



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
PUBLIC BOARD MEETING
MINUTES**

DATE: January 11, 2018

LOCATION: California Northstate University College of Pharmacy
Event Center
9650 West Taron Drive
Elk Grove, CA 95757

**BOARD MEMBERS
PRESENT:** Amy Gutierrez, Licensee Member, President
Victor Law, Licensee Member, Vice President
Allen Schaad, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Ricardo Sanchez, Public Member
Deborah Veale, Licensee Member
Stanley Weisser, Licensee Member
Albert Wong, Licensee Member

**BOARD MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member
Greg Lippe, Public Member
Valerie Muñoz, Public Member
Amjad Khan, Public Member

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Laura Hendricks, Staff Analyst

Note: The materials for this meeting may be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

Thursday, January 11, 2018

Call to Order

9:03 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 9:03 a.m.

Board members present: Lavanza Butler, Victor Law, Amy Gutierrez, Stanley Weisser, Deborah Veale, Ricardo Sanchez, Allen Schaad and Albert Wong.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

A pharmacist asked if the board would be holding one of the *CURES, Prescription Drug Abuse and Preventing Drug Diversion* events in Alameda County. It was noted that one of these training events would be held on January 27, 2018, in San Francisco. The pharmacist also asked that the board consider holding some of the training events on weekdays, as many pharmacists work weekends.

Board member Allen Schaad asked that staff provide information on the citation and fine process at a future Enforcement Committee Meeting.

The board thanked the dean of Northstate University College of Pharmacy, Dr. Hieu Tran, for allowing the board to use their event center for the meeting.

III. Discussion and Consideration of Actions to Implement Legislation Chaptered in 2017

a. Senate Bill 351 (Chapter 623, Statutes of 2017) Hospital Satellite Compounding Pharmacy: License Requirements

President Gutierrez explained that SB 351 creates options for hospitals that wish to obtain additional licenses from the board for purposes of providing pharmaceutical care. Specifically, the board can now issue hospital satellite compounding pharmacy licenses that will not need to be located in the acute care hospital building. She noted that this measure also allows the board to issue a hospital pharmacy license that can be located outside of the general acute care hospital but in another physical plant regulated under the California Department of Public Health's hospital license.

The board's Assistant Executive Officer, Anne Sodergren, reported that staff is working with the department's IT unit to make modifications to the existing computer systems to incorporate the new licensing program. In the interim staff will be manually processing applications and issuing licenses. She noted that draft application forms are under review by DCA and will be released upon approval.

Board member Stanley Weisser asked when the existing computer system would allow for the incorporation of the new license type. Ms. Sodergren responded that the board is currently working with the department on a business modernization project that will help update and improve the board's system capability and streamline processes. She explained that the project is in the early stages and currently staff is identifying the board's IT/database system needs so that the department can begin looking for solutions.

The board expressed significant concern with how long it is taking to modernize the board's IT systems. In particular they noted that the board still does not have the capability to accept online payments. The board asked that a representative from the department come to the next board meeting to report on the business modernization efforts being made.

b. Senate Bill 443 (Chapter 647, Statutes of 2017) Pharmacy: Emergency Medical Services Automated Drug Delivery System

President Gutierrez reported that SB 443 creates an option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. As part of the measure, the board can issue a license for the use of the EMADDS as well as a license to a designated paramedic.

Ms. Sodergren again explained that a service request was submitted to the department to make modifications to the existing computer system to incorporate the new designated paramedic licensing program, and draft application forms are under development. Until programming is completed, staff will be manually processing application and issuing licenses.

Ms. Sodergren added that currently there is a significant cost incurred each time the current database system has to be modified to add a new license type. Because of a lack of funding, integration of the EMADDS into the computer system is not possible, necessitating manual processing in the long term.

The board again expressed its frustration with the lack of modernization of the computer systems and the board's inability to make necessary updates due to lack of funding. They asked that "business modernization efforts" be added as a standing agenda item in the Organizational Development Committee report.

c. Senate Bill 547 (Chapter 429, Statutes of 2017) Professions and Vocations

President Gutierrez stated that SB 547 allows the board to hire its own counsel. She asked staff what recruitment efforts have taken place since the bill took effect on January 1, 2018.

