



California State Board of Pharmacy

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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
MEETING MINUTES**

DATE: September 16, 2014

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

COMMITTEE MEMBERS

PRESENT: Amy Gutierrez, PharmD, Chair, Professional Member
Allen Schaad, RPh, Professional Member
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Greg Murphy, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, PharmD, Supervising Inspector
Christine Acosta, PharmD, Supervising Inspector
Desiree Kellogg, Deputy Attorney General
Susan Cappello, Enforcement Manager

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:18 a.m.

Dr. Gutierrez 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

No public comments were received.

II. ENFORCEMENT MATTERS

a. **FOR DISCUSSION: Evaluation of 16 CCR section 1744 Regarding Required Warning Labels on Prescription Container Labels**

Background

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 a patient's ability to operate a vehicle (and now a vessel) may be impaired. This section has not been revised in a number of years, so recently the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

A number of California's schools of pharmacy offered to assist, but not all schools have yet provided comments.

All proposed changes submitted were aggregated onto the draft below.

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

(1) Muscle relaxants.

~~(2) Analgesics with central nervous system depressant effects.~~

- (3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines. (one commenter left the strike out in)
- (4) Antidepressants with central nervous system depressant effects.
- (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V central nervous system depressant ~~or narcotic controlled substances~~ opioids or sedative-hypnotic as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- (7) Anticholinergic agents and other drugs which may impair vision.
- (8) Ramelteon (Sedation)
- (9) Minoxidil (Hypotension)
- (10) Phosphodiesterase V inhibitors (hearing and visual impairment)
- (11) Bromocriptine (dizziness and fatigue exacerbates alcohol)

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

- (1) Disulfiram and other drugs (e.g. ~~chlorpropamide~~, sulfonylureas, cephalosporins, trimethoprim, isoniazid, isotretinoin, griseofulvin, ketoconazole, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine
- (5) Verapamil (enhanced alcohol intoxication)
- (6) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia)
- (7) Niacin (increased risk of flushing and pruritis)
- (8) Erythromycin (may increase absorption of alcohol)

Or/and

(b)(2) Monoamine oxidase inhibitors (due to the risk of hypertensive crisis if the alcohol contains significant amounts of tyramine (some beer, red wine)

(b)(3) Nitrates due to the risk of additive cardiovascular effects.

Or/And

(c) Corticosteroids (BEERS list to avoid in the elderly)

(d) Dipyridamole (BEERS list to avoid in the elderly)

One commenter stated:

I recommend since specific labeling is required on containers by AB 1136, pharmacy software programs need a list of specific drugs to link to the warnings so they can be indexed to the drug by the software.

However another stated the current list primarily contains drug classes rather than individual drugs. That approach should be maintained since listing individual drugs will quickly become outdated as new drugs are marketed, and again the pharmacist can exercise judgment regarding which individual drugs within a class are of concern.

The committee reviewed and developed new text for section 1744.

Discussion

Dr. Gutierrez recommended that the committee keep the proposed language as broad as possible and not list individual drugs as the drugs will change over time. This also would allow the pharmacist to use his or her professional judgment.

Dr. Gray recommended including a portion of the statute's lead in paragraphs in the proposed revised regulation as the pharmacist tends to go right to the regulation without referring to the statute. Dr. Gray also noted that in the definitions of the Business and Professions Code it stated that Schedule II, III, IV and V drugs refer to any drug listed in the California Health and Safety Code.

Dr. Gutierrez suggested including a portion of the language in Business and Professions Code section 4074(2) (b) as part of the introduction to 1744, specifically, *"If a pharmacist*

exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel." In addition to this language indicate that the list is not all inclusive and a pharmacist is still required to use his or her professional judgment.

Committee Recommendation:

Motion: Recommend that the board adopt the revisions to section 1744 of the Title 16 California Code of Regulations, as follows:

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription. If a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

(a) The following classes are examples of drugs that may impair a person's ability to drive a motor vehicle, vessel or operate machinery when taken alone or in combination with alcohol:

(1) Muscle relaxants.

~~(2) Analgesics with central nervous system depressant effects.~~

(3) Antipsychotic drugs with central nervous system depressant effects ~~including~~ phenothiazines.

(4) Antidepressants with central nervous system depressant effects.

(5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~

- (7) Anticholinergic agents and other drugs which may impair vision.
- (b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:
- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
 - (2) Mono amine oxidase inhibitors.
 - (3) Nitrates.
 - (4) Cycloserine.
 - (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

M/S: Hackworth/Schaad

Support: 4 Oppose: 0 Abstain: 0

b. FOR DISCUSSION AND POSSIBLE ACTION: Remaining Need for Health and Safety Code Section 11164.5(a), Approval to Receive Electronic Prescriptions for Controlled Substance Prescriptions

Background

Health and Safety Code section 11164.5(a) requires the approval of the Board of Pharmacy and the CA Department of Justice (DOJ) before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders. This provision was enacted before the Drug Enforcement Administration (DEA) promulgated their e-prescribing requirements several years ago.

Kaiser Permanente recently requested the board's position on whether this provision is operative and how is the board complying with it.

Board staff do not believe that there is any need to retain this provision since the DEA has promulgated the required regulations to permit e-prescribing, and the staff recommend amending subdivision (a) out of 11164.5. There will likely need to be additional conforming changes to 11164.5 if subdivision (a) is removed. This should be part of the committee's discussion.

Discussion

Dr. Gray provided background on the history of this provision indicating that in 2000, the DEA wanted to move to electronic prescribing but it hadn't come up with a system yet to do so. California changed its law in order to be ready for electronic prescribing, however the DOJ Bureau of Narcotic Enforcement was dissolved and this requirement was never enacted.

Grace Toy of Kaiser's National Compliance Office requested approval from the committee to allow Kaiser to electronically prescribe controlled substances once approved by the DEA, provide Kaiser with an exemption, or provide additional guidance so that Kaiser could proceed in a lawful manner.

Dr. Gutierrez asked DAG Kellogg whether the board needed its own provisions or if the board could just comply with the federal regulations. DAG Kellogg advised that the board no longer needed this provision.

Committee Recommendation

Motion: Recommended that Section 11164.5(a) of the Health and Safety Code be eliminated.

Comments

Dr. Gray agreed that the board no longer needs to approve systems approved by the DEA and that the committee should recommend elimination of section 11164.5(a) to the full board.

Ms. Herold cautioned that striking Health and Safety Code section 11164.5(a) may have consequences to other subdivisions of section 11164.5 and that the board would have to ensure it does not somehow alter other components of 11164.5(b) – (d). Eliminating this section would also require the board to sponsor legislation to amend the Health and Safety Code.

