an intern's experience in the field.

Ms. Sodergren provided that the committee has historically denied similar proposals. She stated that the proposal has been presented before the committee because the practice of pharmacy is changing and the pharmacist's role is evolving. Ms. Sodergren advised that there is no substitute for practice hours.

Dr. Castellblanch questioned why a representative from UCSF was not present to personally make this request.

Ms. Herold indicated that UCSF was notified that the proposal would be presented to the committee. She explained that interns are struggling to achieve positions in order to obtain the experience hours due to the declining economy. Ms. Herold stated that the board may choose to consider input from other groups including pharmacy schools and pharmacists on the minimum hours that would satisfy this requirement.

Chair Lippe suggested that the board consider two different types of licensees to reflect variance in training emphasis inside the pharmacy.

Tappan Zee suggested that the committee recommend that the board consider that the hour requirements be flipped.

Public Comment

William Young provided that many pharmacists feel that recent graduates do not have sufficient experience when entering the profession. He stated that he believes the shift would be detrimental. Mr. Young encouraged the board not to adopt this proposal.

Dr. Steve Gray, representing Kaiser Permanente, provided that without pharmacy experience, graduates are not able to recognize and identify the drugs. He indicated that the National Association of Boards of Pharmacy (NABP) is amending its policy to require an increase to 1700 intern hours of experience prior to licensure.

Robert Ratcliff, Supervising Inspector, indicated that from an enforcement perspective, granting this change would be detrimental to the public. He recommended that the experience hour requirements be increased.

Dr. Gray provided that the American Society of Health-System Pharmacists (ASHP) has reaffirmed its position that by 2020, pharmacist licensure will require a mandatory one-year postgraduate residency prior to licensure. He advised that other associations are also moving towards this policy.

There was no additional committee discussion or public comment.

3. Review of Data Describing the Board of Pharmacy's Audits of Continuing Education Earned by Pharmacists as a Condition of Renewal

Chair Lippe provided that pharmacists are required to complete 30 hours of continuing education as a condition of license renewal. He indicated that these CE hours must be earned within the two years their license was last renewed. Chair Lippe explained that at the time of renewal, every pharmacist must certify under penalty of perjury that he or she has completed the 30 units.

Chair Lippe provided that the board periodically audits a few pharmacists each month to determine their compliance with this requirement. He advised that 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.

Chair Lippe provided that 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.

Chair Lippe provided that 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. He stated that of these, 5 (2 percent) ended up having their licenses converted to inactive status.

Ms. Herold provided that failed CE audits have dropped from 25% to 16%. She advised that both the pharmacist and the employer will be cited and fined if it is found that the pharmacist has been working with an inactive license.

The committee further discussed the CE process. It was suggested that pharmacists submit proof to document completed CE. Concern was expressed that this process will significantly impact work load.

Public Comment

Dr. Steve Gray suggested that the board may want to consider the establishment of CE categories relevant to the practice issues before the profession today. He

stated that targeted categories may make the CE requirement more meaningful and encourage compliance.

It was the consensus of the committee to recommend that the full board discuss the topic of targeted CE. Direction was given to staff to establish parameters in this area.

There was no additional committee discussion or public comment.

4. Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include “Self-Query” Reports From the Healthcare Integrity and Protection Data Bank (HIPDB)

Ms. Herold provided that board staff proposes a change to the application requirements to also include a “self-query” report as part of the application process. She stated that 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 protection mandate.

Ms. Sodergren indicated that a “self-query” costs \$16.00 per report. She stated that if the state was required to run this report, it would cost \$4.75 per report for each state the applicant was licensed with.

No public comment was provided.

MOTION: Recommend that the board take action on this item to adopt the “self-query” report requirement.

M/S: Zee/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

5. Emergency and Disaster Response Planning Update

Chair Lippe provided that 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. He indicated that in 2009, the section was amended to add subdivision (c) to provide for use of temporary facilities during declared emergencies.

Chair Lippe provided that 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.

Chair Lippe read the following motion approved by the board.

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.

Chair Lippe provided that the executive officer was recently asked the following questions 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?

Chair Lippe reviewed the following response provided by the executive officer:

There is no 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.

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

Dr. Castellblanch recommended that the special committee would adjourn to signal the end of the emergency authorization. He encouraged input from the board's counsel on this issue.

