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

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT
September 15, 2017

Allen Schaad, Licensee Member, Chair
Amy Gutierrez, PharmD, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member

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

2. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings
Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

3. Discussion and Consideration of Discrepancies Between the State and Federal Controlled Substance Schedules and Their Impact on Health Care Services, and Potential Changes to Impact Laws and Regulations

Background

Medications with the potential to be the most highly abused or lead to addiction are classified under separate federal and state laws into five lists of "scheduled" drugs. Both federal and California law numbers these schedules by Roman numerals: I, II, III, IV and V. The lower the number, the higher the potential for abuse.

The California controlled substances schedules are codified in the California Health and Safety Code. This is statutory law, and no single agency is responsible for ensuring the lists are current with respect to drugs of abuse and addiction. The federal controlled substances schedules are promulgated federally principally by the DEA and are found the in Code of Federal Regulations.

Schedule I drugs are generally not intended for medicinal use, except under tightly controlled research studies and are considered "illegal" or "street" drugs. (Marijuana is a Schedule I drug federally, and LSD is a Schedule I drug in both federal and state schedules.)

Schedule II drugs have medicinal value and are prescribed under tightly controlled conditions, but they also have high abuse/addiction potential; examples are morphine, oxycodone, hydromorphone and Adderall. In California, these medications must be prescribed on a California security form or e-prescribed according to specific federal requirements, and they cannot generally be ordered via telephone or refilled even one time. (An original new prescription is needed for each dispensing unless the original

prescription has been partially filled, and then there are time limits to fully fill the prescription.)

Schedule III and IV drugs have lesser addictive and abuse potential, but they are still more tightly regulated than prescription medication generally. For example, in California they are subject to more restrictive prescribing requirements (use of a security form if written, limits on refilling a prescription to six months, limits on quantity for the aggregate of all refills, and a limit on the number of refills). However, unlike Schedule II drugs, these medications can be orally ordered for a patient by a prescriber (as well as e-prescribed under federal requirements).

Schedule V drugs generally have lesser addictive and abuse potential than medications classified in Schedules I-IV, but they still are abused. These medications are often cough syrups, including the highly abused and frequent target of pharmacy robberies – promethazine with codeine.

In California prescriptions written for scheduled drugs must be prescribed by prescribers using specialized prescription forms ordered from a CA Department of Justice licensed printer. There are specific security features for these forms (e.g., thermochromic ink, water marks). Scheduled drugs may be prescribed electronically under e-prescribing systems that meet federal requirements, but faxing a prescription (where a written prescription is faxed to a pharmacy) is not authorized because of original signature requirements. Schedule III-V medications can be orally ordered in CA.

Generally, there is a high degree of similarity in how medications are classified under the federal and state schedules. However, there are some differences between the federal and state schedules. For example, federal law classifies hydrocodone as a Schedule II drug; under California law, hydrocodone is a Schedule III drug. Federal law today classifies tramadol as a Schedule IV drug; it is not a scheduled drug under California law.

Yet there is enough difference between the federal and state controlled substances schedules that entry of medications into CURES is done according to the federal controlled substances schedules, not California's.

The lack of agreement in how a given drug is classified between the federal and state schedules makes for interesting results: While a prescription for hydrocodone is a Schedule II drug federally, because it is a Schedule III drug in California, there is a question about whether hydrocodone could be dispensed by refills (which are allowed for a C-III drug but not for a C-II drug).

In addition to hydrocodone being classified in a different federal schedule than California, additional drugs of abuse are federally scheduled but not scheduled at all in California – specifically tramadol and soma.

One last statement regarding the difference between the two sets of schedules: Federal law exempts from scheduling as a controlled drug those combination drugs where the ratio of

the controlled drug ingredient vs. the non-controlled ingredients is at a level low enough to exclude the combination drug from being a controlled drug. Below are examples of such federally exempt combination products. California has NOT adopted the same exemptions.

- Fioricet (CA - CIII), HSC 11056(c)(3) butalbital product with barbaturic acid or any salt thereof.
- Donnatal (CA – CIV), HSC 11057(d)(26).
- Phenobarbital Librax (CA-CIV) HSC 11057(d)(5).
- Clordiazapoxide.

Basically, if it's a combination product that has ingredients (such as clordiazepoxide, phenobarbital, butalbital, pentobarbital, meprobamate, etc.) on the federal exempt list, these medication products remain controlled drugs in California.

Proposal

Following discussion by the committee, direct staff to evaluate systems that could mesh the federal and state schedules in a manner that preserves the requirements of each but ensures that the more highly classified structure of a drug in either schedule would take precedence in California.

If the committee recommends a solution, it most likely would lead to legislation.

4. Discussion and Consideration of Proposed 2018 Board-Sponsored Legislation Regarding CURES

At the January 2017 board meeting, the board identified multiple items for future changes it would like to see made to the CURES program. The board also directed staff to pursue implementation strategies for these proposals. Specifically, the board proposed the following changes:

a. Add "days' supply" of a medication into the viewing screen of a patient when pharmacists access the system.
b. Make modifications to permit prescribers to view the patients and prescriptions in CURES where they are identified as the prescriber.
c. Require dispensers to report data into CURES within 48 hours of dispensing. (Currently this time frame is no longer than 7 days.)
d. Add the reporting of Schedule V medications dispensed to the CURES system. (Currently federal Schedule II – IV medications are required to be entered.)

Item (a) was activated by the Department of Justice soon after the department participated in a discussion with the board. For months, pharmacists have been able to view the days' supply of medication for each medication entered into a patient's profile.

The remaining three items have not been incorporated into CURES. Item (b) may need to be made statutorily; items (c) and (d) will require legislation.

At the July 2017 board meeting, staff from the Department of Justice made a presentation to the board on the CURES 2.0 implementation. During part of that presentation, the DOJ staff indicated a willingness to work with the board on possible statutory modifications to the CURES system in the coming year.

At this meeting
The committee will have an opportunity to discuss these remaining proposals and recommend to the board future action, including possible sponsorship of legislation to accomplish these objectives.

Additionally, California is one of seven states that is not sharing prescription drug monitoring program (PDMP) data across state lines (CURES is California's PDMP). Staff respectfully suggests that the committee also address working with the Department of Justice to secure interstate data exchange of PDMP information.

5. Discussion and Consideration of Board Policy to Conduct Inspections of All Pharmacies Every Four Years

Last year during the board's sunset review, a proposal was made to require that the board perform inspections of all pharmacies once every four years. The goal was to ensure that all pharmacies would have a compliance inspection during this time. The focus of these inspections would be aimed at compliance and education, and not specifically due to performance of a sterile compounding inspection nor due to the need for an investigation of a complaint or possible violation of pharmacy law.

During the discussion, the board concluded that a statutory requirement to perform compliance inspections every four years was not necessary and instead developed a policy that the board's inspectors would inspect all pharmacies once every four years.

Below is inspection data for the prior four years.

