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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE PUBLIC MEETING
MINUTES

DATE: March 27, 2014

LOCATION: DCA Headquarters Building Two
1747 N. Market Boulevard, Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair
Rosalyn Hackworth, Public Member
Allan Schaad, RPh
Victor Law, PharmD

COMMITTEE MEMBERS NOT PRESENT:
Greg Lippe, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, PharmD, Supervising Inspector
Michael Santiago, DCA Staff Counsel
Susan Cappello, Enforcement Manager
Debbie Damoth, Administration Manager
Laura Hendricks, Administrative Analyst

The meeting was called to at 9:32 a.m. Dr. Gutierrez, Chair of the Committee, welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Steve Gray, representing Kaiser Permanente, requested discussion surrounding the timing of issuance of hospital licenses in advance of the issuance of the CDPH license.

II. ENFORCEMENT MATTERS

a. FOR DISCUSSION: Update on Implementation of AB 1136 (Levine) Chapter 304, Statutes of 2013 Regarding Warning Labels on Prescription Container Labels

Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amends existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where their patients ability to operate a vehicle may be impaired.

At the January Board Meeting, Mr. Santiago commented that existing statute already makes the allowance for a pharmacist's professional judgment to decide if a drug could impair a patient's ability to operate a vehicle or vessel so the regulation does not need to say "including but not limited to."

Mr. Santiago further stated that 1744 needed to be amended only if the board wanted to change the list of classes of drugs for which an oral or written warning must be communicated to the patient pursuant to Business and Professions Code section 4074.

The board had no specific action directed as a result of that discussion. Nevertheless, there will be a newsletter article noting the changes made to Business and Professions Code Section 4074 by AB 1136, advising that pharmacists who have a professional opinion that a drug may impair a person's ability to operate a vehicle or vessel must provide a warning label to the prescription container.

Dr. Gutierrez indicated that she believes that a pharmacist's professional judgment should be used in determining that a drug should require such warnings as provided in existing law.

Counsel advised that if a pharmacist is using his or her professional judgment to provide a warning, separate from the 1744 listed drugs, then such a warning must be in writing.

Dr. Gutierrez referenced a handout provided at the meeting titled Multiple Medications and Vehicle Crashes: Analysis of Databases by NTSHA.

The committee commented that it may be prudent to evaluate this information to determine which of the drug classes listed in the handout would be appropriate for inclusion into 1744. Counsel advised that the committee should evaluate if 1744 is currently effective and then what changes need to be made to ensure it remains effective

Dr. Law cautioned that close attention needs to be paid to this issue to ensure that warning labels are not watered down.

Steve Gray, representing himself, indicated that including the list as presented, would essentially require such a warning on all labels or consider that the board prefaces the requirements on 1744 by stating that there may be other conditions under which a label is required.

The committee may also want to consider removing the specific provision from statute. Ms. Herold recommended that the statutory provision serves a need.

The committee stated that the list along with the pharmacist's professional review should be sufficient. The committee also noted that it would like staff to identify regulations that require updating and/or evaluation perhaps annually.

Committee Recommendation:
The committee requested that board direct staff to work on proposed revisions to 1744 and make a recommendation at the next committee meeting.
M/S: Hackworth/Law
Support: 4 Oppose: 0 Abstain: 0

b. FOR DISCUSSION AND POSSIBLE ACTION: Requests from UCLA Health System, Ronald Reagan UCLA Medical Center, for a Waiver as Permitted by California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Section 4128 et seq.

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

In January 2014, the Enforcement Committee discussed an identical request from Sharp Healthcare and Scripps Health. At that meeting, both hospital systems requested that the board approve their waiver requests to forego the specific labeling of elements in section 4128.4 that require the bar code to contain:

(a) The date the medication was prepared
(b) The components used in the drug product
(c) The lot number or control number
(d) The expiration date
(e) The National Drug Code Directory number
(f) The name of the centralized hospital packaging pharmacy

These items appear on the label but not in the bar code because the technology does not possess the capability.

The board voted to approve a five-year waiver for Sharp Healthcare and Scripps Health, so long as the information specified in section 4128.4 is provided on the prescription label, and the bar code on the container can still identify the name of the drug, the strength, and can be read against a bar code on the patient's wrist and patient medication record to ensure it is the right medication for that patient.

Similarly, Ronald Reagan UCLA Medical Center's current computerized physician order entry (CPOE) system is not configured to do a bar code read of the elements in section 4128.4, but it can read the NDC number on the container with a reader to ensure the container is read at the patient's bedside to ensure it is right medication in the right dose for the patient.