Ms. Herold stated that staff would work with legal counsel to review the other sections and bring it forward to the board with the rest of what may need to be done to the section.

Dr. Gray further requested that the board pursue emergency legislation so that the change could go into effect as soon as it was signed by the governor because the legislative process could be drawn out. An alternative suggestion was made that perhaps it could be written into the language that the board would not enforce this section while legislation is pending.

Amended Motion: Recommend that section 11164.5(a) of the Health and Safety Code be eliminated and to include in the language that the board does not need to enforce this section while the legislation is pending.

M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

c. FOR DISCUSSION AND POSSIBLE ACTION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

At the March 2014 Enforcement and Compounding Committee, Chairperson Gutierrez led a discussion of losses of controlled substances reported to the board as required by California Pharmacy law. A pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days.

The board’s staff has compiled some statistics regarding drug losses reported to the board over the last few years. The following tables display the losses of controlled substances reported to the board.

Year	2009	2010	2011	2012	2013	2014 (6 mo.)
Number of Reports	614	749	536	639	1224	678
Loss Type	Total Count Reported					
Armed Robbery		70,786	35,773	106,787	80,464	
Customer Theft		9,550	4,598	5,684	13,175	
Employee Pilferage		252,225	452,877	372,926	125,305	
Lost in Transit		13,239	412,168	*1,657,875	22,310	
Night Break In		505,016	80,971	689,925	154,156	
Other		121,635	532,441	518,432	94,267	
Totals		972,450	1,518,828	3,351,628	489,677	

* In transit losses

DEA 106 Reports by License Category

Category	2011	2012	2013	2014
Pharmacy	376	460	943	551
Hospital	115	104	230	97
Wholesaler	33	35	58	35
Out of State				
Distributor	1	6	8	4
Correctional Facility	10	5	2	5
Clinic	1	2	0	0
Non Resident				
Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
Total	536	613	1244	693

2013 Losses

	<u>No. of Reports</u>	<u>Dosage Units Lost</u>
Chain Store:	652	564,061
Community:	291	533,045
Hospital:	230	28,073

2014 Losses (6 months only)

Chain Store	443	226,866
Community	108	289,751
Hospital	97	990

In 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units reported by a major manufacturer who had a truck stolen.

At the last meeting, it was noted that these numbers are only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

The committee expressed concern about the significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee

pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

At the April 2014 Board Meeting when this topic was discussed, the board asked the committee to draft regulation language to require monthly counts of a pharmacy's fastest controlled substances as a form of inventory control.

Staff's Proposed Language: Add as section 1715.65 to 16 California Code of Regulations:

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

- (a) Every June 30th, each pharmacy and clinic licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
- (b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy or clinic shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
 - (1) The inventory recorded on the first of the preceding month
 - (2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)
 - (3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
 - (4) The drugs in quarantine waiting for the reverse distributor,
 - (5) The final inventory count on the first of the month
 - (6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
 - (7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.
- (e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of the monthly and annual inventories to establish secure methods to prevent losses of all dangerous drugs.

Discussion and Comment

Dr. Gutierrez highlighted the need for pharmacies to perform monthly counts of a pharmacy's fastest moving controlled substances as a form of inventory control.

Performing these counts would allow the pharmacy to find a potential diversion problem early on.

Mr. Lippe sought clarification on what was classified as the loss type of “other” as noted the drug loss report. Ms. Herold indicated that these losses are unaccounted for and the pharmacy does not know why the losses occurred.

Dr. Gutierrez sought clarification on what was classified as the loss type of “customer theft.” Ms. Herold provided scenarios wherein a customer would reach over the counter and grab the bag or a spouse of one of the pharmacy staff would take the controlled drug from a pharmacy.

Ms. Herold commented that the losses at the community pharmacies are similar to those losses at chain stores. Dr. Gutierrez was surprised at the high number of losses at a retail pharmacy compared to a hospital pharmacy.

Dr. Gutierrez recommended that the medical director sign for the inventory in a clinic as the consultant pharmacist only performs quarterly reviews. Dr. Gutierrez recommended changing the language in item (e) as the pharmacy should already have measures in place.

The board heard many comments regarding whether to include hospital pharmacies and clinics in this proposed regulation. It was noted that clinics do not have a pharmacist in charge but a consultant pharmacist that performs quarterly reviews and that the doctors are responsible for the daily operation of the clinic. It was also noted that hospitals routinely perform regular counts of controlled substances and perhaps this regulation was not needed for hospital pharmacies. It was also suggested to include exempt hospitals (known as drug rooms). Some felt the medical director should also be held accountable.

Dr. Gutierrez commented that the language be amended to require consultant pharmacist and medical director sign for the inventory. Ms. Herold inquired if the board should include pharmacies that are licensed under Business and Professions Code section 4057 and require the medical director to perform the monthly inventory.

Dr. Gray recommended, for clarity purposes, that where the proposed language states “clinic” that it is clear that a “clinic” is a clinic licensed by the board, same as for a hospital. It was further noted that clinics do not have a sophisticated computer system and monthly counts would be very difficult to perform because it is only noted in a patient’s medical record with handwritten notes of what was administered. Significant modifications would have to take place for a clinic to adhere to this proposed regulation.

Dr. Gutierrez inquired if the proposed language was intended to affect the clinic at the administration level. Ms. Herold stated that this language is intended to account for what comes in, what goes out, what’s quarantined, what’s in pending, and then what’s the

difference between stock on hand and what records indicates should be in stock. Dr. Gray feels there needs to be some clarification as to who needs to then perform these counts.

Ms. Sodergren suggested that the committee inquire as to how a clinic complies with the records requirement in Business and Professions Code section 4081.

Dr. Gutierrez asked if there was anyone from a clinic in the audience.

Dr. Gutierrez suggested the committee focus on community pharmacies and add hospitals and clinics to the regulation at a later date. Dr. Gutierrez also suggested getting input from clinics at the next committee meeting.

Committee Recommendation

Motion: Recommend the board adopt the proposed language to add as section 1715.65 to 16 California Code of Regulations, for community pharmacies only, as follows:

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

- (a) Every June 30th, each pharmacy licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
- (b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
 - (1) The inventory recorded on the first of the preceding month
 - (2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)
 - (3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
 - (4) The drugs in quarantine waiting for the reverse distributor,
 - (5) The final inventory count on the first of the month
 - (6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
 - (7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.