Total Inspections: FY 13-14 thru FY 16-17 by Visit Type

Inspection Type	FY 13-14	FY 14-15	FY 15-16	FY 16-17	Total
Routine	287	342	235	300	1164
Investigation	875	926	1065	757	3623
Probation/PRP	139	227	208	311	885
Sterile Compounding	996	1067	1123	976	4162
Other	32	26	9	9	76
Grand Total	**2329**	**2588**	**2640**	**2353**	**9910**

Education of licensees is an important part of the board's operations. The board educates licensees in various ways as described below.

- **The Script:** The board's primary means of education for licensees is its newsletter, which is published once per quarter and is available on the board's website. http://www.pharmacy.ca.gov/publications/script.shtml

- **Presentations:** The board provides presentations at various events such as association meetings and schools of pharmacy. The presentations usually include updates to pharmacy law or board priorities. Often CE units are provided for attendees.

- **Subscriber alert system:** The board utilizes an electronic subscriber alert system to provide information directly to licensees about new laws or regulations as they take effect and provides links to the board website where licensees can learn more about a new requirement.

- **Self-assessment forms:** Completing the self-assessment forms allows licensees to identify key laws that impact their practice to ensure compliance.

- **"Ask an inspector:"** The board has reinstated the "ask an inspector" program to give licensees the opportunity to speak with a board inspector regarding questions of pharmacy law.

Additionally, the board now requires every pharmacist to take at least two CE units of education provided directly by the board as a condition of license renewal.

A periodic inspection by a board inspector where compliance is the focus would further benefit the public through improved education of board licensees. It would also allow identification of violations before they come to the board's attention in other ways as well.

During this meeting, the committee will have the opportunity to discuss its progress in achieving its goal of inspecting all pharmacies once every four years.

6. Discussion and Consideration of Possible Statutory or Regulatory Changes to Expand the Use of Automated Drug Delivery Systems (ADDS)

Attachment 1

There is increasing interest and demand for expanded use of ADDS in pharmacies, clinics and other environments to provide medications to patients. 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, ADDS that comply with requirements established by California Code of Regulation section 1713 for refills that

patients opt in to use from a machine adjacent to a pharmacy counter, use of ADDS via remote technology as authorized in clinics licensed by Business and Professions Code section 4186).

At a technology summit held by the board earlier this year, various forms of technology were demonstrated to the board. A summary of the technology was categorized and organized into a table, which is provided as **Attachment 1**.

This year in the California Legislature there are 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.

The committee may wish to use a portion of this meeting to discuss the components it believes are necessary for regulation of the machines.

Attachment 2 contains three sections of California Pharmacy Law that specifically address ADDS machines**. Attachment 2** also contains an article published in the June 2017 issue of *The Script* regarding who can restock ADDS machines.

As stated above, there are currently two types of environments for the ADDS:

1. Where medication will be stored for unit dose administration to patients by health care personnel.
2. Where a patient will be directly dispensed a medication.

Among the questions that the committee needs to address are:

- Under Health and Safety Code section 1261.6 (where can medication be stored for unit dose administration to patients by health care personnel after the medication is delivered to the facility):
  - Who can refill the machines?
  - Who can deliver the medication to the facility? Should storage in vehicles be permitted? What type of security during transportation is required?
  - Can the refill medications be stored at the facility before loaded into the machine? If so, where?
  - How will expired medication be removed from an ADDS?

- Under Business and Professions Code sections 4105.5, 4186 and California Code of Regulations section 1713 (where patients will be dispensed their medication):
  - Is patient consent required to use the ADDS? How often does it need to be reviewed/reaffirmed?
  - Is patient consultation required? When? Only on initial fills?

- Is a phone connection adequate, or is a video camera also needed?
- How can language interpretations be secured via ADDS?
- Should ADDS be placed in non-pharmacy areas? If so, how should security of the medication and patient confidentiality be provided?
- How long may a refill be provided?
- Should all medication be available via an ADDS dispensing?
- Should patients be reminded about the need for some drug therapy to be monitored periodically via testing? If so, how should this be meshed into patient care?

- General questions:
  - Who can own/operate an ADDS (a licensed pharmacy, a pharmacist, anyone)?
  - If a pharmacy must own the ADDS, can it do so from an out of state location?

- Questions involving UCSD:
  - Should ADDS be allowed in expanded areas instead of being limited to "adjacent to the pharmacy counter," and if so, what provisions are needed?
  - Should any expanded use of ADDs be allowed only for refills? If allowed for first-time fills, how will consultation be handled?
  - Should every medication dispensed through an ADDS be counseled at least annually?

7. Discussion and Consideration of the University of California San Diego's Experimental Program Regarding Access to Medications from an ADDS -- Pursuant to California Code of Regulations, Title 15 Section 1706.5

Attachment 3 and 4

At the July 2017 board meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. This study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter.

During the July board meeting, the board heard the final report of this study and considered a request from UCSD to extend the study for one year to provide additional data regarding study and time for the board to consider a regulation modification involving ADDS to provide medication to patients. The board had a number of questions regarding the study that are highlighted in draft meeting minutes from this portion of the board meeting (**Attachment 3**).

Following the discussion, the board approved the following motion: Extend the pilot UC San Diego study for another 12 months (July 26, 2017 -July 25, 2018); additionally, request that the data provided to the board include a distinction between new prescriptions (as defined by law) and previously dispensed prescriptions.

During the meeting

UCSD researcher Jan Hirsch will provide a presentation on the proposed future direction of the study. Also as background, Asteres has provided additional material regarding the use of ADDS machines nationally. The availability of this information was referenced by Asteres during the July board meeting. A copy of this material is provided in **Attachment 4**.

A copy of Dr. Hirsch's planned presentation is provided in **Attachment 4**.

During the committee meeting, committee members will have an opportunity to discuss and offer suggestions about what data they would like to see from the extended study.

Below are questions that Dr. Hirsch and Dr. Allen asked the executive officer during a meeting following the July board meeting. Dr. Hirsch will amend the IRB for the study once decisions from the board have been made.

1. Proposed data for collection during the one-year extension:
   a. Counseling: UCSD requests performing data collection through a log at the pharmacy when a kiosk patient is counseled by the pharmacist that would categorize "new" prescriptions as new to patient, new to the pharmacy but not the patient, or a rewrite.
   b. Therapeutic Class: UCSD proposes to remove this category from data collection.
   c. Return to Stock (RTS): Data will continue to be collected for kiosk and counter (not including specific therapeutic class categories).
   d. Time from verify to pick up: Data will continue to be collected for kiosk and counter (not including specific therapeutic class categories).
   e. Patient survey data: Conducted at kiosk.

2. When does the committee want a data presentation from the amended protocol? (At a full board meeting or the June 2018 Enforcement Committee Meeting?) Is one year a realistic timeframe if section 1713 will be amended? Would 18 months be more realistic?