Becky Natali, representing UCLA, provided the board with a presentation on the need for the waiver, including current technology limitations that prevent full compliance with the provisions of Business and Professions Code section 4128.4. Ms. Natali indicated that due to UCLA's currently technology only the NDC number is included within the bar code and the remaining requirements would be listed on the label.

The committee advised that the centralized hospital packaging will not be used for sterile compounded products and will only be used for high volume drugs that are not currently available in unit dose packaging.

UCLA will update its technology when available. Steve Gray, representing CSHP, stated that it will be revising the legal requirements to solve this issue on a long term basis in legislation this year.

Committee Recommendation:
Recommend that the board approve the waiver request of UCLA for five years, identical to the requirements approved at the January Board Meeting.
M/S: Hackworth/Law
Support: 4 Oppose: 0 Abstain: 0

c. FOR DISCUSSION AND POSSIBLE ACTION: Opportunity to Provide Written Comments to the Federal Drug Enforcement Administration on the Possible Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 21 CFR Part 1308 [Federal Register Docket No. DEA-389]

Hydrocodone combination products are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for the marketing for the treatment of pain and for cough suppression.

The Drug Enforcement Administration (DEA) recently published a notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act.

Hydrocodone is a frequently prescribed drug for pain. Often the quantities prescribed for a patient greatly exceed the amount needed by a patient, so patients may have hydrocodone stored in their medicine cabinets. Hydrocodone is also a widely abused prescription medication, and a frequently diverted drug from pharmacies. Depending on the strength and local availability, a pill may be worth $2-$10 each.

Hydrocodone is the predominant controlled drug prescribed in California. During the joint DEA/Board of Pharmacy Prescription Drug Abuse presentations for which pharmacists could earn 6 units of CE, hydrocodone is a frequent discussion point.

In recent years, hydrocodone has been identified as a stepping stone drug, where individuals start with hydrocodone, like the feeling, take more and more of the widely available drug as they become habituated, and then move to stronger drugs like hydromorphone and then to oxycodone. And then when it becomes too expensive to obtain and purchase these drugs, leads individuals to heroin (which is much cheaper).

The question before the DEA and this Federal Register docket is whether hydrocodone should be rescheduled to federal Schedule II. If so, this drug will not be able to be refilled or prescribed orally. Instead, each time another fill of hydrocodone is needed, a new prescription will be required, much like that which occurs for oxycodone or Dilaudid.

Dr. Gutierrez highlighted the frequency of use of hydrocodone and the benefits of rescheduling hydrocodone containing products to a schedule II drug. The committee was advised that because of the timing of the comment period, the board will have time to comment if it should be a schedule II.

Dr. Law commented that the committee should recommend support of the rescheduling.

Committee Recommendation:
The Committee recommended that the board submit comments to the DEA to support the rescheduling of hydrocodone from Schedule III to Schedule II.
M/S: Law/Hackworth
Support: 4 Oppose: 0 Abstain: 0

d. FOR DISCUSSION: Opportunity to Submit Comments on the Standards for the Interoperable Exchange of Information for the Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket, Federal Register, Food and Drug Administration [Docket No. FDA-2014-N-0200]

The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving prescription drugs to comply with the new requirements in the Drug Supply Chain Security Act (DSCSA). Written comments are due by April 21, 2014.

This is one of the early steps undertaken by the FDA to develop a national system to secure the pharmaceutical supply. This content of the proposal was a frequent inquiry to the board when the board was working to implement California's e-pedigree system; however, the board declined to specify such a system.

Dr. Gutierrez provided an overview of the item. The committee was advised that there may not be the need to submit comments on this item because this appears to be more of a supply chain issue versus something that would directly impact the board's regulatory activities.

No action was taken on this item.

e. FOR INFORMATION: Development of an Alternative Process for Pharmacists to Become Registered to Access CURES

Last year, SB 809 (DeSaulnier) was enacted to enhance the CURES prescription drug monitoring program.

Part of the discussion associated with the bill's progression through the Legislature was the growing concern about the need for pharmacists and prescribers to access CURES before dispensing or prescribing controlled drugs. To access CURES to see the history of controlled drugs dispensed to a single patient over the last year, a prescriber or pharmacist must have

been preapproved by the CA Department of Justice. However, an abysmally low number of prescribers and dispensers have applied for and been granted access to CURES.