It was the consensus of the committee to discuss this item at the July 2010 Board Meeting and to establish procedures for mobile pharmacies.

No public comment was provided.

6. Competency Committee Report

Chair Lippe highlighted the following items.

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.

No public comment was provided.

7. **Review of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies**

Chair Lippe provided that the 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. He stated that these specialized pharmacies may be either hospital pharmacies or community pharmacies. Chair Lippe advised that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. He indicated that this is the only category of board licensure that requires annual inspections as a condition of renewal.

Chair Lippe provided that currently the board has 243 such licensed facilities in California, and 93 nonresident pharmacies with such permits.

Chair Lippe provided that 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.

Chair Lippe provided that 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). He stated that 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.

Chair Lippe provided that 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. He indicated that recently the board modified its regulations for pharmacies that compound medication. Chair Lippe explained that included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. He stated that 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.)

Chair Lippe provided that 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. He stated that in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. Chair Lippe indicated that 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. He advised that 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.

Chair Lippe provided that at the April 2010 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.

Chair Lippe provided that 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. He indicated that 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).

Chair Lippe provided that 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)

Janice Dang, Supervising Inspector, provided a review of each agency to assess a pharmacy's ability to meet the board's requirements for sterile injectable compounding pharmacies. She highlighted both the current requirements and the new requirements for each agency.

Ms. Dang expressed concern that the surveyors for each agency may not be adequately familiar with California modified pharmacy law. She indicated that the agencies may not be compliant with new compounding laws effective July 2010.

Ms. Herold indicated that Ms. Dang's full report will be brought to the full board at the July 2010 Board Meeting.

Patrick Horine, representing Det Norske Veritas (DNV) Healthcare Inc., provided an overview of the DNV accreditation program, National Integrated Accreditation for Healthcare Organizations (NIAHO). He indicated that 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. Mr. Horine stated that the model's standards are consistent with California pharmacy law.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, recommended that the board invite the Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations, to present their processes in this area at a future meeting.

There was no additional committee discussion or public comment.

8. Licensing Statistics

Chair Lippe provided that the board continues to experience significant increases in applications, most notably in pharmacy technicians. He reviewed the following significant increases from July 1, 2009 through May 31, 2010.

Applications Received:

Pharmacy Technicians	10%
Sterile Compounding	13%
Wholesalers	21%

Licenses Issued:

Pharmacy Technicians	25%
Wholesalers	21%

Ms. Sodergren advised that the statistics reflect the growth from this fiscal year compared to last fiscal year. She stated that board staff have been notified that the applicant tracking reporting system that generates the data has experienced an error. Ms. Sodergren indicated that a new revised report including a three year comparison will be provided at the July 2010 Board Meeting.

There was no additional committee discussion. No public comment was provided.

9. Update of the Licensing Committee's Strategic Plan for 2010-2011

Ms. Herold provided that board staff strive to manage its operations by the strategic plan. She stated that 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).

Ms. Herold provided that the 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

The committee discussed the organization of the strategic plan. Clarification on the included objectives was requested.

10. Public Comment for Items Not on the Agenda

William Young provided comment on the prevalence of perjury on the continuing education (CE) certification on the licensure renewal. He recommended that the board consider its CE methodology and tracking as one of its initiatives.

The committee discussed the submission of CE certificates as proof of completion of the CE requirement. Consideration was given to the increased workload impact this would have.

The meeting was adjourned at 4:07 p.m.



MANAGING RISK

DNV

**Introduction to DNV Healthcare and
NIAHOSM
A New Choice for Hospital Accreditation**



California State Board of Pharmacy
Licensing Committee
June 16, 2010

DNV Healthcare Inc.

MANAGING RISK



- a US corporation, HQ in Houston, TX with offices in Cincinnati, OH
- DNV Healthcare is wholly owned by DNV
- DNV is an private, autonomous, self supported, tax-paying foundation
- Established in 1864, operating in the US since 1898. DNV is HQ in Oslo, Norway, is operating in 100 countries and has over 8,000 employees, with annual sales of \$1.5b
- Sole purpose of DNV is “Safeguarding Life, property and the environment”
- DNV’s Vision is to have a “global impact for sustainable and safe future”
- Values:
 - We build trust and confidence
 - We never compromise on quality or integrity
 - We care for our customers and each other
 - We are committed to teamwork and innovation
- DNV received CMS deeming authority on September 26, 2008 (5 year exhaustive process)