3. The board requested analysis of "truly new" prescriptions (i.e., new to patient or to pharmacy). UCSD states that it would be unable to provide this type of analysis since it is not possible to make this determination using an automated process. However, UCSD did a manual analysis for a 10-month period (March – December 2016) and the average percentage of "truly new" prescriptions per month was about 55% (range 33% to 71%).

4. UCSD requests that the committee discuss amending Regulation 1713.

8. Status Report on Waivers for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4.

Background

Title 16 of California Code of Regulations (CCR) section 1735.6 (f) states that where

compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. There is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

An application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver.

Initial review of the waiver is performed by staff led by the executive officer, who approves or denies the waiver request. Approval or denial of a waiver is provided to facilities in writing. If a waiver is denied by the executive officer, there is an appeal process which will be reviewed by two board members, currently board members Schaad and Law.

The goal of the construction waiver process is to secure full compliance at the earliest possible time and no later than the implementation date of USP <800> on July 1, 2018.

Update

The waiver review process is ongoing as pharmacies continue to seek extensions or modifications (often due to construction delays) in their facilities to comply with <USP> 800. The executive officer has provided specific timelines to facilities requesting a waiver with respect to the Office of Statewide Health Planning and Development (OSHPD) approval, status reports of construction and final completion dates.

Facilities which have been denied a waiver have been made aware that there is an appeal process to the compliance waiver process. Such waiver appeals go to the subcommittee of Mr. Schaad and Mr. Law. There have been no additional appeals made since July 1, 2017.

Most request waiver sections are 1735.6(e) and 1751.4(g) for the external venting requirement.

In the next few weeks, the board will add to its website the pharmacies which have been given waivers.

Status of Waiver Requests Received as of 9/11/17:

- Total Waivers Received: 666.
- Total Waivers Processed: 624.
    - Denied: 40 - 6.4 percent.
    - Withdrawn: 102 - 16.2 percent.
    - Approved: 393 - 64 percent.
    - Non-responsive letters sent: 22 - 3.5 percent.
    - In process: 42 – 6.7 percent.
- Total Waivers Pending Review: 42
- Total Waiver Extensions Granted: 93

- Pending Review for Extensions: 19

9. Enforcement Statistics

Attachment 5 contains the enforcement statistics for the first two-and-a-half months of FY 2017/2018.

10. Future Committee Meeting Dates

The board is in the process of scheduling an additional committee meeting prior to the February 2018 board meeting. When the meeting date is finalized, the board's website will be updated and a subscriber alert will be sent.

Below are the scheduled committee dates for 2018:

- March 28, 2018.
- June 7, 2018.
- September 5, 2018.
- December 13, 2018.

Attachment 1

State Board of Pharmacy- Enforcement Committee
Review- Pharmacy Automation Technology

Background: Multiple pharmacy automation vendors provided presentations at the February 17, 2017 Board meeting. These vendors provided an overview of existing technology, and dispensing/restocking workflow for their respective products. Each vendor also requested modification of existing pharmacy law to accommodate use of their technology. The Enforcement Committee was asked to review these requests and provide recommendations to the full Board of any changes needed to the law to enable technology that is believed to be safe, accurate, minimizes ability for drug diversion, and improves patient access.

In an effort to provide a framework for this discussion, a table was prepared that outlines the various technologies presented (so far) as well as policy discussion items for each.

CATEGORY 1: Medication dispensing technology that is accessed by Nursing at the remote site to obtain medications that are then administered to the patient at the remote site. Examples of remote sites include skilled nursing facilities and correctional settings.

Category I Technology	Description	Medication dispensing	Replenishment of medications	Transport of Medication	Who performs replenishment	Policy discussion items
A1	Automated Dispensing Cabinets- hosted by pharmacy not physically located at remote site	Nurse at remote site	Host Pharmacy replenishes medication in unit dose packets. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Sealed tamper-proof sealed plastic container with a chip that identifies the canister. Container will not allow placement into technology if tampered with.	Various workflows described: Nurse at remote site Pharmacist physically places into ADC Pharmacy technician, under pharmacist supervision, physically places into ADC	• Is the medication stored in the remote site ADC part of the pharmacy inventory? If the licensed clinic owns the ADC, what role does pharmacy play in restocking? • Who should be allowed to place the sealed tamper-proof plastic container into the ADC? Is Nursing allowed to place the tamper-proof canister into the ADC after receipt from the pharmacy? • If controlled drugs are supplied, does this require a DEA 222 form for each restock? • Should the remote site be licensed?
A2	Automated Dispensing Cabinets- hosted by pharmacy not	Nurse at remote site	Host Pharmacy replenishes medication in unit dose packets. Stock levels and reports	Sealed medication delivery bags are utilized to transport medication	Various workflows described: Nurse at remote site Pharmacist	Same as A1 above, plus: • Are there concerns for drug diversion due to less than secure transport workflow? • How will pharmacy be assured that all medication arrived at location?

	physically located at remote site		are accessed from the pharmacy location to facilitate replenishment	from pharmacy to remote site. May or may not have tamper proof seal; no plastic container. Remote site replenishment involves placement of individual doses into ADC cell manually (no canister with chip)	physically places into ADC Pharmacy technician, under pharmacist supervision, physically places into ADC	
B1	Medication Canisters with patient-specific packaging that is performed at the remote site	Nurse at remote site-typically in 24-hour patient-specific plastic packets for oral solids	Host pharmacy replenishes drug-specific oral solid canisters that are placed into the device at the remote site. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Sealed tamper-proof sealed plastic container with a chip that identifies the canister. Container will not allow placement into technology if tampered with.	Nurse physically places the drug-specific oral solid canister into the device.	• Is the medication stored at the remote site part of the pharmacy inventory? If the licensed clinic owns the technology, what role does pharmacy play in restocking? • Who should be allowed to place the sealed tamper-proof plastic container into the device? Is Nursing allowed to place the tamper-proof canister into the device after receipt from the pharmacy? • If controlled drugs are supplied, does this require a DEA 222 form for each restock? • Should the remote site be licensed?