Provisions enacted in SB 809 require all prescribers and pharmacists to be registered with the DOJ to access CURES by January 1, 2016. However, the new computer system and funding for staffing for the DOJ to operate the CURES system will not be available until perhaps July 2015. Meanwhile, the Department of Consumer Affairs' agencies are transferring to a new computer system of their own that will create new systems for license issuance and renewal. Only the first one-third of DCA's boards have converted to the new BreEZe system. It may be late 2014 before phase II converts (this board is part of this group).

As such, it appears likely that few if any DCA boards will be able to comply with the January 1, 2016 CURES registration deadline for licensees.

The current process for CURES registration is frustrating and laborious. Individuals must start an email contact with the DOJ, then fill out an application they download, and then copy various documents (driver's license, professional license) and have the whole package notarized and then mailed to the DOJ. Lacking staff, the DOJ is taking months to process this material.

Board staff have discussed with the DOJ a process whereby the board could authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. Details are still being worked out, but a general process has been drafted.

Dr. Gutierrez provided an overview of the item, including concerns about the low enrollment rate of practitioners, including pharmacists, in the PDMP.

Dr. Gutierrez expressed need for the board to help facilitate the enrollment. Ms. Herold highlighted some of the barriers to enrollment in the PDMP including the need to notarize documents when the enrollment does not happen in person. Ms. Herold highlighted some of the current efforts by the DOJ to enroll pharmacists at events including CE presentations.

Ms. Herold indicated that board staff will now also collect and authenticate identification for purposes of CURES PDMP enrollment. Ms. Herold highlighted the steps that will be necessary to facilitate implementation of this new method of enrollment as well as the timeline for implementation. All present were advised that submission of the enrollment application can be done at the next board meeting.

The committee commented that there should be a more streamlined fashion to facilitate enrollment using technology. Ms. Herold highlighted some of the current technology challenges including a transition to a new computer system by both DCA as well as DOJ.

The committee also expressed concern about the board's lack of control over the current situation. Ms. Herold detailed the co-governance between DCA agencies and DOJ that was established recently as a condition of the additional funding.

The committee queried if there is an alternate way to access the system or receive CURES information and was advised there is currently no other way to receive the information. The committee was also advised that the new computer system for CURES should greatly improve ease of access.

Dr. Gutierrez requested that the board work with CSHP and CPhA to facilitate enrollment of pharmacists in the PDMP. She was advised that DOJ will be present at CPhA's annual meeting to enroll pharmacists that are attending.

Public comment indicated that they recommended that the board encourage local associations to reach out to DOJ for CURES registration at their events as well. Public comment also included that actual access to the system in pharmacies is another obstacle because employers do not provide access to the internet in a pharmacy. This is something that needs to be remedied - - other states' boards have sought legislative changes to require access in a pharmacy.

Other comments included does a pharmacist not practicing require enrollment in the PDMP. Such items should be included in the Script.

Ms. Herold highlighted some additional activities involved in improving the CURES system as well as a current legislative proposal to include schedule V into the CURES system.

The committee requested inclusion of an article in the Script on how it can be used. Staff will develop a Q&A document and a subscriber alert will be sent out to facilitate submission of questions.

The committee requested that for the next enforcement meeting an agenda item address the need for pharmacists to have internet access to the CURES system in all pharmacies.

The committee did not take any formal action on this item.

f. FOR DISCUSSION AND POSSIBLE ACTION: <u>Losses of Controlled Drugs Reported in California</u>

A pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days. A separate requirement also mandates these entities to notify the DEA of significant losses of controlled drugs (a loss is reported on a form DEA 106).

Recently, the board's staff compiled some statistics regarding drug losses reported to the board in order to respond to press inquiries. The staggering results will be shared during the board meeting.

Dr. Gutierrez provided an overview of the item, included the mandatory reporting requirement of drug losses to the board as well as to the DEA. Dr. Gutierrez indicated that based on preliminary review of the data generated from the aggregated data, significant losses are being reported.

Dr. Gutierrez expressed concern about the significant losses and perhaps the need for more stringent inventory controls as a way to more quickly identify losses resulting from employee pilferage.

The committee discussed the need to mandate reconciliation between invoices and disposition and encourage more current inventory practices are needed.

The committee was advised that during the next meeting, statistical analysis and trends over the past couple of years will be evaluated.

Ms. Herold noted that these losses represent drugs being diverted for self-use or to the street.