Ms. Sodergren responded that to date no recruitments efforts have taken place.

Board member Victor Law asked how the recruitment would take place. The board's Executive Officer, Virginia Herold, provided a brief overview of the state civil service recruitment process. President Gutierrez asked who would make the final hiring decision. Ms. Herold responded that she and Ms. Sodergren would likely make the final decision.

Mr. Weisser asked if a board member should be part of the interview committee. Ms. Herold responded that it would be unusual for a board member to be part of the interview process. Board member Deborah Veale stated that the board should delegate authority to staff to conduct the interview and make the hiring decision.

Mr. Weisser asked what the duties would be for the position. Ms. Herold responded that he or she would be the board's legal expert. President Gutierrez added that the board needs a dedicated lawyer to help reduce the regulation timelines.

Motion: Direct staff to begin the recruitment process to hire its own legal counsel per SB 547.

M/S: Weisser/Veale

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe				x
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

d. Senate Bill 752 (Chapter 598, Statutes of 2017) Pharmacy: Designated Representative-Reverse Distributors

President Gutierrez reported that SB 752 establishes the creation of a designated representative-reverse distributor license and shortens the period an applicant must wait to retake the pharmacist licensure examination to 45 days.

President Gutierrez explained that under the provisions related to the designated representative-reverse distributor, one pathway to licensure includes completion of a training program approved by the board that addresses specified areas.

Ms. Sodergren stated that staff recommends that implementation of this item should be referred to the Licensing Committee to develop the training requirements for promulgation as regulations. She explained that while the Licensing Committee is developing the regulations the board could delegate authority to staff to review individual training programs and make recommendations for approval/denial by the full board.

The board agreed with Ms. Sodergren's recommendation.

Motion: Direct the Licensing Committee to develop the training requirements for promulgation as regulations. In the interim, delegate authority to staff to review training programs and provide recommendations to the full board to approve or deny the program.

M/S: Weisser/Law

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x

Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe				x
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

e. Assembly Bill 401 (Chapter 548, Statutes of 2017) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy: Shared Clinics

President Gutierrez explained that AB 401 does the following:

- Establishes regulatory framework for telepharmacy (via a remote dispensing site pharmacy)
- Establishes mandatory reporting by wholesalers of suspicious drug orders
- Establishes the authority for two clinics to operate from a single location.

President Gutierrez reported that service requests were submitted to the department to make modifications to the existing computer system to incorporate the new licensing program and co-located clinics. In the interim, staff will be manually processing applications and issuing licenses. Draft application forms are currently being developed.

Ms. Sodergren reported that the clinic application should be finalized in the next two weeks.

President Gutierrez stated that the Licensing Committee would be working to develop regulations for telepharmacy locations.

President Gutierrez asked if a medical assistant could become licensed as a pharmacy technician and work in a telepharmacy location. Ms. Sodergren responded that if he or she obtained licensure as a technician then he or she could work as a technician at a telepharmacy.

Mr. Law and Ms. Butler expressed concern that a pharmacist would be supervising two technicians at the telepharmacy location as well as supervising the staff in their physical pharmacy.

Ms. Sodergren noted that this bill has already been enacted and the board is now responsible for developing the regulations that shall apply to pharmacy technicians at these remote dispensing sites. Ms. Freedman added that the law requires that the technicians must meet very specific requirements in order to work in the remote locations. Mr. Room stated that the Legislature determined that the need to increase medical services in remote areas outweighs the possible oversight issues that the board is concerned about.

President Gutierrez asked that board staff monitor these locations closely and reported that the Licensing Committee would be responsible for creating the requirements for the technicians working in these locations.

President Gutierrez explained that this bill also requires wholesalers to report suspicious orders to the board. She asked how many reports the board has received. Ms. Herold responded that approximately 50 have been received. She added that she is meeting with the wholesalers to discuss the requirements.

President Gutierrez recommended that the Enforcement Committee review the suspicious order protocols and asked if the wholesalers could present information about their criteria for reviewing orders. The board agreed with this recommendation and Ms. Herold stated she would invite the wholesalers to attend future meeting.

A pharmacist stated that there is a nationwide shortage of injectable opioids in hospitals, so when any become available hospitals purchase large quantities. He recommended that the board consider the current marketplace when reviewing wholesale orders.