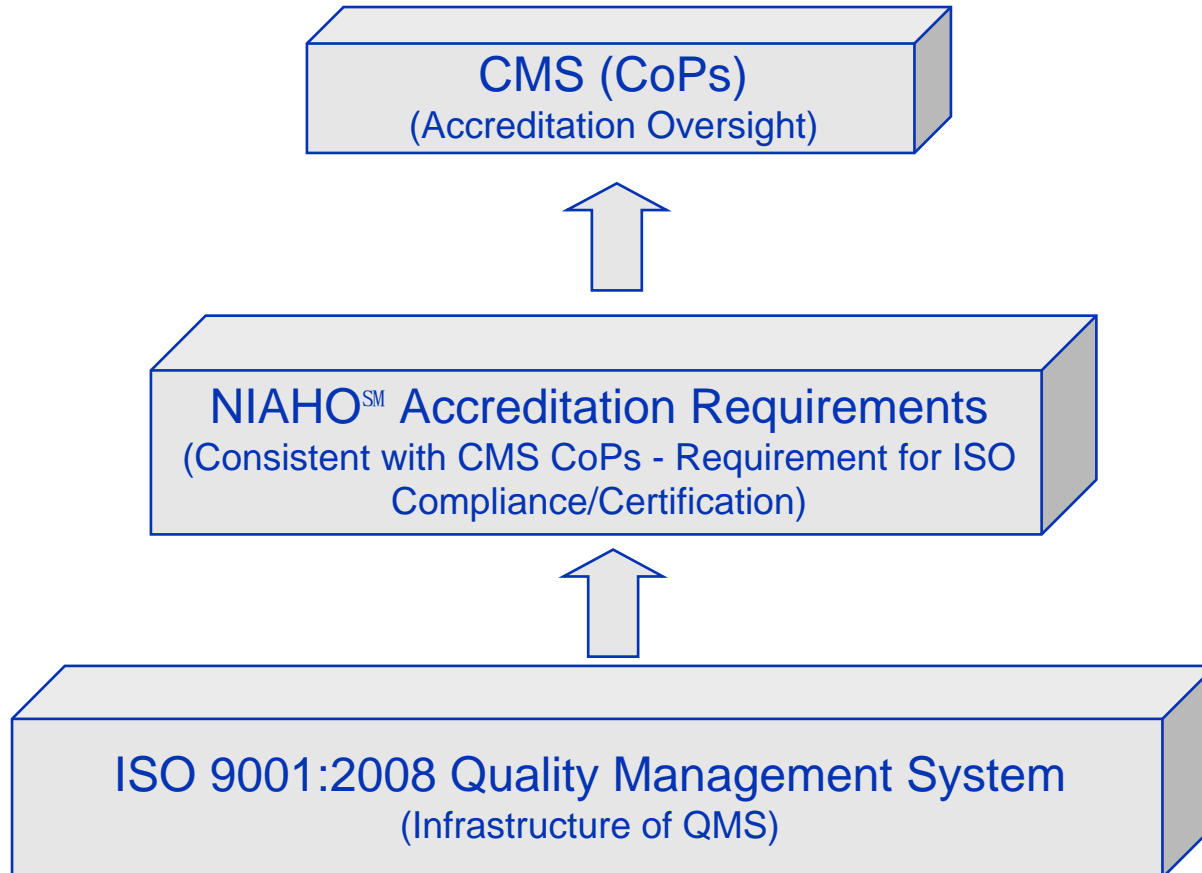
- Head office
- Local offices

NIAHOSM and ISO 9001 Quality
Management System



**Hospital Accreditation: Integration of NIAHOSM Standards with
ISO 9001 Quality Management System Standards**

Infrastructure and Accreditation



Integrated Accreditation Model

- Integrates ISO 9001 and Medicare CoP compliance
 - ISO 9001 provides the framework for a sustainable CoP implementation
 - ISO 9001 allows hospitals to use its combined knowledge, wisdom, and innovation to improve quality and safety
 - ISO 9001 is the framework within which methodologies such as LEAN and Six Sigma are better understood and utilized
- The DNV Surveyors make the difference
 - Training and competence in ISO 9001 and NIAHOSM
 - Clinical, Administrative, and Physical Environment expertise
- Combined result drives quality transformation into the organization's core processes