The committee discussed possible steps to require tighter inventory controls which could be done either by regulation, statute or policy -- perhaps monthly reconciliation on the top ten drugs for the pharmacy. The committee noted that further discussion is necessary to determine the appropriate solution. Requesting a monthly printout of scheduled drugs and taking a look at the data would greatly assist in facilitating a monthly reconciliation.

The committee discussed that the landscape has changed and tighter controls are necessary.

Committee Recommendation:
The committee recommended that the board promulgate a regulation to require monthly counts on the top ten controlled substances in volume by all pharmacies and clinics.
M/S: Law/Schaad
Support: 4 Oppose: 0 Abstain: 0

There were no comments from the public.

Dr. Gutierrez recessed for 10 minute break at 10:55 a.m.

The meeting reconvened at 11:09 a.m.

g. FOR INFORMATION: <u>Presentation on "What We Find When We (the Board of Pharmacy) Inspect Pharmacies"</u>

The board's executive officer continues to be asked to speak about pharmaceutical supply chain issues that have been discovered by the board. At this meeting, a short PowerPoint presentation was given by the executive officer regarding what the board finds when inspecting pharmacies or reading the industry's journals.

Ms. Herold highlighted the need for supply chain traceability and the possible impact or concerns with the delay in implementation of such requirements. Ms. Herold highlighted the several forms of drug compromise including recycled drugs, counterfeit drugs, selling drugs that have been stolen, unlicensed sales (e.g.) Craigslist, selling of samples, etc.

The committee questioned who regulates the internet purchases and was advised that the NABP is working to strengthen controls over internet purchases via the pharmacy suffix.

There was no public comment on this item.

h. FOR INFORMATION: <u>Demonstration by Omnicell Regarding Technology Currently in Use for Pharmacies Providing Automated Drug Delivery Systems in Health Care Facilities Licensed Under Health and Safety Code section 1250 (c), (d) or (k)</u>

During this meeting Rich Hooper, System Sales Director Non-Acute Care, Omnicell and Omnicare, provided a demonstration on restocking procedures of their automated dispensing cabinet (ADC) as it is used in long term care for emergency/first dose medication.

Omnicell's technology provides for the restocking of automated dispensing cabinets being used as emergency kits. The committee was provided an overview of why automated solutions in skilled nursing facilities are necessary in that automation helps to reduce the use of tackle boxes of medications and helps ensure that patients are not readmitted into a hospital.

Representatives provided the committee with an overview of the current practice of delivering drugs to SNFs from a pharmacy without the use of technology and indicated it was their intent to discuss the intent of Health and Safety Code section 1261.6 on who can restock a machine. Omnicell representatives asked if a pharmacy technician can restock an automated dispensing cabinet. They asserted that the intent of the regulation is to ensure sufficient controls are in place and that their solution provides for such controls.

Omnicell stated that CDPH has advised them that a nurse can perform the restocking.

The committee asked about electronic supervision and was advised there is none. Since this system is only being used as an e-kit. The committee was advised that the device is owned by the pharmacy.

Ms. Herold requested that Omnicell formalize their request in writing to the board including exactly what they are requesting. The committee suggested that the proposal also highlight where the pharmacist is involved in the process.

The committee did not take action on this item.

Steve Gray, representing himself, suggested that when the analysis is done, consider the state of technology when the legislation was enacted years ago. Dr. Gray also referenced the need to clarify the meaning of "supervision." Dr. Gray indicated that he believes that the technology solution provides for better security.

Rita Shane, representing Cedars Sinai, indicated the machine security levels need to be closely evaluated and managed, irrespective of who owns the devices.

Robert Menet, representing CDPH, clarified that the function of restocking of the machine would not be done by a nurse.

III. COMPOUNDING MATTERS

a. FOR DISCUSSION AND POSSIBLE ACTION: General Discussion on the Board's Proposed Compounding Regulations

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.). The 45-day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

During the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

After reviewing and considering the written and oral comments received, board staff recommends the following for discussion and possible action:

1. Withdraw the current rulemaking file originally noticed November 29, 2013.
2. Provide general guidance from the sterile compounding workgroup to develop new updated language based on the comments received by the board, and notice the revised language as a new rulemaking.

Dr. Gutierrez provided a brief overview of the timeline for the compounding regulations, including the release of the proposed language and commented that many written as well as oral comments were received.

Dr. Gutierrez reminded the committee that during the January 2014 board meeting, the board directed a subcommittee to evaluate all of the comments and make recommendations at the next board meeting on how to move forward.