IV. Discussion and Consideration of Draft Reports to the Legislature

President Gutierrez explained that in 2014 following enactment of board-sponsored legislation, the board implemented new requirements for the licensure of sterile compounding pharmacies. One new provision requires board-conducted inspections before licensure or renewal each year of a nonresident sterile compounding pharmacy. She added that this was an unusual activity and responsibility for the board, and included in the enabling legislation was a requirement for the board to prepare a legislative report on its inspection activities out of state.

President Gutierrez reported that in 2016, the board sponsored additional provisions to license outsourcing facilities and to require board-conducted inspections of nonresident outsourcing facilities. She explained that this legislation was enacted as part of the board's sunset review process, and it also required a legislative report by January 1, 2018, regarding the inspection of nonresident outsourcing facilities.

President Gutierrez stated that the board was asked to answer four questions in both the nonresident sterile compounding report and the nonresident outsourcing report. These questions have been provided below.

- 1. A detailed description of board activities related to the inspection and licensure of nonresident pharmacies (or outsourcing facilities).*
- 2. Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.*

Or in the case of outsourcing facilities:

Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

- 3. The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.*

Or in the case of outsourcing facilities:

The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

- 4. If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.*

Or in the case of outsourcing facilities:

If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

President Gutierrez asked Ms. Herold to briefly review each report. She noted that the draft reports were provided to the Legislature to meet the January 1, 2018, deadline and the board would need to approve each report so that the final reports could be provided.

Report Required by Business and Professions Code Section 4127.2(g) – Nonresident Sterile Compounding Pharmacies

Ms. Herold reviewed the draft report, which has been provided immediately following these minutes.

President Gutierrez asked if sterile compounding pharmacies are under greater scrutiny than a regular pharmacy. Ms. Herold responded that these locations are inspected more frequently and with greater scrutiny than a regular pharmacy because the potential for patient harm on a large scale is greater. Ms. Veale added that a mistake in sterile compounding can result in death of numerous patients.

It was noted that in the report it shows that two sterile compounding pharmacies did not pay the travel costs as required. Ms. Herold explained that this is likely because the board denied their application or renewal. The board asked Ms. Herold to review these two pharmacies and report back

to the board on why they did not pay.

President Gutierrez asked that information be added to the report regarding how the board uses USP standards when reviewing regulations and conducting inspections.

Board member Allen Schaad noted that one of the questions was inadvertently copied and pasted twice in the report. Ms. Herold stated that she would correct this error.

Ms. Herold stated that “proposal one” on page 10 of the draft report is incorrectly listed as a change to Health and Safety Code 1250.4(5). She explained that this is not a statute change and the amendments are actually going to occur in the building standards requirements and therefore this proposal will be removed from the report. The board agreed with this modification.

Mr. Law asked if the board really needs to inspect sterile compounding pharmacies each year. President Gutierrez and Ms. Veale stated because the board has such high standards and there is such a great risk for patient harm, it is appropriate for these pharmacies to be inspected annually.

President Gutierrez asked that a spelling and grammar check also be completed on the report.

There were no comments from the public.

Motion: Approve the report required by Business and Professions Code Section 4127.2 (nonresident sterile compounding pharmacies) with the changes discussed by the board during the meeting.

M/S: Veale/Sanchez

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Khan				X
Law	X			
Lippe				X
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

Report Required by Business and Professions Code Section 4129.3 – Nonresident Outsourcing Facilities

Ms. Herold reviewed the draft report, which has been provided immediately following these minutes.

Ms. Veale noted that the outsourcing report includes the first six months of data for FY 17/18 and the

sterile compounding report does not. After discussion, the board decided not to add any more data to the sterile compounding report. The board asked that the headings of the tables in the outsourcing report be modified to show that FY 17/18 only includes the first six months of data.

Ms. Herold noted that the board will be re-assessing the application fee for outsourcing facilities after more data becomes available.

President Gutierrez asked that a spelling and grammar check also be completed on the report.

There were no comments from the public.

Motion: Approve the report required by Business and Professions Code Section 4129.3 (nonresident outsourcing facilities) with the changes discussed by the board during the meeting.