CATEGORY 2: Medication dispensing technology that is accessed by healthcare providers in order to provide the patient at the remote site to access medications for at home self-administration

Category I Technology	Description	Medication dispensing	Replenishment of medications	Transport of Medication	Who performs replenishment	Policy discussion items
A1	Robot that dispenses medication through	Staff at remote site. Robot labels the patient	Host Pharmacy replenishes medication in drug specific	Various	Staff at remote site	• Is the medication stored in the remote site part of the pharmacy inventory? If the licensed clinic owns the technology, what role does pharmacy play in restocking? • Who should be allowed to place the containers into the

	direct real-time link with pharmacist	medication containers per information input by remote pharmacist.	containers. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment			technology? Is Nursing allowed to place the medication after receipt from the pharmacy? • Some vendors cited the use of a wholesaler to replenish the inventory in the automated device. Should the board allow wholesalers to receive and restock medication on behalf of a pharmacy? • If controlled drugs are supplied, does this require a DEA 222 form for each restock? • Should the remote site be licensed? • How is patient counseling performed? Is the patient interaction conducive to patient teaching (screen size, technology, etc.) Is patient counseling always provided (some state only upon patient request) • Does the label meet state label requirements? • How is drug diversion detected if transport does not include tamper-proof sealed canisters? How is drug diversion detected from a wholesaler or other non-pharmacy replenishment?
A2	Robot that dispenses medication through direct real-time link with pharmacistq	Staff at remote site. Staff must assemble medication container, and label printed separately and affix the label to the container at remote site	Host Pharmacy replenishes medication in drug specific containers. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Various	Staff at remote site	All of the above plus: • Are there any patient safety concerns with someone other than a pharmacist affixing a medication label?
B	Technology that dispenses pharmacy-filled medications to facilitate patient access	Performed within the pharmacy	Host pharmacy places filled patient-specific patient medication bags into technology to facilitate patient pick-up from a remote location.	Pharmacy	Pharmacy	Current pilot ongoing with UCSD; awaiting pilot results. • How is patient counseling performed? • How is drug diversion detected? • Should the remote site be licensed?

Attachment 2

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must Be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

State of California

BUSINESS AND PROFESSIONS CODE

Section 4105.5

4105.5. (a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

(Added by Stats. 2016, Ch. 484, Sec. 18. (SB 1193) Effective January 1, 2017.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 4186

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(Added by Stats. 2001, Ch. 310, Sec. 1. Effective January 1, 2002.)

State of California

HEALTH AND SAFETY CODE

Section 1261.6

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may

be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards,

drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(Amended by Stats. 2016, Ch. 484, Sec. 54. (SB 1193) Effective January 1, 2017.)

Register ADDS

Continued from Page 1

B&PC section 4105.5 was enacted in 2016 by SB 1193 (Hill, Chapter 484, Statutes of 2016). The law requires pharmacies that own or provide drugs dispensed through automated drug delivery systems to register by providing the board in writing with the location of each device within 30 days of installation. A pharmacy must reaffirm the information upon annual license renewal and must notify the board within 30 days if the pharmacy discontinues operating the system.

An exemption from registration is allowed for an automated drug delivery system operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license under Health and Safety Code section 1250.8.

The law sets specific conditions for operating automated drug delivery systems:

- The use must be consistent with legal requirements. The new regulation does not expand conditions under which automated drug delivery systems may be used.
- The pharmacy must have policies and procedures for the device that include security measures and monitoring inventory to prevent theft and diversion.
- The pharmacy must report drug losses from the device to the board as required by law.
- The pharmacy license must be current and not subject to disciplinary conditions.

Section 4105.5 also authorizes the board to prohibit use of an automated drug delivery system if a pharmacy cannot meet the specified conditions for operating the device. A pharmacy may request an office conference to appeal a prohibition within 30 days of written notice, and the executive officer or a designee may affirm or overturn the prohibition.

Restocking an Automated Drug Delivery System (ADDS) Device In Licensed Health Facilities

California Pharmacy Law permits a licensed pharmacy to "provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system [ADDS] that need not be located at the same location as the pharmacy." (Bus. & Prof. Code, § 4119.1, subd. (a).) This remotely-located ADDS functions as an extension of the licensed pharmacy on the licensed health facility premises. As such, the pharmacy remains at all times responsible for operation of the ADDS, which must be operated under the supervision of a licensed pharmacist. (§ 4119.1, subd. (d).) The ADDS must be owned and operated by the pharmacy (§ 4119.1, subd. (c)(2)); all drugs in the ADDS are part of the inventory of the pharmacy; and all drugs dispensed from the ADDS are considered dispensed by the pharmacy. (§ 4119.1, subd. (b).) The pharmacy and the facility must "develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and maintenance of the quality, potency, and purity of stored drugs"; those policies and procedures must also define access to the ADDS and limits on access to the equipment and drugs. (§ 4119.1, subd. (c)(4); Health & Saf. Code, § 1261.6, subd. (d)(1).) The pharmacy is also required to "maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the [ADDS] separate from other pharmacy records." And the pharmacy is required to "provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system." (§ 4119.1, subd. (c)(3).) And finally, the ADDS must be operated in conformity with Health and Safety Code section 1261.6. (§ 4119.1, subd. (c)(4).)

Health and Safety Code section 1261.6, in turn, confirms a general expectation that use of an ADDS placed by a licensed pharmacy in a licensed facility pursuant to Business and Professions Code section 4119.1 shall be the responsibility of and be controlled by the licensed pharmacy/pharmacist. (Health & Saf. Code, § 1261.6, subds. (f), (g).) Further, the ADDS is itself required to "collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability." (Health & Saf. Code, § 1261.6, subd. (a)(1).) The pharmacy must review the drugs, operation and maintenance of the ADDS on a monthly basis; a pharmacist must perform the review, including a physical inspection, of the ADDS, its drugs and the transaction records. (Health & Saf. Code, § 1261.6, subd. (h).)

Consistent with these principles, stocking and restocking of an ADDS device is generally the sole province of the licensed pharmacy/pharmacist. (Health & Saf. Code, § 1261.6, subd. (f) ["The stocking of an automated drug delivery system shall be performed by a pharmacist."].) In general, neither licensed facility staff nor any other persons are permitted to access an ADDS device for this purpose. However, there is a narrow exception provided by Health and Safety Code section 1261.6, subdivision (g), solely for those ADDS devices utilizing "removable pockets, cards, drawers, or similar technology, or unit of use or single dose containers as defined by the United States

See **Restocking ADDS**, Page 5

Restocking ADDS

Continued from page 4

Pharmacopeia." For these devices, a pharmacy may permit certain facility staff to do stocking or restocking using prefilled pockets, cards, drawers, or unit of use or single dose containers, when all these conditions are met:

1. The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers, is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

2. The removable pockets, cards, drawers, or unit of use or single dose containers, are transported between the pharmacy and the facility in a secure tamper-evident container.

3. The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, drawers, or unit of use or single dose containers, are properly placed into the automated drug delivery system.

Even for these sorts of ADDS devices, however, access must be limited/controlled. Access must be limited to facility or contract personnel authorized by law to administer drugs. (Health & Saf. Code, § 1261.6, subd. (c).) Moreover, the pharmacy is still required to exercise control over the ADDS, its contents, and personnel with access to the ADDS. (See Bus. & Prof. Code, § 4119.1, subds. (c)(3), (d); Health & Saf. Code, § 1261.6, subds. (f), (g).)