(e) The pharmacist-in-charge shall perform a quality assurance review of the monthly and annual inventories and take appropriate actions to maintain secure methods to prevent losses of all dangerous drugs.

M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

d. FOR DISCUSSION: Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for identification of Medication Diversion from These Units

Chairperson Gutierrez is considering a future meeting agenda item where the committee can learn about drug storage security features to deter diversion that are built into automated dispensing and storage devices used in hospitals and skilled nursing facilities. Time will be devoted at this meeting for a discussion of this topic, but a more in-depth review will be scheduled for a future meeting where the committee will be able to view some of the anti-diversion technology or features in use in California.

Discussion and Comments

Dr. Gutierrez indicated that a hospital has a different set of circumstances than a retail pharmacy. Dr. Gutierrez further stated that it would be a good idea to see what the technology provides to prevent drug diversion. She recommended that for future agenda items, the committee invite some of the larger automated vendors to provide background on how their technology can identify and address drug diversion in a hospital setting.

Mr. Lippe concurred with Dr. Gutierrez that it would be a good idea to see these demonstrations.

A representative from DYNA Labs volunteered the co-founder of DYNA Labs to speak at a future meeting on this topic.

Ms. Herold stated that the committee is looking for presentations on this topic and the kinds of reports are available from these types of devices. Ms. Herold further stated that the board has recently sent some California hospital pharmacies to the Attorney General's Office because the pyxis machine had been raided by staff and an access report was never pulled or reviewed. Ms. Herold suggested that if a pharmacy has an access report to a dispensing unit, to start looking at it. Dr. Gutierrez stated that there needs to be some kind of reconciliation. Ms. Herold further stated that the reports are reviewed, they offer really good protection.

Ms. Herold asked the committee if they wanted her to start contacting entities that the board knows use these devices to provide demonstrations. It was noted that Omnicell, Pyxis, and Talyst were three entities that sell this type of machine.

Lynn Paulsen, UCSF, asked about having the software companies provide a presentation. These companies would focus on auditing rather than on how cool the machine is. Dr. Gutierrez noted that software packages were add-ons and marketed themselves. Dr. Gutierrez stated that auditing is only a portion of what the board is looking at and there are a lot of security issues. Dr. Paulsen indicated that the manufacturers may not tell you their weakest points. Dr. Paulsen also commented that most machines throughout the United States have the same keys that open the back of the machines.

Dr. Gray noted that there will be vendors at the CSHP annual seminar meeting in San Francisco at the end of October 2014 that they will have these machines on display. The board could ask CSHP for the list of which companies will be attending. In addition, ASHP will also have vendors at its annual clinical meeting in Anaheim in December 2014.

Dr. Gutierrez suggested that the board start with some of the vendors that the board has had to report to the Attorney General's Office.

No further comment was provided from the committee or public.

e. FOR DISCUSSION: The Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication

On Tuesday, September 9, the DEA released its regulations on the take back of drugs from the public – specifically the take back of controlled substances.

The final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

Attachment 4 contains the DEA's requirements for drug take back (pages 151-200) along with their comments to written comments received in response to the prior proposed regulation.

The committee will have the opportunity to discuss the DEA's requirements and options for future action, if any, by the board in this area. **Attachment 4** also contains a *Wall Street Journal* article about the regulations.

Discussion and Comment

Dr. Gutierrez stated that she found the *NY Times* article interesting because it talked about how it's going to be positive on the one side but on the other side its introducing a whole new stream of drugs coming back into the pharmacy.

Ms. Herold stated that the DEA is calling the drugs waste and trying to keep them separate which is why the board needs to have some regulations in place in this area.

The DEA developed some requirements that offer opportunities for the board to move in the right direction. The board recommended dual key lock boxes in a pharmacy but DEA wanted one key with two people auditing the contents. The board has already been contacted by Senator Jackson's office asking when the board's regulations will be ready. The regulations also need to include some inventory requirements.

Ms. Herold will have staff draft proposed language. Ms. Herold feels that the board will need a series of public meetings before the board moves forward with a regulation package.

Dr. Gutierrez asked the audience if there were any facilities interested in participating. No volunteers came forward.

Dr. Gray stated that pharmacies are being pressured politically locally for healthcare organizations to get involved. He further indicated that healthcare organizations would be forced by local ordinances to get involved. Dr. Gray felt that the local city or county would pass laws that mandate pharmacies get a DEA permit and then establish these programs.

Dr. Gray was also unclear if the pharmacy was expected to inventory or separate the drugs as it was his impression that the board did not want these drugs inventoried as it would make it easier for diversion, safety and contamination. Lastly he questioned who the inventory requirement fell on, the pharmacy or the reverse distributor.

Ms. Herold further stated that the DEA and the board want these programs to be voluntary.

Ms. Herold advised Dr. Gutierrez that the board will have something for the committee to review at a future meeting.

f. FOR DISCUSSION: Rescheduling of Hydrocodone to Schedule II

Background

Hydrocodone combination products (HCP) 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) has secured the "up scheduling" of hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act. At the April 2014 board meeting, the board directed that the

board submit a letter of support to the DEA, along with a request for a transition period to fully implement this change.

Attachment 5 includes a copy of the board's letter of support.

Below is a copy of a subscriber alert the board will release after the discussion at this meeting.

1. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?

A: Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes, the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs before October 6, 2014 that are presented to the pharmacy for dispensing on or after October 6, 2014: are these to be dispensed as a Schedule II or Schedule III controlled substance?

A: On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

The DEA has stated, however, that it will allow refills on HCPs written before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (before April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written before October 6, even if provided to the pharmacy on or after October 6 to the maximum allowable period for Schedule III refills (before April 8, 2015).

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?

A: According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that was written before October 6, 2014 with refills, can the

refills be honored?

A: Yes, up to April 8, 2015, so long as the original date on the prescription does not exceed 180 days, or the maximum allowable period for Schedule III refills.

5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?

A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

6. Like some states, is California precluding pharmacies from refilling HCPs prescriptions written prior to October 6, 2014?

A: No, the federal allows such refills to be filled pursuant to limitation in existing law for refilling Schedule III drugs.

From the federal announcement:

On Friday, August 22, 2014, the DEA published in the Federal Register the final rule to transfer HCPs from federal Schedule III to federal Schedule II. HCPs have been controlled in schedule III since enactment of the Controlled Substances Act (CSA) in 1971. HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.