M/S: Weisser/Sanchez

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Khan				X
Law	X			
Lippe				X
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

V. Discussion and Consideration of Possible Statutory Proposal Relating to the Use of Automated Drug Delivery Devices

President Gutierrez stated that as the board has previously discussed, there appears to be an increasing interest and demand for expanded use of ADDS in pharmacies, clinics and other environments to provide medications to patients. She explained that generally, there are two major forms of these machines:

1. Storage of medication until a specific dose is needed for a patient (e.g., Pyxis machines in hospitals and skilled nursing facilities), where the medication is obtained by a health care provider after it has been ordered for a patient.
2. Storage of a full dosing regimen for a specific patient awaiting patient pick up (e.g., Asteres machine currently under study by UCSD).

President Gutierrez reported that a technology summit was convened earlier last year where the board learned about various forms of technology. She added that this year in the California

Legislature there were two proposals to allow for additional uses of the machines:

- A machine that can store medication in fire departments and EMSA offices to replenish ambulance supplies when convenient for the ambulance (sponsored by the board).
- A machine installed in clinics, operated by a pharmacy, to dispense 240B drugs to qualified patients. (This measure stalled in committee.)

President Gutierrez stated that the Enforcement and Compounding Committee has been working on development of a statutory proposal to expand the conditions under which an ADDS machine could be used. The committee noted that ADDS units benefit patients by increasing their access to medications, but that appropriate security measures must be in place and the board must be notified if any theft or diversion occurs. The committee also underscored the need for patient consultation when the ADDS machine is used to deliver the medication to the patient, the need for development of a self-assessment form addressing specifically the use of machines, and the need for ADDS locations to be inspected by the board.

President Gutierrez explained that the committee recommended creating separate requirements based on the two different types of machines (unit dose **administered** to a patient versus medications **dispensed** to a patient).

President Gutierrez reported that the Enforcement Committee considered the basic framework from which a legislative proposal could be secured. She stated that the committee is recommending that existing statutes and regulations for ADDS be replaced and incorporated into the framework provided below.

1. Definitions - creating, by definition, a delineation of the two different types of systems - - "Automated Unit Dose System (AUDS)" and "Automated Patient Dispensing System (APDS)."
2. General Requirements:
 - a. Device must be licensed by the board to operate. (Hospitals using unit dose machines for administration to inpatients would be exempt from licensure; however, an ADDS machine for dispensing in a hospital would be required to secure licensure.)
 - b. Licensure limited to licensed pharmacies/hospitals located in California.
 - c. Prelicensure inspection of the location where the device will be located.
 - d. The ADDS license would be cancelled by operation of law if the underlying pharmacy license is cancelled or revoked.
 - e. Pharmacy must own the drugs and be responsible for the drugs (storage, security, etc.) until the medication is either dispensed or administered.
 - f. Application and annual renewal fee of \$200. Renewal will be synced with that of the underlying pharmacy license.
 - g. Specify locations where ADDS units can be used to include a pharmacy, health facility, clinic or medical office.
 - h. Limit the number of APDS units to five.
 - i. Pharmacy is responsible for delivery of the medications.
 - j. Pharmacy staff must stock ADDS units immediately upon delivery except in limited circumstances when drugs may be stored securely for up to 48 hours.
 - k. Self-Assessments are required annually or upon designation of a new PIC.
 - l. Recordkeeping and QA requirements must be satisfied, and records maintained within

the licensed pharmacy, and separated from other pharmacy records.

- m. For APDS:
 - i. all clinical services provided as part of the dispensing process must be provided by a California licensed pharmacist.
 - ii. Patient consultation must be provided consistent with the provisions of CCR 1707.2.
 - iii. All devices used for dispensing must have a posted notice providing the name of the pharmacy that operates the ADDs in compliance with notice requirement in CCR 1707.6.
 - iv. All devices used for dispensing must meet all prescription labeling requirements.

Joshua Room explained that there are two different types of systems. An “Automated Unit Dose System (AUDS)” is a machine where the medication is delivered to a healthcare practitioners for unit dosing. An “Automated Patient Dispensing System (APDS)” is a machine that dispensed the medication directly to the patient. He reported that both types of machines must be owned and operated by a California pharmacy.

Mr. Room explained that there is no limit on how many AUDS that a pharmacy can own and operate and stated that these are commonly used in hospitals. He added that an individual pharmacy can only own and operate five ADPS machines.