Advantages to DNV Healthcare Accreditation

MANAGING RISK



- Meets and exceeds CoP requirements (as well as applicable requirements under State law)
- Includes ISO 9001 Quality Management System (proven basis for continual improvement)
- Annual visits – added accountability
- Demeanor of the Survey Team
- Focus on sequence and interactions of processes throughout the hospital
- Hospital accountable for providing a corrective action plan for all nonconformities identified and subsequent support documentation be provided or subject to follow up survey when required
- Leads to improvement of patient safety and reduction in hospital's internal cost of accreditation
- Accreditation as a strategic business asset



NIAHOSM Surveyors & Survey Activities



Clinical, Generalist, & Physical Environment Surveyors must successfully complete the following:

- The DNVHC NIAHOSM 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
- Observation surveys
- Additionally, the Physical Environment / Life Safety 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.
 - All must attend annual surveyor training & complete 45 hours CEUs every 3 years
 - Hospital staff OPTION as a contract surveyor

■ Clinical Surveyor

- Patient Care Unit Visits (Clinical Settings)
- Med-Surg, ICU, CCU, Obstetrics, Emergency Department
- High acuity units

■ Generalist Surveyor

- Quality Management Review
- Medication Management
- Medical Staff and Human Resources Review
- Utilization Review Interview
- Patient Grievance Interview
- Med-Surg & Ancillary / Support Services Review (Lab, Medical Imaging, Rehab, etc.)

■ Physical Environment / Life Safety Specialist

- All Physical Environment aspects and Management Plans
- Physical Environment / Comprehensive Building Tour
- Biomedical Engineering & Calibration of Equipment

Survey activities are carried out as follows:

- A comprehensive review includes observation of care/services provided to the patient in all patient care areas, both in and out, patient and/or family interview(s), staff interview(s), and medical record review.
- Using Tracer methodology, department/patient unit visits to include staff interviews and open medical record review as appropriate (both clinical and support departments)
 - identify performance issues
 - handoff between steps
 - Tracer methodology
- Visits to non-clinical support areas
- Comprehensive Building Tour (days, not hours)

■ Category 1 Nonconformities

- Submit Corrective Action Plan within 10 days from receipt of Final Report
- The organization shall submit performance measure(s) data, findings, results of internal audits, or other supporting documentation, including timelines, to verify implementation of the corrective action measure(s).

■ Category 2 Nonconformities

- Submit Corrective Action Plan within 10 days from receipt of Final Report
- Validation of effective implementation of the agreed Corrective Action Plan will take place at the next annual survey.

■ *Category One Condition Level Finding – requires re-survey to clear – egregious findings*

■ **Managed Care Organizations and Other Third Party Payors**

- To our knowledge no barriers have been encountered regarding contractual revisions to recognize DNV Healthcare as an approved accreditation organization since we are approved by CMS as an accreditation organization with deeming authority for hospitals in accordance with Section 1865 of the Social Security Act.



MANAGING RISK



Meeting the Expectations and Requirements/Regulations of The California State Board of Pharmacy