- Effective October 6, 2014, HCPs will be controlled as Schedule II substances under the Controlled Substances Act (CSA).
- DEA is also permitting legitimate HCP prescriptions issued before October 6, 2014 to be refilled until April 8, 2015, if the prescription authorizes refills.
- The Notice of Proposed Rulemaking (NPRM), Final Rule, and its supporting documents (i.e., medical and scientific evaluations, and economic impact analysis) may be viewed online at www.regulations.gov<<http://www.regulations.gov>>, Docket No. DEA-389.
- Alternatively, the documents can be obtained on the DEA website at www.deadiversion.usdoj.gov<<http://www.deadiversion.usdoj.gov>>.

Questions and Answers;

- a. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?

A: Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes,

the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs **before** October 6, 2014 that are presented to the pharmacy for dispensing on October 6, 2014: are these dispensed as a Schedule II or Schedule III controlled substance?
A: On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.
3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?
A: According to guidance from the DEA, yes.
4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that is written on October 6, 2014 with refills, can the refills be honored?
A: No, the DEA stated the prescription needed to be presented before October 6 to use the refills.
5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?
A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

Discussion and Comments

Dr. Gutierrez asked how this change would work for CURES and was advised that it was a software problem and the pharmacy will need to secure the necessary software changes. Ms. Herold stated this was a transition period and the pharmacy will have to figure out how to manage it. Mr. Lippe asked if the pharmacy would get in trouble if they chose not to refill a prescription if they didn't want to or could accommodate refills of a Schedule II drug

during the DEA's six-month transition. He was advised that the pharmacy would not be disciplined for this.

Jeff Nehira representing Dignity Health asked if the board could comment on what if the prescription was transferred after October 6. The committee questioned if a prescription for HCPs transferred could be filled as a refill prescription because it would be hard to validate when that prescription was filled and refilled.

Dr. Gray representing Kaiser Permanente, stated that the ability to refill is permissive, not required. There isn't one system that allows you to change from Schedule III to II. The board should be prepared to receive some complaints from patients who are unable to get their prescription refilled. Dr. Gray suggested that since the state is looking ahead with electronic prescribing, the statute should be changed, as these prescriptions will be received electronically through a very secured DEA system and that a pharmacy should be able to fill an out of state prescription.

Scott Clark representing the California Medical Association encouraged the board to work with the pharmacies and the pharmacists to let prescribers know how the board intends to implement the transition period so that there is not an impact on the patient and prescribers.

Ms. Herold advised the audience that the Medical Board and the Dental Board are aware of the change. Ms. Herold further stated that she had shared the Q&A list with those boards. Dr. Gutierrez requested board staff to work with the Medical Board to get the word out.

Dr. Paulson feels that even though the DEA said there could be refills it should be communicated as no refills. She stated the systems are just not going to allow it and it should be communicated as no refills.

Dr. Acosta commented that maybe the software could re-write the prescription or if the pharmacy could find a way for the pharmacy to identify if there were refills remaining. Dr. Ratcliff stated if you could access the original prescription and track on this document how many refills were remaining during this transition period.

g. FOR DISCUSSION: Rescheduling of Tramadol to Schedule IV

Background

Tramadol is a centrally acting opioid analgesic that has been on the market since the mid-1990s. Subsequently, the FDA approved for marketing generic, combination, and extended release tramadol products as dangerous drugs but not as controlled substances. However, over the years, the board and other entities have identified instances where tramadol was misused in part because as a dangerous drug, it was more readily available than a controlled substance would be.

In mid- August, the DEA secured the scheduling of tramadol into Schedule IV of the controlled substances schedule.

Attachment 6 includes a copy the board's subscriber alert and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Final Rule

At this meeting, the committee reviewed the subscriber alert and article from the Federal Register. There was no committee or public comment.

h. FOR INFORMATION: Update on the Alternative Process for Pharmacists to Become Registered to Access CURES

Last year, SB 809 (DeSaulnier) was enacted to enhance and rev up 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 more frequently 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, a 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 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 at this time.

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

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. The DOJ is currently taking about one month to process this material.

Board staff has implemented a process whereby the board can authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. The board began accepting applications in July 2014 and has to date received approximately 150 applications.

Currently there are 9,268 pharmacists registered with CURES, about 25 percent of all pharmacists.

Ms. Herold indicated the board would come prepared to accept CURES registration applications at the California Society Health System Pharmacists (CSHP) booth at the end of October 2014.

Public Comment

Holly Strom indicated that a DEA number was not required for CURES registrations and urged all pharmacists to register.

Satinder Sandhu, representing Walgreens, inquired as to the length of time it was taking to process CURES applications and was advised that the application process was taking approximately three weeks. Ms. Herold also stated that if you don't access CURES at least once every six weeks, you'll be bounced off. It was recommended that pharmacists sign-in at the beginning of every month so that they don't get placed in the inactive status and have to go through the revalidation process.

Jill Hacker, CSHP, inquired if all licensed pharmacists were required to register even if they weren't currently dispensing or if they were living out of state. Ms. Hacker was advised that the law states that all licensed pharmacists must register for CURES. Ms. Hacker indicated that CSHP may consider legislation to amend the law for exemptions in the future.

No additional committee or public comment was provided.

i. FOR DISCUSSION: Presentation by Rita Shane, PharmD, FASHP, FCSHP on Medication Reconciliation in Health Care Facilities

Medication reconciliation is intended to ensure the accuracy of a medication list of drugs taken by a patient. It involves the review, update, and reconciliation of medications at each encounter.

Rita Shane, PharmD, has advised that given the errors in medication lists that occur when patients are admitted to the hospital, evidence supports that pharmacy staff need to ensure these lists are updated and corrected in order to prevent hospital medication errors, reduce readmissions and prevent medication errors when the patients go home.

A physician colleague of Dr. Shane recently completed a randomized controlled trial showing there were seven errors per medication list for patients admitted to the hospital. The same trial also showed the impact of pharmacy staff on reducing these errors.

A PowerPoint presentation was provided by Dr. Shane regarding medication reconciliation in health care facilities.

A related article on this topic is provided in **Attachment 7**.

The PowerPoint slides can be found at the back of the minutes.

Dr. Gutierrez sought clarification on whether the study was based on the patient being a good historian of all medications he or she takes or the “gold standard” pharmacist. Dr. Shane indicated that the study was based on the gold standard pharmacist as well as consulting with the primary care and/or prescribing physician.

Mr. Lippe asked Dr. Shane to explain what SureScript’s function was. Dr. Shane explained that SureScript’s is a hub for prescription data that is e-prescribed to which all the different prescription benefit management (PBM) companies upload information.