Ms. Veale asked how the five ADPS limit was determined. Mr. Room stated that five was selected so that the board had a place to start the discussion to determine an appropriate limit.

Ms. Butler expressed concern that five machines are too many for one pharmacy to safely oversee.

Mr. Law stated he does not think that there is actually a great demand for these machines. He stated he would not support the use of these machines as face-to-face consultations by pharmacists is essential to patient care. He also expressed concern that these machines discriminate against patients who do not speak English.

President Gutierrez stated that she believed that these machines are in demand by patients who cannot get to a regular pharmacy during business hours. She added that mail order pharmacies have become popular for this reason. Ms. Veale noted that these machines would be very helpful in medically underserved areas.

Ms. Herold stated that if the board does not step in and regulate these machines the Legislature will likely take action and may not be as focused on patient safety as the board. President Gutierrez added that the board’s main concern always needs to be patient safety.

Sara Lake representing Asteres Inc. stated that their machines are used successfully in many other states and offered to provide data to the board. She added that these machines give patients options on how to get their medications. Ms. Lake explained that their machines have the ability to provide face-to-face counseling via video conferencing and the medication is tracked at every step of the dispensing process.

Mr. Law asked how many of the prescriptions filled by Asteres machines are filled after hours. Ms. Lake responded that approximately 30 percent of their prescriptions are picked up after hours.

Dr. Wong expressed concern with the security of the machines. Ms. Veale stated that she has seen many of these machines and they have a lot of security features. President Gutierrez added that the locations of the machines will be inspected by the board to ensure that they are located in safe locations.

Mr. Law asked if the machines that are currently being used adjacent to a pharmacy have had any problems. Ms. Herold responded that there are not many of these machines being used in California, but the board has not received any complaints about the machines. Ms. Lake added that in other states they are successfully used.

Ms. Veale encouraged the board to recognize that these machines are going to become more common in the future and the board needs to take action to ensure that they are properly regulated to protect consumers.

Ms. Butler asked where the machines will be allowed to be located. Ms. Sodergren explained that the machines can only be located in the locations listed below.

- (1) A pharmacy licensed by the board;
- (2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code;
- (3) A clinic licensed pursuant to Section 1204 or Section 1204.1 of the Health and Safety Code, or Section 4180 or Section 4190 of this Code;
- (4) A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and where drugs are routinely dispensed pursuant to Section 4170.

Pharmacist Art Whitney asked if a machine dispensing medications to a nurse in a skilled nursing facility for administration to a patient would be considered an APDS or an AUDA. Mr. Room responded that it would be considered an AUDA because it is being delivered to a healthcare practitioner.

Daniel Martinez stated that CPhA does not have an official position on the use of these machines. However, members have expressed concern with how a person will be identified by the machine in order to ensure that he or she is the actual patient. He added that members are also concerned that the patient will have no way of verifying that he or she is receiving a consultation from a pharmacist.

President Gutierrez recommended that the board vote to determine if it wants to pursue legislation to allow for ADDS machines and if the motion passes then the board can discuss the specific requirements.

Motion: Sponsor legislation to allow for the use of ADDS machines in locations not adjacent to a pharmacy.

M/S: Veale/Weisser

Support: 5 Oppose: 3 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		

Gutierrez	x			
Khan				x
Law		x		
Lippe				x
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong		x		

The board recessed for a break at 11:00 a.m. and resumed at 11:15 a.m.

Note: Ms. Veale left the room at 11:15 a.m. and returned at 11:45 a.m.

Mr. Room reviewed the core principles of the language as provided below so that the board could determine what principles staff should use when drafting language.