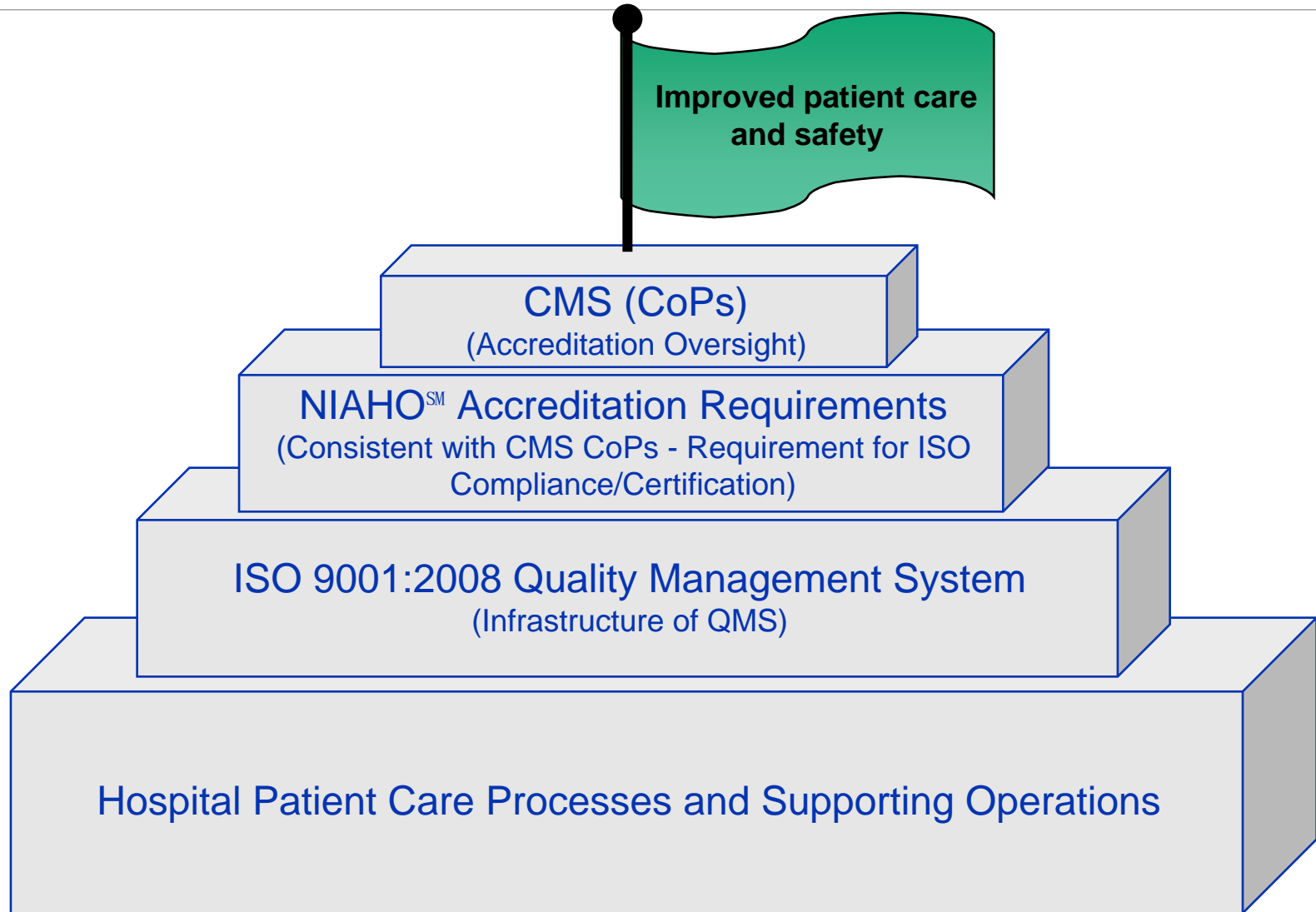
- DNVHC has developed standards consistent with California Code of Regulations (effective 7/6/2010). Provided for review to the Licensing Committee. Upon the acceptance/approval of the Licensing Committee, these will be sent to the Standards and Appeals Board for final approval and formal issuance.
 - Hospital Pharmacies seeking compliance in lieu of licensure will be required to meet the applicable requirements under MM.8 Sterile Compounding of the NIAHOSM Accreditation Requirements. Additional requirements may be added as applicable to other States that recognize DNVHC accreditation in lieu of separate licensure for Sterile Compounding.

- DNVHC conducts annual (unannounced) surveys of our accredited hospitals. The hospital receive accreditation valid for three (3) years from the effective date of accreditation, subject to annual surveys. In order to maintain accreditation, corrective action plans must be addressed and submitted for approval for each survey conducted.
 - For those Hospital Pharmacies seeking accreditation to serve in lieu of separate State licensure, the requirements under MM.8 Sterile Compounding of the NIAHOSM Accreditation Requirements must be met.
 - Additional survey time and surveyors be allocated in order to complete the review of the Pharmacy in order to assess compliance with the Sterile Compounding requirements.

- DNVHC will submit documentation of survey findings of noncompliance and other supporting information as requested to the California State Board of Pharmacy. DNVHC will maintain a list of accredited hospitals to identify those hospital Pharmacies in compliance with the Sterile Compounding requirements.
 - We will inform any accredited hospital meeting the requirements for Sterile Compounding that they are subject to any unannounced inspection from the California State Board of Pharmacy as a means for validation of the effectiveness of the DNVHC survey process as well as investigation for complaint. This would also include any referral to the State Board of Pharmacy for investigation and subsequent action possible for disciplinary action.