Dr. Gutierrez asked Dr. Shane what she was proposing. Dr. Shane stated she would like the committee to consider regulations that require hospitals to create better and more accurate medication lists.

Ms. Herold asked if this process was being implemented at Cedar’s Sinai and as advised that Cedar’s Sinai started doing medication reconciliation with high risk patients and emergency admissions in 2011.

It was asked if pharmacy technicians could perform this task. It is unclear if these tasks are viewed as discretionary or nondiscretionary. It was recommended that a specially trained pharmacy technician perform this duty.

Dr. Shane further stated that California pharmacies should take a leadership role in owning the medication lists.

Dr. Gutierrez suggested sharing this data with California Hospital Association (CHA) Medication Safety Committee, as a first step and get some recommendations by the committee. Ms. Herold commented that she’d like to see this as a collaboration across professions.

Public comment supported the idea of medication reconciliation lists and to continue discussions with all groups. It was also noted that there is a regular nationally published newsletter on medication reconciliation findings. Outpatient pharmacy technicians were found to be better suited for cataloging medications.

No additional committee or public comment was provided.

Dr. Gutierrez recessed for a 30-minute lunch break at 12:30 p.m.

The meeting reconvened at 1:04 p.m.

III. COMPOUNDING MATTERS

a. **FOR DISCUSSION: FDA's Expectations for Human Drug Compounders**

The Food and Drug Administration (FDA) is proposing to amend its regulations to revise the list of drug products that may not be compounded under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (FD&C Act) because the drug products have been withdrawn or removed from the market after the drug products or components of such drug products were found to be unsafe or not effective. Specifically, the proposed rule would add 25 drug products and modify the description of one drug product on this list to add an exception. These revisions are necessary because new information has come to the FDA's attention since March 8, 1999, when FDA published the original list as a final rule. FDA is also withdrawing the previous proposed rule regarding additions to this list (see the Federal Register of January 4, 2000).

Attachment 8 includes a copy of the FDA Press Release and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Proposed Rule

This information was provided to the committee for information.

At this meeting, the committee reviewed the press release and article from the Federal Register. There was no committee or public comment.

b. **FOR DISCUSSION: Request by Kaiser Permanente for Clarification Regarding End-Product Testing as Required by 16 CCR section 1751.7**

Attachment 9

Background

Kaiser Permanente has requested an opportunity to discuss enforcement of Title 16 California Code of Regulations section 1751.7. This section specifies the requirements of a Quality Assurance Program for sterile compounding pharmacies. Specifically, the law provides that:

1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (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:

- (1) Cleaning and sanitization of the parenteral medication preparation area.

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- (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (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 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 manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.
- (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.
- (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.

Kaiser Permanente indicates that various inspectors are interpreting section 1751.7(a) differently. They have asked for the board to clarify. A copy of the request is provided in **Attachment 9**.

At this meeting, Steve Gray and Doug O'Brien of Kaiser Permanente, sought clarification regarding the need for end product testing as they are concerned with interpretation and misunderstanding by board inspectors related to testing.

Kaiser indicates that over the past 18 months, especially during sterile compounding pharmacy inspections, they have encountered substantial variation in interpretation of the regulations among Board inspectors. These variations range from no findings, to consultative recommendations, to orders of correction despite Kaiser's consistent policies, procedures and practices.

The committee was advised by Dr. Gray that Kaiser is referring to sterile to sterile and general non-sterile compounding.

Dr. Gray indicated that there have been inconsistencies with the interpretation of 16 CCR 1735 and 16 CCR 1751 by inspectors during non-sterile and sterile compounding inspections over the past year and a historical context for misinterpretation going back to before 2006 and these are not the principles that was agreed upon.

Ms. Herold cautioned all those in attendance that most of what was presented is part of a pending regulation where there is an open 45-day comment period and any discussion would complicate the rulemaking and that the committee cannot provide any comment on the pending regulation.

Ms. Herold further stated that there is a process set up to review a final outcome of an investigation where some sort of action was taken and that is an office conference where additional information can be presented to resolve discrepancies. Additionally, the board provides training sessions with board inspectors where supervisors work to build a single set of standards. The board has spent considerable time to ensure that staff has been trained.

Ms. Herold indicated that testing for potency should be completed to validate what the prescription states.

Dr. Gray indicated that testing is not always possible or necessary such as in a topical cream however the process could be validated.

Dr. Gutierrez asked if staff could come up with a letter of expectations from a testing perspective that is consistent with the law so that everyone is on the same page what the requirements are.

Dr. Ratcliff asked Dr. Gray his interpretation of Section 16 CCR 1735.8 (c) and the meaning of "...include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products..." and what his definition of analysis was. Dr. Gray advised that nowhere in that section does it refer to "testing."

Dr. Gray further stated that if he developed a quality assurance plan that has standards of qualitative and quantitative integrity, potency, quality and that plan is followed then he is satisfied that product meets label strength requirements. Dr. Gray states that process validation is not the same as potency testing. Ms. Herold disagreed and that the board has always expected some kind of testing to be performed on routinely compounded products. Dr. Gray suggested that the board have a discussion with staff and the board on how to test a product where there is no testing available on a periodic basis.

Dr. Ratcliff referenced 16 CCR 1751.7(a) and asked how Kaiser performs a periodic sampling to assure that a product meets required specifications. Dr. Ratcliff was advised that the pharmacist validates that the pharmacy technician has good technique; the room is good, the hood is good, and the technician is periodically watched compounding things and as a result the product is fully tested because of all the processes that were followed. Dr. Ratcliff indicted that Kaiser doesn't seem to be complying with 1751.7(a).

Public comment included that testing for potency is problematic because there are no tests for a lot of medications. It was also noted that the package inserts are relied upon that the end product will meet the criteria. Costs would be ridiculously high to obtain a potency test and be cost prohibitive. There should be some consideration when following the manufacturer's instructions that no analysis be required.

No additional comments from the committee or public were received.

c. FOR INFORMATION: Results of the Board's Implementation and Inspections of California Sterile Compounding Facilities

At this meeting

Supervising Inspector Robert Ratcliff, PharmD, provided an update regarding the board's implementation and inspections of California sterile compounding pharmacies.

Attachment 10 includes the data found as a result of sterile compounding inspections in California.

Dr. Gutierrez recessed for a 10-minute break at 2:19 p.m.

The meeting reconvened at 2:30 p.m.

d. FOR INFORMATION: Data on Violations Found During Out-of-State Compounding Inspections

Supervising Inspector Robert Ratcliff, PharmD, provided an update regarding the board's inspections of out of state sterile compounding pharmacies.