The primary question directed to the board by members of the regulated industry has been whether it is permissible to have nurses in licensed facilities perform restocking functions on ADDS devices, using pre-filled pockets, cards, drawers, or unit of use or single dose containers. The answer is yes, but only under appropriate circumstances. First, the ADDS device must be appropriately placed. A pharmacy may only place an ADDS device in a facility licensed for skilled nursing, intermediate care, or both. (Bus. & Prof. Code, § 4119.1, subd. (a); Health & Saf. Code, § 1250, subds. (c), (d).) Second, the ADDS device must use removable pockets, cards, drawers, or unit of use or single dose containers. Third, the prefilling and delivery of those removable pockets, cards, drawers, or unit of use or single dose containers must be compliant with Health & Safety Code section 1261.6, subdivision (g). Fourth, the facility and pharmacy's jointly developed written policies and procedures must ensure that the pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. And fifth, only facility or contract personnel authorized by law to administer drugs may access an ADDS to perform restocking by placing prefilled pockets, cards, drawers, or unit of use or single dose containers into the ADDS.

The required written policies and procedures with respect to an ADDS must be located at both the pharmacy operating the ADDS and the licensed facility where the ADDS is being used. (Health & Saf. Code, § 1261.6, subd. (d).) Inspectors from either the Department of Public Health or the board may inspect such records for compliance with relevant laws.

President's Message

Continued from page 2

Public Health (CDPH) to encourage pharmacies and pharmacists to register and submit timely immunization information to an immunization registry.

Meanwhile, CDPH has been working diligently to transition pharmacies in seven regions throughout the state to a new registry system known as the California Immunization Registry 2 (CAIR2), which was completed on March 20, 2017. Immunization data can be submitted to CAIR2 electronically or manually. Information for pharmacies about enrolling in CAIR2 and how to submit data electronically and manually is available online here.

Over the past year, I have noted increased participation at board meetings by a variety of stakeholders. This is an important trend, and greatly appreciated by the board, as active participation leads to more effective decisions. Please continue to participate and give a voice to the future of pharmacy practice within our great state.

Attachment 3

Excerpt from the July 25-26, 2017, Board Meeting Minutes
Draft

XIII. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System (ADDS) Not Immediately Adjacent to the Pharmacy, Including Medications Requiring Consultation by a Pharmacist

At the April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated drug delivery system (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills. The board authorized this study pursuant to its authority under 16 CA Code of Regulations 1706.5.

The study's researcher, Jan Hirsch, BS Pharm, PhD. And Kim Allen from Sharp Hospital provided a presentation of the final report (the presentation has been provided immediately following these minutes). The board also viewed a video of the ADDS as it operates at Sharp.

Following the presentation, the board asked Ms. Allen and Dr. Hirsch questions regarding the outcome of the study.

Board member Veale noted that she was surprised that patients delayed picking up their medications when they used the kiosk rather than picking it up right away. Ms. Allen stated that they were surprised as well; however, she noted that the kiosk allowed the patient more flexibility in deciding what time worked best for them to pick up the medication.

Board member Lippe stated that the anticipated usage of the kiosk higher than the actual usage. Ms. Allen stated that there were some barriers

Dr. Wong asked if there was a breakdown of new prescriptions vs. refill prescriptions. Dr. Hirsch stated that there were 1,484 prescriptions picked up from the kiosk. She explained that 474 were new prescriptions, 426 were refill prescriptions, and 584 were over-the-counter medications.

Ms. Sodergren asked what the definition of a new prescription was for the purposes of the study. Ms. Allen stated that Asteres views every new prescription number as a new prescription, however the law defines new prescriptions as any change in dose, new physician, or medication the patient has never received.

Ms. Sodergren stated that the law currently allows the use of these machines for previously dispensed medications. She asked if of the prescriptions that were categorized as "new" in the study, how many were previously dispensed medications. Dr. Hirsch stated that they do not have that data. Sara Lake, representing Asteres, stated that in the study consultations were only given for prescriptions that were "new" as defined by the law, so the number of consultations would equal the number of new prescriptions as defined by the law.

Ms. Sodergren stated that it would be helpful if the board could be provided with a breakout of the number of previously dispensed medications. She explained that when the board is

considering changes in the law it is useful understand the expansion of new prescriptions so that the board could determine if there is a correlation with patient care.

Board member Victor Law stated that many of the employees did not sign up for the program. Ms. Allen explained that they conducted outreach, but it is often difficult to onboard participants. Mr. Law stated that it did not seem that there was demand for these machines by the employees.

Board member Weisser stated that given the fact that the participation was less than expected and the pick-up time was longer when using the kiosk, he wondered if these kiosks were necessary.

Board member Albert Wong stated that employees may have been worried that their personal medical information would be used by their employer.

Board member Greg Lippe stated that he didn't see the downside of using the machines, however he questioned how economical the machines would be for the employer.

Ms. Veale stated that these machines are the going be part of the future of pharmacy and the board needs to seriously look at their use and would like to see the parameters expanded to allow for more use of the machines.

Board member Lavanza Butler stated that this study was a good starting point.

Ms. Allen stated that they would like to continue to use the kiosk so they are requesting to continue the study while the board amends 1713 to allow for the use of the machines in locations not immediately adjacent to a pharmacy. Mr. Weisser asked what they would like to change in 1713. Ms. Allen responded that they would like to change it to allow for new prescriptions to be dispensed from the machines and to allow the machines to be in locations not immediately adjacent to a pharmacy.

President Gutierrez stated that these ADDS machines are going to be the wave of the future and the board needs to determine how to regulate them.

Staff counsel, Laura Freedman, stated that the board would need to agendize modifying 1713 for a future meeting.

Ms. Freedman stated that she would need to review the original study parameters to determine if the waiver can be extended, thus allowing the machine to continue to be used.

Dr. Hirsch stated that she would be willing to work with the board on amending 1713 at future meetings. She also noted that if the study were to continue they would request that the board remove the requirement to compare the kiosk data to the data for patients that used the actual pharmacy. She explained that gathering the data from the pharmacy is time consuming and costly.

Ms. Freedman explained that the provision that allows the board to waive the provisions of 1713 is intended to allow the board to gather data via a study. Now that the study if complete, she would need to consider if an extension can be granted. She requested that the board give her time to review the original study parameters.

President Gutierrez asked if 340B drugs are dispensed via the kiosk. Ms. Allen stated that they are a contract pharmacy for 340B entities so it is possible that there are 340B drugs in the machine.

Sara Lake, stated that the only reason they are willing to extend the study so that patients can continue to use the kiosk.

Ms. Sodergren stated that the board needs to determine if additional study is necessary in order to make an informed decision to modify 1713.

President Gutierrez noted that 40 percent of the medications dispensed from the kiosk were for over-the-counter medications. She stated that the board could consider expanding the study to allow for non-employees to use the kiosk.

Ms. Sodergren stated that it would be helpful to receive data on the number of new prescriptions vs. previously dispensed prescriptions.

Ms. Freedman asked if the IRB has been extended. Dr. Hirsch stated that it had been extended to September.

A representative from Scripps Health stated that they are very interested in seeing the use of the kiosks expanded.

Mark Curry, representing Asteres, stated that large organizations have begun using the Asteres machines, including the Department of Defense. He stated that he would be happy to provide board members with tours of military bases the use the machines.

The board moved on to another agenda item to allow Ms. Freedman time to consider the study parameters.