1. Definitions - creating, by definition, a delineation of the two different types of systems - - “Automated Unit Dose System (AUDS)” and “Automated Patient Dispensing System (APDS).”
2. General Requirements:
 - a. Device must be licensed by the board to operate. (Hospitals using unit dose machines for administration to inpatients would be exempt from licensure; however, an ADDS machine for dispensing in a hospital would be required to secure licensure.)
 - b. Licensure limited to licensed pharmacies/hospitals located in California.
 - c. Prelicensure inspection of the location where the device will be located.
 - d. The ADDS license would be cancelled by operation of law if the underlying pharmacy license is cancelled or revoked.
 - e. Pharmacy must own the drugs and be responsible for the drugs (storage, security, etc.) until the medication is either dispensed or administered.
 - f. Application and annual renewal fee of \$200. Renewal will be synced with that of the underlying pharmacy license.
 - g. Specify locations where ADDS units can be used to include a pharmacy, health facility, clinic or medical office.
 - h. Limit the number of APDS units to five.
 - i. Pharmacy is responsible for delivery of the medications.
 - j. Pharmacy staff must stock ADDS units immediately upon delivery except in limited circumstances when drugs may be stored securely for up to 48 hours.
 - k. Self-Assessments are required annually or upon designation of a new PIC.
 - l. Recordkeeping and QA requirements must be satisfied, and records maintained within the licensed pharmacy, and separated from other pharmacy records.
 - m. For APDS:
 - i. All clinical services provided as part of the dispensing process must be provided by a California licensed pharmacist.
 - ii. Patient consultation must be provided consistent with the provisions of CCR 1707.2.
 - iii. All devices used for dispensing must have a posted notice providing the name of the

pharmacy that operates the ADDs in compliance with notice requirement in CCR 1707.6.

- iv. All devices used for dispensing must meet all prescription labeling requirements.

Mr. Room noted that during the break staff confirmed that at the last Enforcement Committee meeting the committee voted to allow a pharmacy to own and operate a maximum of five APDS machines. Ms. Butler stated that five machines are too many for a pharmacy to safely oversee. Mr. Room stated that staff will research other state's number limitations and will draft language with a few alternatives for the board to consider. Ms. Freedman added that the language could be drafted so that the board can specify the number through regulations.

Mr. Schaad asked if the fees will apply to both AUCS and APDS machines. Mr. Room responded that the fee would apply to both as the fee covers the board's licensing costs.

President Gutierrez asked the Licensing Committee to discuss if it may be appropriate for an advanced pharmacy technician to restock these machines.

VI. Discussion and Consideration of Possible Statutory Proposal to Require E-Prescribing of Prescription Drugs

President Gutierrez explained that since at least 1994, California was positioned to allow e-prescribing for dangerous drugs and controlled substances; however, for prescribing controlled substances, California had to wait for the DEA to finish its federal requirements in 2010.

President Gutierrez reported that the DEA's Final Rule for Electronic Prescriptions for Controlled Substances (EPCS) was published on March 31, 2010, at 75 FR 16236-16319 and became effective on June 1, 2010. These regulations paved the way for controlled substance prescriptions to be issued electronically.

President Gutierrez explained that prescription medications may be prescribed on paper, verbally or electronically. She noted that controlled medications, a subset of prescription medication, have special restrictions that specify conditions for oral or written prescriptions; electronic prescriptions must comply with federal requirements.

President Gutierrez stated that in California, if written, the prescriptions must generally be written on prescription forms printed by DOJ-licensed printers with 14 specific features. Schedule II controlled medications, with rare exceptions, cannot be orally ordered or refilled.

President Gutierrez stated that over the past decade, the abuse of pharmaceutical drugs, both controlled and noncontrolled, has skyrocketed in the United States and has led to the current opioid epidemic throughout the country. In California specifically, through this system of paper prescriptions, criminal organizations have been able to take advantage of weaknesses and lack of oversight of the printing program resulting in their ability to counterfeit prescriptions. This has led to the diverting of the most dangerous and addictive drugs prescribed.

President Gutierrez reported that as recently as November 29, 2017, a member of a drug trafficking organization that illegally acquired and distributed at least 50,000 oxycodone tablets

valued at \$1.5 million using counterfeit security form prescriptions during a three-year span was convicted in federal court in San Diego.

President Gutierrez explained that some patients who have become addicted to drugs or simply want to divert drugs alter prescriptions to increase the quantity prescribed, add additional drugs, or add refills. Some steal entire prescription pads from prescribers, which are sold to criminal organizations or used by addicts to fill the drugs of their choice. She noted that prescribers routinely report losing their pads to the Board of Pharmacy as well as to other agencies (and the board posts this information online).