Attachment 10 also includes the data describing results from sterile compounding inspections of out-of-state sterile compounding pharmacies.

Dr. Ratcliff introduced new compounding Supervising Inspector Christine Acosta.

Dr. Ratcliff stated that there were 140 sterile compounding inspections conducted and 137 violations were found during June 26, 2014 to September 5, 2014. The top violations found were incomplete compounding records; ceiling, walls and surfaces were not cleaned

weekly; incomplete compounding self-assessments; incomplete master formulas; and policy and procedures were not reviewed annually.

Dr. Ratcliff indicated that board inspectors have been instructed to check the FDA website for warning letters and FDA's 483 inspection reports prior to inspecting the larger pharmacies and out-of-state pharmacies.

Dr. Gutierrez inquired whether the out-of-state pharmacies were 503(b)s and was advised that about half of the out of state inspections were of 503(b)s. Dr. Gutierrez inquired whether the out-of-state pharmacies are performing testing and was advised they were.

Public Comment

Marie Cottman representing Pacific Compounding Pharmacy indicated that they have been asked to provide a lot compounded products to doctors' offices. Ms. Cottman asked where the board stood since these compounded medications were not patient specific as required by the FDA. It was suggested that they review Business and Professions Code section 4052.

e. **FOR INFORMATION: Recalls of Compounded Drugs Throughout the United States**

Between November 8, 2013 and September 11, 2014, the board posted seven subscriber alerts related to compounding drug recalls.

Attachment 11 includes copies of the subscriber alerts.

The committee reviewed the attachments. Dr. Gutierrez noted that there are still quite a bit of recalls occurring. There was no committee or public comments.

IV. MEETING DATES FOR 2014

Dr. Gutierrez reminded the audience that the next enforcement and compounding committee meeting was scheduled for December 17, 2014.

In addition, Dr. Gutierrez informed the audience that the sterile compounding public hearing was scheduled for November 4, 2014 in Sacramento. She also indicated that if anyone was interested in submitting written comments on the proposed language that there was a specific format requested and that format could be found on the board's website.

Ms. Herold informed the audience that at this hearing, there would be time allowed for oral comments to be provided on to the proposed changes, but the commenter would be not be receiving comments in response.

V. FUTURE MEETING DATES

The committee will select meeting dates for 2015. Once established, these dates will be posted on the board's website under the Board Meetings tab.

Dr. Gutierrez adjourned the meeting at 2:50 p.m.

Recommendations to Improve Medication Safety: Risks Associated with Medication Reconciliation and Transitions of Care

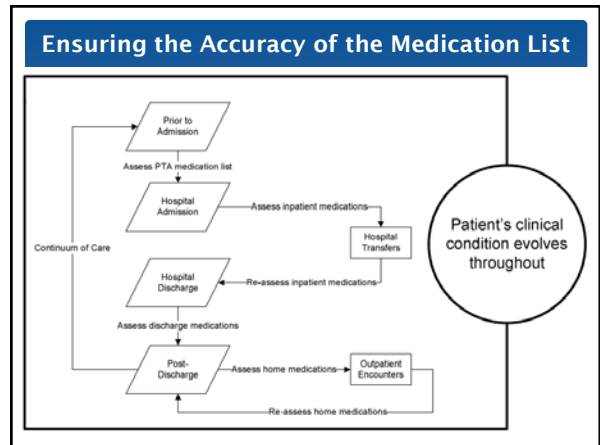
Rita Shane, Pharm.D., FASHP, FCSHP
 Chief Pharmacy Officer
 Cedars-Sinai Medical Center, Los Angeles
 Assistant Dean, Clinical Pharmacy
 UCSF School of Pharmacy

Background

- Medication reconciliation (med rec) is required by The Joint Commission and the Center for Medicare/Medicaid Services as part of Meaningful Use
- The process is intended to ensure the accuracy of the medication list at each patient encounter
- Medication lists are entered into electronic health records (EHR) by a variety of individuals (both licensed and unlicensed) across different healthcare settings
- The medications entered are not always accurate
- These lists are used to create hospital medication orders resulting in continuation of inaccurate and/or incorrect medications

Background

- Clinicians rely on the information and prescribe medications that are listed even though the information may be inaccurate
- The requirement for med rec and adoption of the EHR has increased the potential for harmful medication errors with the unintended consequence of creating "med wreck"
- A medication order is a sentence
 - If any element: drug, dose, dosage form, route, frequency, duration are incorrect, incomplete or unclear, patient harm can result
- Evidence supports the need to improve current processes to prevent medication errors and patient harm



Evidence

- 54-86% of patients have discrepancies in medications upon admission to the hospital with an estimated 3.3 discrepancies or errors/patient^{1,2}
- Reported rates of inpatient medication errors range from 45% to 76% due to inaccuracies in medication histories and reconciliation with most errors occurring on admission³
- 14-80% of patients experienced at least 1 medication discrepancy or error post-discharge⁴⁻⁷
- 19% of patients experienced an adverse event within 3 weeks of hospital discharge, 67% were attributed to medications and 12% of the adverse drug events were preventable⁸

Sources of Medication Lists

Errors introduced in any of these settings can become "hardwired" into the pt record

Home	Outpatient Settings	ED/Hospital	Skilled Nursing Facility
<ul style="list-style-type: none"> Pt Family members Caregivers Home Health nurses 	<ul style="list-style-type: none"> Certified medical assistants Physicians Community pharmacies Patients 	<ul style="list-style-type: none"> Nurses Physicians Pharmacists Pharmacy technicians Pharmacy residents, students 	<ul style="list-style-type: none"> Nurses Physicians

CMS 2012-Meaningful Use

- Any licensed healthcare professional and *credentialed medical assistants*, can enter orders into the medical record
- Credentialed medical assistants are:
 - Certified medical assistants-graduates of an accredited medical assisting program
 - Training requirements: 2-6 units of pharmacology training. (based on evaluation of 4 California programs)
 - Medical assistants (who are not certified) who have completed a required order entry course

http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stages_EPCore_1_CPOE_MedicationOrders.pdf, accessed April 30, 2014.