The board returned to agenda item XIII: Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System (ADDS) Not Immediately Adjacent to the Pharmacy, Including Medications Requiring Consultation by a Pharmacist**.**

Ms. Freedman stated that following her review of the study parameters, she has concluded that the board could extend the study in its current form. She also stated that the board could modify specific aspects of the study in order to gather certain data. Ms. Freedman recommended against modifying the foundation of the study.

President Gutierrez asked if the board if could extend the current study and ask Dr. Hirsch and Ms. Allen to return to the Enforcement Committee to discuss beginning a new study. Ms. Freedman responded that this was possible.

Ms. Freedman expressed concern with the request from Dr. Hirsch to remove the data collection from the physical pharmacy because this was a core element of the original study approved by the board. She stated that the board could modify the study parameters to collect data on new vs. previously dispensed medications.

Ms. Freedman again explained that in order for the board to waive requirements of a regulation, it must be done in order to gather data necessary to determine if modification of the regulation is appropriate. Waivers cannot be granted simply to allow patients to continue to use the kiosk.

Ms. Allen asked if the board is agreeing to amend 1713 if they extend the study. Ms. Freedman stated that the board cannot agree to this, the board must receive and consider the data from the study and then make their determination.

President Gutierrez explained that the board is concerned that the study size is not large enough and too many of the medications that were dispensed were over-the-counter for the board to use the study data as a justification to modify 1713.

Ms. Lake, stated that Asteres can provide the board with data from the other major organizations that use the machines. She stated that they do not want to continue the study if in the end the board will not be modifying 1713. President Gutierrez responded that the additional studies may be helpful, but it will not help the board determine if it is appropriate to extend the study. Ms. Freedman added that modifying regulations takes time.

Ms. Freedman stated that the board can extend the study if the board believes that that new information will be obtained that will assist them in making the determination to modify the regulation. She added that the board could make the motion to extend the study and then Asteres and UC San Diego could determine if from a business standpoint they would like to continue on with the study.

Motion: Extend the pilot study UC San Diego study for another 12 months. Additionally, request that the data provided to the board include a distinction between new prescriptions (as define by law) and previously dispensed prescriptions.

M/S: Veale/Weisser

Support: 10 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			

Dr. Hirsch asked if the board would allow the study to be modified to allow for a *sampling* of the counseling logs at the kiosk. Ms. Freedman recommended that the executive officer and board president review this request to determine if it is consistent with the study parameters authorized.

Study of Expanded Use of an Automated Delivery Device

FINAL STUDY RESULTS
July 26, 2017

EXECUTIVE SUMMARY

Jan D. Hirsch, BPharm, PhD

UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

UC San Diego Health Sciences

Outline

- **Kiosk Process & Operations**
- **Study Question Results**
- **Conclusion**
- **Next Steps**
- **Questions**

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Kiosk = ScriptCenter

ScriptCenter Kiosk
Sharp Memorial Hospital

First Floor Lobby Sharp Memorial Hospital

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Kiosk Process at Sharp

SRS Pharmacy

Prescription processed and verified by SRS pharmacist.

Prescriptions transferred via secure tote by pharmacy staff to kiosk

Sharp Memorial Hospital

Prescriptions loaded in kiosk by pharmacy staff

Notification sent to patient. If counseling required, patient is alerted they need to speak with pharmacist before Rx pickup.

Patient calls pharmacist for counseling

SRS Pharmacist counsels patient

Prescription released in AsteresCentral®

Patient picks up prescription 24/7

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How it works

Demo Video

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Results Summary

Majority of employees surveyed agreed

- Would benefit from being able to pick up at work
- More likely to pick up medications if had easier access

Kiosk usage

- Fairly evenly divided among New, Refill and OTCs
- Majority Rxs (new & refill) picked up during pharmacy hours
  - However, kiosk used every hour of the day

Majority Kiosk users agreed

- Questions were answered regarding prescriptions
- If had questions knew how to call pharmacist

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Results Summary (continued)

Kiosk vs. Regular Counter

- No Differences
  - Return to Stock (RTS) rate
  - Pharmacists' assessment of their ability to counsel

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RTS Rate: Regular Counter vs. Kiosk

	Total Rx Filled	Total Rx Picked Up	Total Rx RTS	Mean* Monthly RTS (%)
Regular Counter+ (6 months prior)	4,924	4,668	256	5.2 ± 1.2
Regular Counter+ (study period)	7,015	6,643	372	5.3 ± 1.3
Kiosk**	943	893	50	5.0 ± 3.9

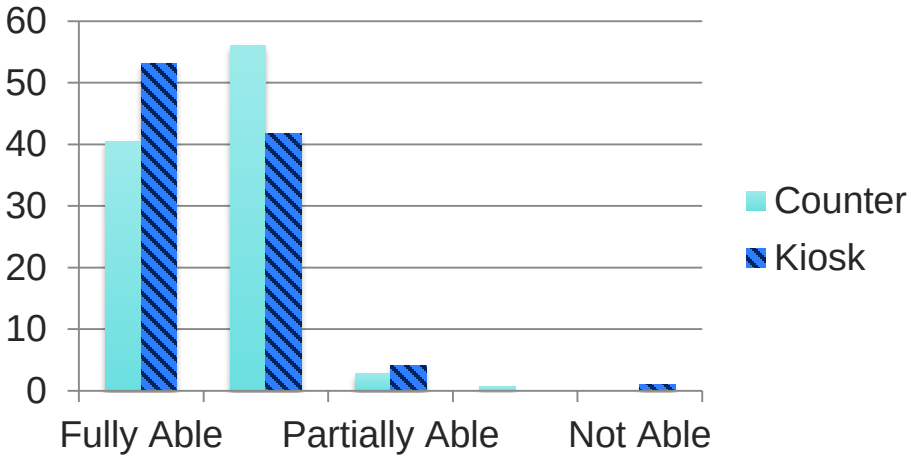
No significant difference in mean RTS at Kiosk vs. Regular Counter
(p = 0.942 6 months prior, p = 0.834 study period)

+Regular Counter = Employees and Dependents only to "match" group using Kiosk

* Monthly mean over 10 month study period or 6 month pre-study
** 1 Kiosk patient had 3 RTS for 2 and 4 RTS for 1 of 10 months,
1 Kiosk patient had 1 RTS for 4 and 4 RTS for 2 of 10 months