President Gutierrez reported that currently, there are seven states that have passed legislation on e-prescribing. Laws already exist in three states (NY, MN, and ME), while the remaining four will become effective in 2018. Of the three states with active laws:

- Minnesota requires prescribers, pharmacies and health systems to have the capabilities to e-prescribe but does not mandate its use.
- However, NY and ME mandate the use of e-prescribing as the primary means of prescribing any medication.

President Gutierrez stated that according to Surescripts data, 98 percent of retail pharmacies are able to accept e-prescriptions, and 45.3 million prescriptions for controlled substances were delivered electronically in 2016 - a 256 percent increase from the 12.81 million controlled substance e-prescriptions in 2015.

President Gutierrez reported that in New York, which has had a mandate since March 2016 for both controlled and noncontrolled prescriptions to be e-prescribed:

- 98.1 percent of pharmacies were EPCS-enabled
- 72.1 percent of prescribers were EPCS-enabled (one year before, only 47% of New York prescribers could use EPCS)
- 91.9 percent of controlled substance prescriptions were sent electronically

President Gutierrez explained that the use of e-prescribing in California is increasing because e-prescribing helps to:

- Reduce overall mistakes made in interpreting prescribers' handwriting
- Allow for the prescription information to auto populate in the pharmacy without staff input
- Reduce patients' wait times for filling prescriptions
- Enable fast retrieval of records
- Save space by e-storing records
- Substantially reduce the opportunities for persons to steal, alter, "doctor shop," or counterfeit prescriptions, thus decreasing unsupervised access to medication

President Gutierrez reported that at a December 2017 committee meeting, the Enforcement and Compounding Committee considered the proposal to require e-prescribing as the primary mode for ordering controlled and other prescription drugs in CA.

President Gutierrez stated that the committee considered that the proposal would need to allow for exemptions to the e-prescribing requirements to address some scenarios, e.g., for terminally ill patients, or when the electronic system is not available. There would still be a need for paper prescriptions and existing patient-care exemptions, etc.

Mr. Room stated that this requirement would apply to both doctors and pharmacists so legal staff will work to determine what section of the law it would be placed in.

Mr. Room explained that by 2021 all doctors would be required to submit, and all pharmacies must be able to receive, both controlled and non-controlled prescriptions (excluding specific exemptions).

Mr. Weisser stated that it is important to collaborate with the other healing arts boards to develop the requirements. The board agreed with Mr. Weisser's statement.

Ms. Herold noted that veterinarians will be excluded from e-prescribing.

The board discussed the transfer requirements for controlled prescriptions.

Ms. Herold reported that an author has already been secured for this legislation.

Mr. Law asked that staff consider the allowance for phone prescriptions when drafting language.

Lori Womsley stated that Walgreens is very supportive of e-prescribing and offered to provide any data that the board needs. She added that Walgreens has not had any problems with the implementation of e-prescribing.

Ms. Womsley asked if e-prescribing would be required for all prescriptions or just controlled substances. Mr. Room responded the intent is to require it for all prescriptions.

President Gutierrez expressed concern that there will be opposition from the California Medical Association if the board requires e-prescribing for all prescriptions. After discussion, the board decided to approve language that requires e-prescribing for all prescriptions and allow stakeholders to provide feedback during the legislative process.

A pharmacist explained that the internet at her pharmacy often stops working and asked if there is an exemption for electronic failure. Mr. Room confirmed that there is an exemption.

The board discussed if there should be an exemption for a patient that has a prescription for a controlled substance but does not know what pharmacy he or she wants it filled at. Ms. Herold stated that she would research how New York handled this situation.

Ms. Herold reported that in New York one year after the law was finalized doctor shopping was reduced by 90 percent.

Motion: Recommend that the board sponsor legislation to require e-prescribing but allow for exemptions, including terminally ill exemptions, ER provisions, etc.

M/S: Weisser/Butler

Support: 7 Oppose: 1 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe				x
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong		x		

Ms. Freedman asked that the board return to the ADDS agenda item. She asked the board to clarify if it wanted staff to draft language and find a sponsor for the bill.

The board confirmed that it would like staff to draft language based on their discussion and find a sponsor for the bill.

Ms. Freedman asked if the board wanted to staff to draft the language with a maximum of five APDS machines per pharmacy. After discussion, the board decided to allow a maximum of five APDS per pharmacy but include language that would allow the board to modify the number via regulation.