Medical Assistants Requirements for Order Entry into Electronic Health Records

- 2 yr recent experience in a health care facility under the supervision of a licensed health care provider (LHP)
- Application signed by supervising LHP attesting proficiency in areas including pharmacology
- Completion of Assessment-Based Recognition in Order Entry (ABR-OE) training-5 courses (1 hr each)
 - Clinical Laboratory Testing
 - Lost in Translation: Eliminate Medical Errors
 - Medical Records: A Vital Wave
 - Disease Screening
 - Legal Aspects of Patient Care Documentation

Prior to Admission Medication History Drug-Related Problems in High Risk Patients (Errors or Discrepancies)

November 2011 - March 2013

Drug-Related Problems (DRPs) Resolved: 6,184 (803 patients)

Average : 7.7/patient

- 54% of resolved DRPs were classified as life-threatening or serious
- 35% of inpatient orders needed to be corrected
- Based on risk stratification algorithm only 25% of patients had both high medication adherence and literacy

Prior to Admission (PTA) Drug-Related Problems (DRPs) Examples

Medication on PTA List	Drug-Related Problem	DRP Type	Capacity for Harm
Flecainide	PTA List: Med not listed on PTA med list Finding: Pt reports taking flecainide 50 mg BID	Omission of Medication	Life-Threatening
Clopidogrel	PTA List: Med not listed on PTA med list Finding: Pt reports taking Plavix 75 mg daily	Omission of Medication	Serious
Methotrexate	PTA list: methotrexate 10mg daily Finding: Pt reports taking 10mg every Sunday	Wrong frequency	Life-Threatening
Mycophenolate	PTA List: Mycophenolate 360 mg BID Finding: Pt reports taking 720 mg BID	Wrong Dose	Serious

Resolution of Post-Discharge Drug-Related Problems (DRPs)

Post-discharge Medication Reconciliation

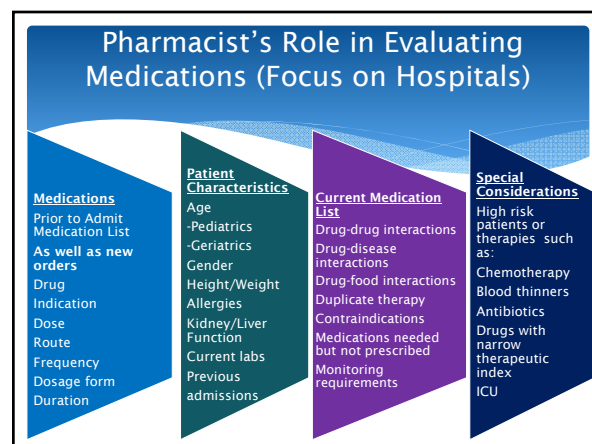
January 2013 - June 2013

DRPs Resolved: 601 (207 patients)

Average: 2.9 DRPs/patient

- 58% of patients had discrepancies between their discharge medication list and what they were taking
- 33% of patients were taking more medications than were prescribed*
- Estimated 16% of patients would have been readmitted base on physician evaluation**

*Excludes vitamins, herbals, OTC supplements
**Validated by hospitalist physicians

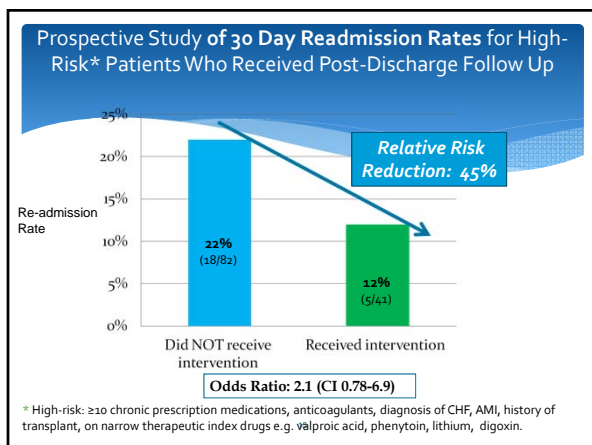


Examples of Pharmacist Post-Discharge Follow-up

Reason for Admission	Drug-Related Problems Identified Post-Discharge and Pharmacist Intervention	Adverse Outcome Prevented
54 y/o w/ HTN & DVT admitted for sickle cell crisis & left parietal stroke	Issue discovered: Pt had self-discontinued warfarin, amlodipine, and carvedilol Intervention: Pharmacist contacted MD and confirmed that warfarin and anti-hypertensives should be restarted. Pharmacist educated pt on medications and instructed pt to not adjust any med w/o speaking to MD	Avoided potential thrombo-embolism, readmission, and/or death
92 y/o w/ altered mental status found to have a UTI & toxic digoxin level, also w/ arrhythmias & low blood pressure	Issue discovered: Pt had continued taking medications that had been stopped, including digoxin, metoprolol, and zolpidem Intervention: Instructed patient to d/c these medications	Avoided potential drug toxicity, life-threatening arrhythmias, recurrence of confusion, readmission, and/or death

Examples of Pharmacist Post-Discharge Follow-Up Skilled Nursing Facility Patients

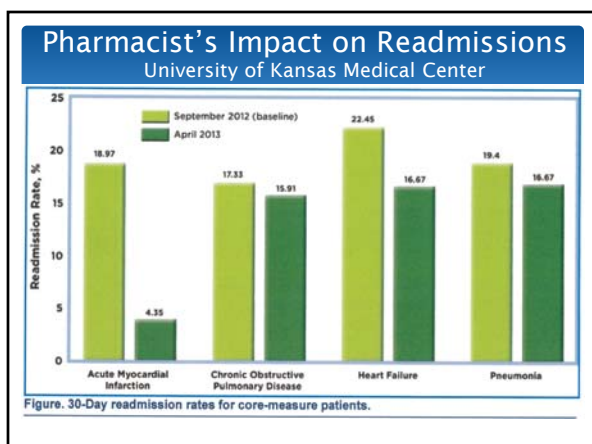
Reason for Hospital Admission	Drug-Related Problems Identified Post-Discharge and Pharmacist Intervention	Adverse Outcome Prevented
98 y/o M from home w/ hip fracture and multiple medical issues.	Issue discovered: Pt was a new start on fentanyl 25mcg patch as an inpatient. Dose was increased to 50mcg 1 hour prior to discharge. Intervention: Called SNF to d/c fentanyl 50mcg patch order. Informed SNF RN that the patch was already placed on the pt. SNF RN was unaware.	Avoided severe respiratory depression or death due to potential supra-therapeutic dose of fentanyl.
79 y/o M w/ ESRD - HD on TuThSat - with catheter-related <i>S. aureus</i> bacteremia.	Issue discovered: Per ID, vancomycin after dialysis to be continued after d/c and was on discharge medication list. There was an order at the SNF for vancomycin but not at the dialysis center. Pt dialyzed on Sat after d/c but did not receive vancomycin. Intervention: Ensured vancomycin administration occurred.	Avoided progression of bacteremia and catheter re-infection d/t missed doses of antibiotics.