- Any DNVHC accredited hospital operating a Pharmacy providing sterile compounding outside the State of California, but shipping compounded drugs to the State of California as a non-resident Pharmacy will be subject to meeting the requirements under MM.8 Sterile Compounding of the NIAHOSM Accreditation Requirements.

Infrastructure and Accreditation





DNV HEALTHCARE INC.

CERTIFICATE OF ACCREDITATION

Certificate No 12345-AHC-IISA-NIAHO

This is to certify, that

ABC Medical Center

at

1234 Hospital Avenue, Cincinnati, OH 45255

Complies with the requirements of the

NIAHOSM Hospital Accreditation Program

Pursuant to the authority granted to Det Norske Veritas Healthcare, Inc. by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, this organization is deemed in compliance with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482). This certificate is valid for a period of three (3) years from the Effective Date of Accreditation.

Effective Date of Accreditation:
December 1, 2008



Patrick Horne
Executive Vice President, Accreditation



For the Accreditation Body:

DET NORSKE VERITAS
HEALTHCARE, INC.
HOUSTON, TEXAS



Yehuda Eror
President

Lack of continual fulfillment of the conditions set out in the Certification/Accreditation Agreement may render this Certificate invalid.

DET NORSKE VERITAS HEALTHCARE, INC., 16948 PARK TEN PLACE, HOUSTON, TX 77064, TEL: 281-721-6600 - WWW.DNVACCREDITATION.COM



www.dnv.com

Yehuda Dror, President
Yehuda.Dror@dnv.com

Rebecca (Becky) Wise, COO
rebecca.wise@dnv.com
513-388-4866

Patrick (Pat) Horine, EVP
patrick.horine@dnv.com
513-388-4888

Darrel Scott, SVP
darrel.scott@dnv.com
513-388-4862

www.dnvaccreditation.com

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

<p>Objective 2.1</p> <p>Measure:</p>	<p>Issue licenses within three working days of a completed application by June 30, 2011.</p> <p>Percentage of licenses issued within three work days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Review 100 percent of all applications within seven work days of receipt. 2. Process 100 percent of all deficiency documents within five work days of receipt. 3. Make a licensing decision within three work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. <ul style="list-style-type: none"> • Pharmacists • Intern pharmacists • Pharmacy technicians • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Designated Representatives (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors • Sterile Compounders 5. Withdrawn licenses to applicants not meeting board requirements. 6. Deny applications to those who do not meet California standards. 7. Respond to e-mail status requests and inquiries to designated e-mail addresses. 8. Respond to telephone status request and inquiries.
<p>Objective 2.2</p> <p>Measure:</p>	<p>Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.</p> <p>Percentage of revenue cashiered application within 2 working days.</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Cashier application fees. 2. Cashier renewal fees. 3. Cashier citations with fines. 4. Cashier probation and cost recovery fees. 5. Cashier request for information/license verification fees. 6. Cashier fingerprint fees.

<p>Objective 2.3</p> <p>Measure:</p>	<p>Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.</p> <p>Percentage of licensing records changes within five working days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Make address and name changes. 2. Process off-site storage applications. 3. Transfer intern hours to other states
<p>Objective 2.4</p> <p>Measure:</p>	<p>Implement at least 25 changes to improve licensing decisions by June 30, 2011.</p> <p>Number of implemented changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. 2. Evaluate the drug distribution system of clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. 7. Review requirements for qualifications of pharmacy technicians with stakeholders. 8. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. Note: I-Licensing system has been cancelled and the BreZE system will take its place. 9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards. 10. Implement new test administration requirements for the CPJE. 11. Participate in ACPE reviews of California Schools of Pharmacy. 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training. 13. Convene Committee to evaluate drug distribution within hospitals. 14. Improve reporting of and accounting for intern hours. 15. Participate in initiatives to increase the number of pharmacists in California to meet demand. 16. Assess the operations of specialty pharmacy services. 17. Encourage use of technology where it benefits the public. 18. Secure the implementation of e-prescribing in California by the earliest possible date. 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic. 20. Initiate changes to improve internal processing of application process. 21. Initiate internal and external processing of pharmacy technician applications. 22. Implement Fingerprint Requirement for Pharmacist Renewal upon approval of regulation from the Office of Administrative Law. 23. Initiate internal and external processing of site licensing applications.