Motion: Direct staff to draft language based on the general provisions provided below and find a sponsor for the bill.

1. Definitions - creating, by definition, a delineation of the two different types of systems - - “Automated Unit Dose System (AUDS)” and “Automated Patient Dispensing System (APDS).”
2. General Requirements:
 - a. Device must be licensed by the board to operate. (Hospitals using unit dose machines for administration to inpatients would be exempt from licensure; however, an ADDS machine for dispensing in a hospital would be required to secure licensure.)
 - b. Licensure limited to licensed pharmacies/hospitals located in California.
 - c. Prelicensure inspection of the location where the device will be located.
 - d. The ADDS license would be cancelled by operation of law if the underlying pharmacy license is cancelled or revoked.
 - e. Pharmacy must own the drugs and be responsible for the drugs (storage, security, etc.) until the medication is either dispensed or administered.
 - f. Application and annual renewal fee of \$200. Renewal will be synced with that of the underlying pharmacy license.
 - g. Specify locations where ADDS units can be used to include a pharmacy, health facility,

- clinic or medical office.
- h. Limit the number of APDS units to five or to some number set by the board by regulation.
- i. Pharmacy is responsible for delivery of the medications.
- j. Pharmacy staff must stock ADDS units immediately upon delivery except in limited circumstances when drugs make be stored securely for up to 48 hours.
- k. Self-Assessments are required annually or upon designation of a new PIC.
- l. Recordkeeping and QA requirements must be satisfied, and records maintained within the licensed pharmacy, and separated from other pharmacy records.
- m. For APDS:
 - i. All clinical services provided as part of the dispensing process must be provided by a California licensed pharmacist.
 - ii. Patient consultation must be provided consistent with the provisions of CCR 1707.2.
 - iii. All devices used for dispensing must have a posted notice providing the name of the pharmacy that operates the ADDs in compliance with notice requirement in CCR 1707.6.
 - iv. All devices used for dispensing must meet all prescription labeling requirements.

M/S: Veale/Sanchez

Support: 5 Oppose: 3 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X	X		
Gutierrez	X			
Khan				X
Law		X		
Lippe				X
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong		X		

VII. Discussion and Consideration of Possible Statutory Proposal to Reconcile Federal and State Controlled Substances Schedules

President Gutierrez reported that at the November Board Meeting, the board discussed the possibility of finding a means to address differences in federal and state controlled substances schedules so that the more restrictive provision would prevail.

Mr. Room explained that in order to eliminate the discrepancies between the federal and state schedules the definition of controlled substances in both the Business and Professions Code and the Health and Safety Code was expanded to clarify that in the event of any conflict between the federal and California schedules, whichever set of schedules is more stringent will apply.

Motion: Approve the language as provided below.

Business and Professions Code section 4021. “Controlled substance” defined

“Controlled substance” means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code and any substance listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any substance listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.

Health and Safety Code section 11007. Controlled substance

“Controlled substance,” unless otherwise specified, means a drug, substance, or immediate precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058 and any drug, substance, or immediate precursor which is listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any drug, substance, or immediate precursor listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.

M/S: Law/Butler

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Khan				X
Law	X			
Lippe				X
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

VIII. Discussion and Consideration of Allowing Continuing Education Credit for Board’s Pharmacy Law Update Course

President Gutierrez reported that on December 6, 2017, the Executive Officer provided a presentation at California Northstate University School of Pharmacy. The presentation covered new 2018 pharmacy laws and was attended by approximately 30 licensees. She explained that the Executive Officer is requesting that the board approve 1.5 hours of continuing education for the attendees.

Note: As board member Schaad attended the training he abstained from the vote.

There were no comments from the board or from the public.

Motion: Approve 1.5 hours of CE for the new pharmacy law presentation provided on December 6, 2017, at California Northstate University School of Pharmacy.

M/S: Law/Wong

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe				x
Munoz				x
Sanchez	x			
Schaad			x	
Veale	x			
Weisser	x			
Wong	x			

IX. Closed Session

The board recessed to closed session at 12:10 p.m.

X. Reconvene Open Session

The board returned to open session at 12:30 p.m.

President Gutierrez adjourned the meeting at 12:32 p.m.