Pharmacist's Impact on Readmissions

	Einstein Health-care Network	Froedtert Hospital	Hennepin County Medical Center	Johns Hopkins	University of Pittsburgh Medical Center	University of Utah Hospital and Clinics
Re-admissions Reduction	50% (21.4% vs. 10.6%)	34% (30.37% vs. 20.13%)	65% (23% vs. 8%)	15% (13.7% vs. 11.7%)	56% (23.7% vs. 10.5%)	28-38% (20.5-22.1% vs 16.0%)

Source: ASHP-APhA Medication Management in Care Transitions Best Practices. 2013



Minimizing Errors in Medication Histories Obtained at Hospital Admission

Randomized Controlled Trial

- Usual Care: MD or RN
- Pharmacist
- Trained Technician

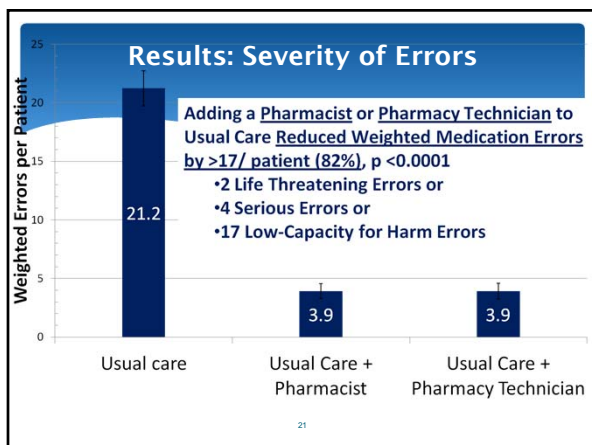
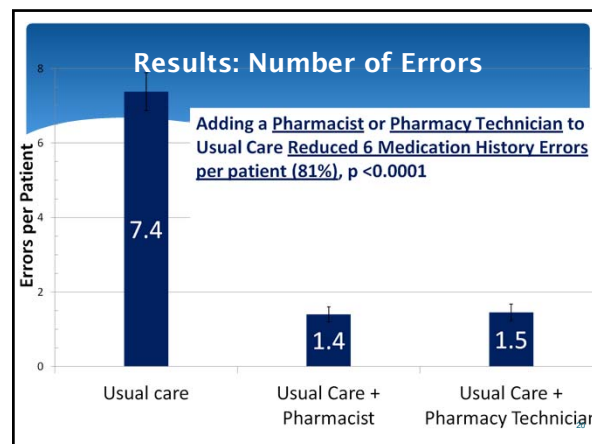
- High Risk Patients* admitted via Emergency Dept
- 300 pt enrolled; 283 in final analysis
- Median age: ~76 (range: 50-83)
- Median # of meds* 14 (range; 10-19)

*High risk: ≥ 10 chronic meds, Acute MI, CHF, admitted from SNF, on anticoagulants, insulin, narrow therapeutic drugs, history of transplant

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Minimizing Errors in Medication Histories Obtained at Hospital Admission *Randomized Controlled Trial*

- Pt histories independently evaluated within 24 hr by gold standard pharmacist (proven study methodology)
- Gold standard pharmacist took patient history, compared with history taken, determined # errors and severity of errors:
 - Low capacity for harm: vitamin, laxative
 - Serious: beta blocker for hypertension
 - Life Threatening: transplant drug



Recommendations to Ensure Patient Safety

Patient Safety Imperatives

- Medication lists are frequently inaccurate and can lead to harm
- Ensuring the accuracy of the medication list at each transition of care is essential, especially when patients are admitted to and discharged from the hospital setting

Recommendations to Ensure Patient Safety

- Hospital pharmacies should be responsible for ensuring the medication list is accurate upon admission
- Evidence supports that trained technicians can gather prescription information for the medication list for the pharmacist's review
- For high risk pts, pharmacists should conduct post-discharge follow up to prevent adverse drug events and admissions

Appendix

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MedAL Score Medication Adherence and Literacy Score

		Medication Literacy (Scale 0-4)		
		High Literacy (4 points)	Intermediate (2-3 points)	Low Literacy (0-1 point)
Medication Adherence (Scale 0-4)	High Adherence (4 points)	No Post DC Follow-up	No Post DC Follow-up	Perform Post DC Follow-up
	Intermediate (2-3 points)	No Post DC Follow-up	Score 6: No Post DC Follow-Up Score <6: Perform Post DC Follow-Up	Perform Post DC Follow-up
	Low Adherence (0-1 point)	Perform Post DC Follow-up	Perform Post DC Follow-up	Perform Post DC Follow-up

DC= Discharge from hospital

1. Impact of Pharmacist Post-discharge Phone Calls on Hospital Readmission and Patient Medication Literacy and Adherence. <http://clinicaltrials.gov/show/NCT00949496>

2. Medication Adherence and Literacy as Predictors of Hospital Readmission. American Geriatrics Society Meeting 2014

3. Transitions triecta: calibrating the mobility of drug related problems, medication adherence, and literacy in a high-risk population [Abstract]. Presented at ASHP The Midyear on December 10, 2013.

Use of the Medication Adherence and Literacy Algorithm to Identify Pts At Risk for 30-Day Readmission

Retrospective Cohort Study (2/13-7/13): 278 pts
Pts admitted to hospitalist service and identified as high risk

Primary objective:
Determine if the Medication Adherence and Literacy (MedAL) algorithm effectively identifies patients at risk of readmission within 30 days

- High literacy/adherence (n=115)
- 30 day readmission: 10% (12/115)
- Low literacy/adherence (n=163)
- 30 day readmissions: 24% (39/143)

Secondary objective:
Determine if post-discharge (post D/C) follow-up impacts 30-day readmission rates for pts identified by MedAL algorithm

- Post-D/C follow-up completed (n=102)
- 30 day readmission: 14% (14/102)
- Post-D/C follow-up not able to complete (n=61)
- 30 day readmission 41% (26/61)

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Use of the Medication Adherence and Literacy Algorithm to Identify Pts At Risk for 30-Day Readmission Value as Predictive Indicator

The odds of readmission for the group identified as needing post-discharge follow-up was 2.8 times greater than for the group identified as not needed post-discharge follow-up (95% CI 0.172 - 0.710, p=0.0045)

Conclusion: The MedAL algorithm can serve as a tool to identify patients that are at risk for readmission within 30 days. Post-discharge follow-up of patients identified by the MedAL algorithm may reduce 30-day admission rates.