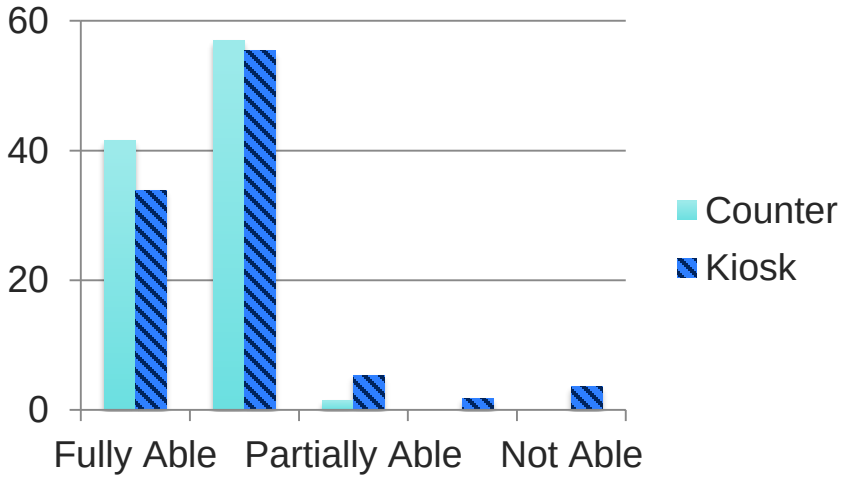
Pharmacist Assessments of Ability to:

Build Therapeutic Relationship



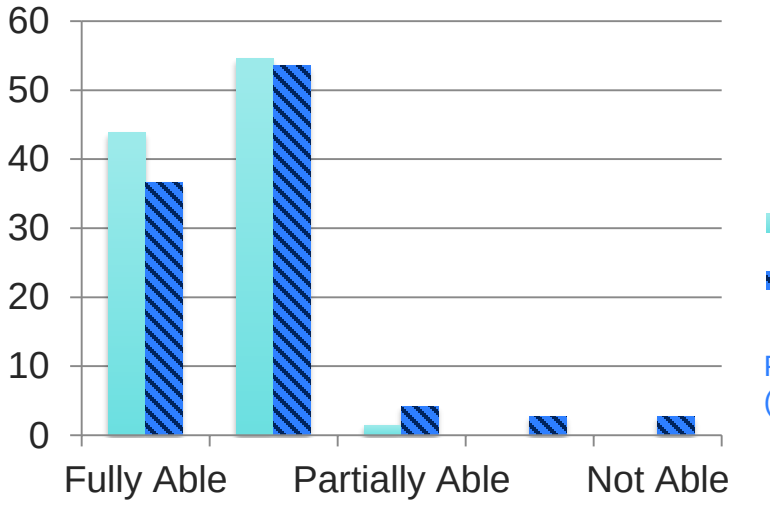
Pharmacist indicated not applicable (N/A): Counter n=10, Kiosk n=71

Establish Management Plan



Pharmacist indicated not applicable (N/A): Counter n=16, Kiosk n=113

Negotiate Safety Netting Strategies



Pharmacist indicated not applicable (N/A): Counter n=21, Kiosk n=98

Percentages may not add to 100% due to rounding error

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

Results Summary (continued)

Kiosk vs. Regular Counter

- No Differences
  - Return to Stock (RTS) rate
  - Pharmacists' assessment of their ability to counsel
- Differences
  - Mean time to pick up was about one day greater at Kiosk
  - Percentage consultations with *no more questions* greater at Kiosk (81% vs 66%)

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Time Verify to Pick Up: Regular Counter vs Kiosk

	Days (Mean* ± SD)	Hours (Mean* ± SD)	Range
Regular Counter	1.8 ± 0.2	42.2 ± 3.9	15 sec to 28.9 days
Kiosk	3.0 ± 0.6	71.5 ± 14.5	7 min to 17.6 days

Mean time to pick up was greater at Kiosk vs. Regular Counter

($p < 0.001$)

Regular Counter = Employees and Dependents only to “match” group using Kiosk

* Monthly mean over 10 month study period

Did patients have questions at end of consultation?

	Counter	Kiosk
No	100 (66.2%)	137 (81.1%)
Yes	51 (33.8%)	32 (18.9%)
Total	151	169

Fewer patients had additional questions at kiosk vs. Counter (p =0.002)

A sampling of counseling sessions at the Regular Counter was conducted.
Counseling logs completed during 3 one week periods (May, June, December 2016)

Number and Types of Patient Questions

Pharmacist wrote in number of questions and specified question asked.

	Regular counter	Kiosk
Average number of questions if patient had more questions	1.1 (56 questions from 51 patients)	1.1 (35 questions from 32 patients)
Question Type*		
Kiosk Operations	0 (0%)	5 (15%)
General Pharmacy	0 (0%)	4 (12%)
Drug Related	44 (100%)	24 (73%)

*Type based on examination of “Types of Questions” appendix slides. Number of questions lower than above since appendices did not report duplicates and pharmacist did not always specify type of question.

A sampling of counseling sessions at the Regular Counter was conducted.
Counseling logs completed during 3 one week periods (May, June, December 2016)

Conclusions

- The kiosk was a convenient, safe extension of the SRS pharmacy with similar pick up and consultation patterns as the regular counter.
  - *Clinical significance of differences in time to pick up and patients with no remaining questions after consultations cannot be determined from this study.*

- Patients were satisfied with pharmacist access and kiosk operations. There were no complaints.

- Pharmacists agreed their ability to counsel kiosk patients was similar to regular counter patients.

- The fact that kiosk usage continues to increase even after study enrollment has closed is another indication that the kiosk offers an additional option for patients to receive their prescription medications in a secure and timely manner.

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Next Steps

- Continue Kiosk operation at Sharp Memorial Hospital
- Continue to study the Kiosk & update BOP
  - RTS rate, Time to pick-up from load, Patient satisfaction
- Amend 1713 to include all prescriptions & allow placement away from pharmacy
  - Work with the BOP over next 3 months for Board to consider (see next slide)
- Pursue publication of results

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Recommendations for Board to consider based on Sharp's implementation

1. Location in licensed facility
2. Must be licensed and serviced by a pharmacy and/or pharmacist in charge within 50 miles
3. Must have security-video surveillance and security guard on site
4. Secure log-in, username, password & biometrics for each pharmacy employee and patient
5. Allow new and previously dispensed prescriptions: controlled and non-controlled medications
6. Mandatory consultation on every new prescription and any previously dispensed prescription if the pharmacist deems necessary
7. 24/7 trained pharmacist on call with access to patient records and pharmacy system
8. Kiosk must collect, control and maintain all transaction information to track movement of drugs in and out of kiosk
9. Pharmacist has ultimate control of pharmacy staff privileges and access to kiosk, releasing prescription from hold and reconciliation of items loaded and unloaded into the kiosk
10. Pharmacy responsible and in control for loading and unloading the kiosk and all aspects of security of medication and policies and procedures related to kiosk.
11. The PIC shall develop, adopt, and maintain policies and procedures detailing the provisions under which the kiosk will operate. At a minimum, the policies and procedures shall address (i) inventory controls, (ii) training, (iii) storage and security of the dangerous drugs and dangerous devices, and (iv) safeguards to limit access to the kiosk to only authorized pharmacy staff.
12. Pharmacy employee shall stock & inventory the dangerous drugs & devices in kiosk.
13. The PIC (or designated pharmacist) shall review, on a monthly basis, the operation of the kiosk for compliance with inventory controls specified in the policies and procedures.