Dr. Gutierrez highlighted the overwhelming number of written and oral comments received and the work completed by the subcommittee members, board attorneys, and board staff to review these comments.

Dr. Gutierrez further commented that after review of the written and oral comments it created a whole new area that needed to be considered for sterile compounding in hospitals related to hazardous materials, negative pressure and immediate use and 12-hour immediate use, etc.

Committee Recommendation:
The Committee recommended that the board withdraw the current compounding rulemaking, revise the language to incorporate many comments submitted in response to the initial regulation notice and notice the new language as a new rulemaking.
M/S: Hackworth/Law
Support: 4 Oppose: 0 Abstain: 0

Jerra Bandworth applauded the board's deliberative process in the development of the regulations. USP Chapter 800 is being released tomorrow and provides an opportunity for public comment on their new proposed requirements.

Anne Carlson, UCSD Medical Center, requested clarification on how this recommendation will impact licensure requirements for sterile compounding. She was advised that licensure is required July 1, 2014 and hospitals must comply with current regulations that have already been promulgated.

b. FOR INFORMATION: Update on Compounding Provisions Enacted by HR 3204, The Federal Drug Quality and Security Act and the Recent Meeting Between the FDA and the States' Boards of Pharmacy

Included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by

"outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities.

California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with our board and comply with California requirements as sterile compounding pharmacies. The FDA may also require or encourage licensure as an outsourcing facility.

Ms. Herold provided a brief overview of a recent meeting convened by the FDA with state board of pharmacy representatives, relating to the regulation of compounding pharmacies. The ultimate goal was to develop a policy relating to the regulation of compounding pharmacies as well as outsourcing facilities. Ms. Herold reiterated that the board will continue to regulate compounding pharmacies; however compounding pharmacies may also be regulated by the FDA. Ms. Herold noted that federally many things remain in flux. Ms. Herold noted that the FDA will post their "483 inspections" on line if there are violations. FDA will also issue warning letters.

Ms. Herold advised the committee that there is currently no draft MOU with the FDA yet available and the board has not entered into such an agreement yet.

Joe Grasela, University Compounding Pharmacy, encouraged the board to continue to allow prescriber office use and that anticipatory compounding is in the best interest of the patient. He suggested that if necessary, a limit could be placed to limit the practice. He suggested that a definition of "for office use" could provide clarity.

William Blair, McGuff, suggested that California could help alleviate drug shortages by allowing anticipatory compounding for delivery to a location other than a prescriber's office, e.g., a hospital. Current law does not allow a pharmacy to compound for a hospital. It appears there is a conflict between what an outsourcing facility can do independent of California requirements. One area of concern identified is an outsourcing facility can provide compounded medications to a hospital, however if also licensed as a pharmacy, that the entity would be prohibited from doing so.

Public comment included questions about what the FDA is going to require as part of the MOU. Public comment suggested that the board may need to consider all areas where compounding occurs as well as the definition of "prescriber office use" and consider how Texas currently interprets a similar provision.

The committee did not take action on this item.

c. FOR DISCUSSION: Data Collected on Violations Found During Compounding Inspections in California

During the FDA's recent meeting of all state boards of pharmacy convened to discuss their activities with respect to compounding, the board's executive officer was one of several asked to provide an overview of compounding within the state.

Ms. Herold provided the presentation she provided during the FDA meeting. The presentation included the history of compounding in California and actions taken by the board to ensure public safety is not compromised by sterile compounding practices. Ms. Herold highlighted recent law changes enacted in SB 294 including reporting and licensure requirements. Ms. Herold highlighted the cease and desists orders issued since September 2012 as well as inspection findings. Ms. Herold highlighted the top ten violations found during compounding inspections which included lack of compounding self-assessment, quality assurance issues, facility issues, adequate compounding attire, general compounding quality assurance issues, process validations issues, insufficient or nonexistent policies and procedures, substandard equipment used, and lack of training.

There was no public or committee discussion.

d. FOR INFORMATION: Update on the National Shortage of IV Solutions

The committee reviewed an article.

There was no public or committee discussion.

IV. MEETING DATES FOR 2014

Meeting dates for the remainder of 2014 have been scheduled for:

- June 26, 2014
- September 30, 2014
- December 17, 2014

Additional Item for Future Agenda:
Rita Shane, requested discussion on medication lists that are entered into medical records by non-licensed persons. This is an issue because someone with limited medical knowledge is creating a document related to healthcare. that is causing medication errors because of inaccurate data entry.

The meeting was adjourned at 1:20.