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Questions?

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Attachment 4

ScriptCenter®

CA Board of Pharmacy

Enforcement Committee Meeting

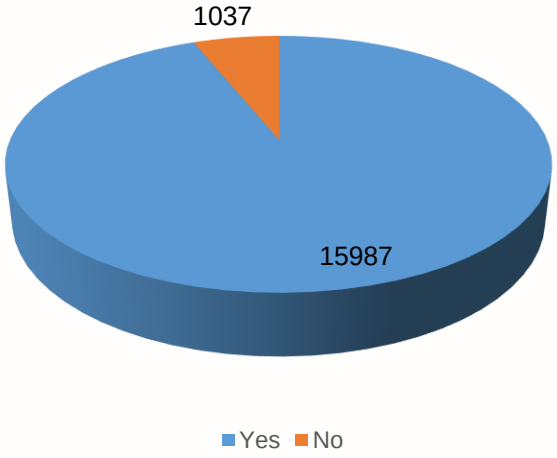
September 15, 2017

ScriptCenter Patient Survey Data

23,000 surveys offered* – 76% answer rate

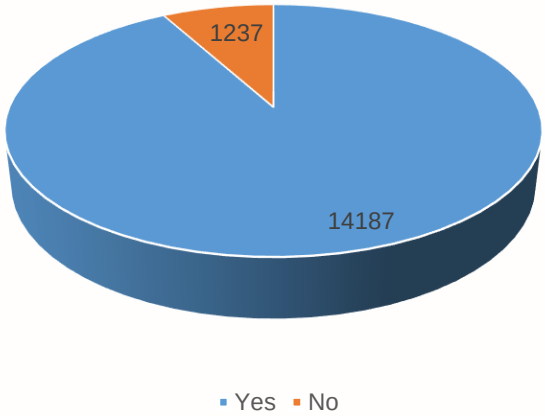
** Survey offered one time at second pickup with offer to skip.*

Would you recommend ScriptCenter to a friend or colleague?



94% Said Yes

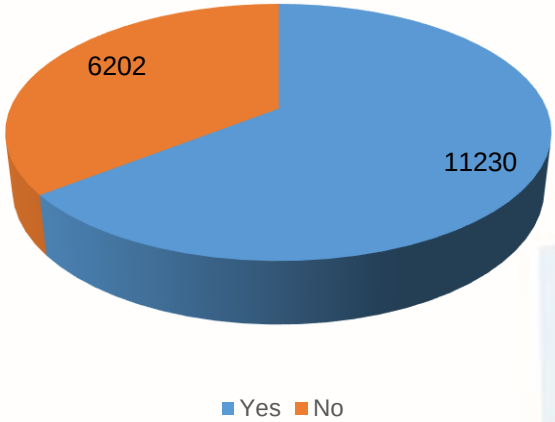
Is the convenience of after hours prescription pick-up an important reason to use this pharmacy?



92% Said Yes

97% Said Yes at Sharp

Is ScriptCenter a **key** reason to use this pharmacy?



64% Said Yes

73% Said Yes at Sharp

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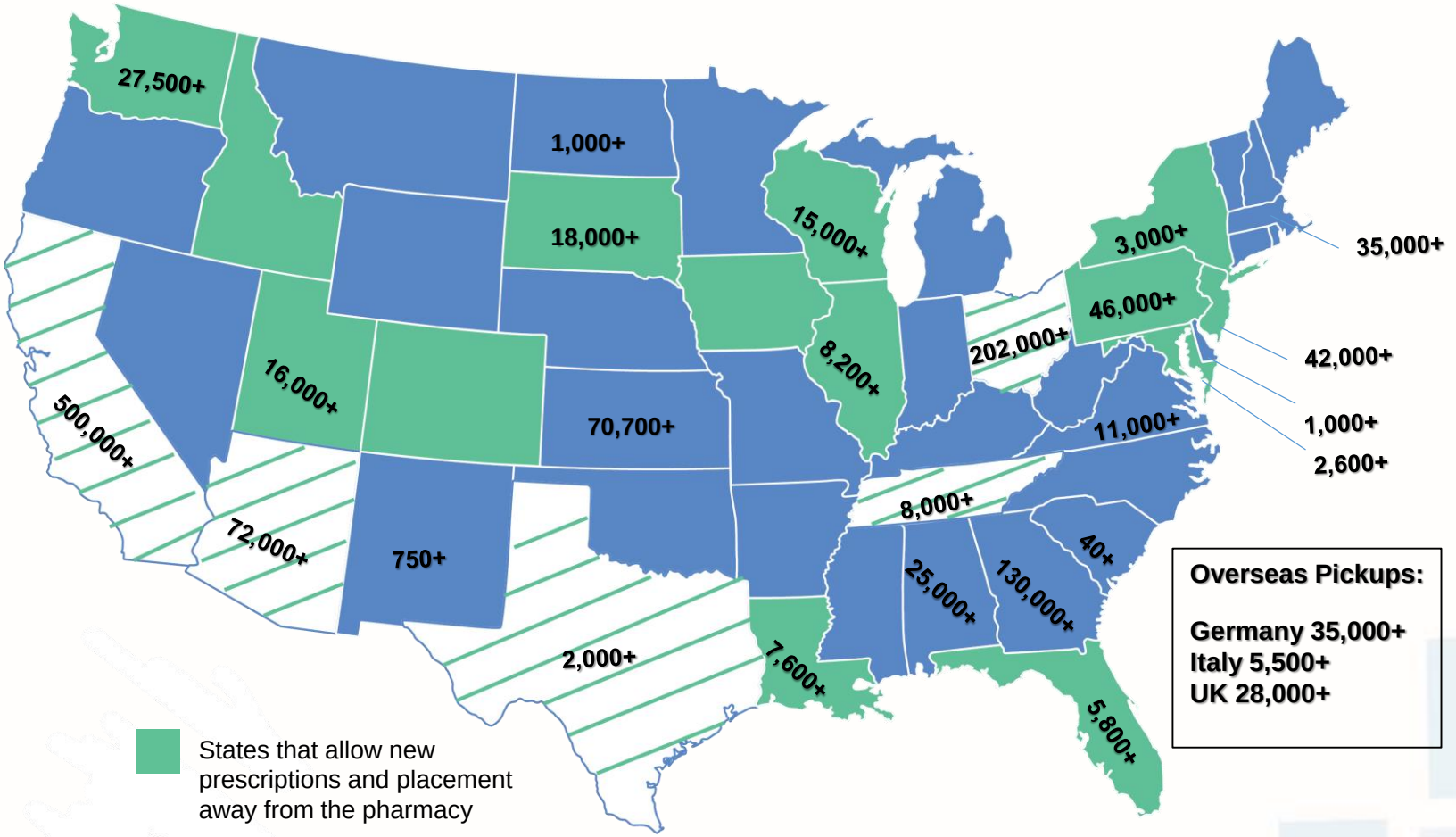
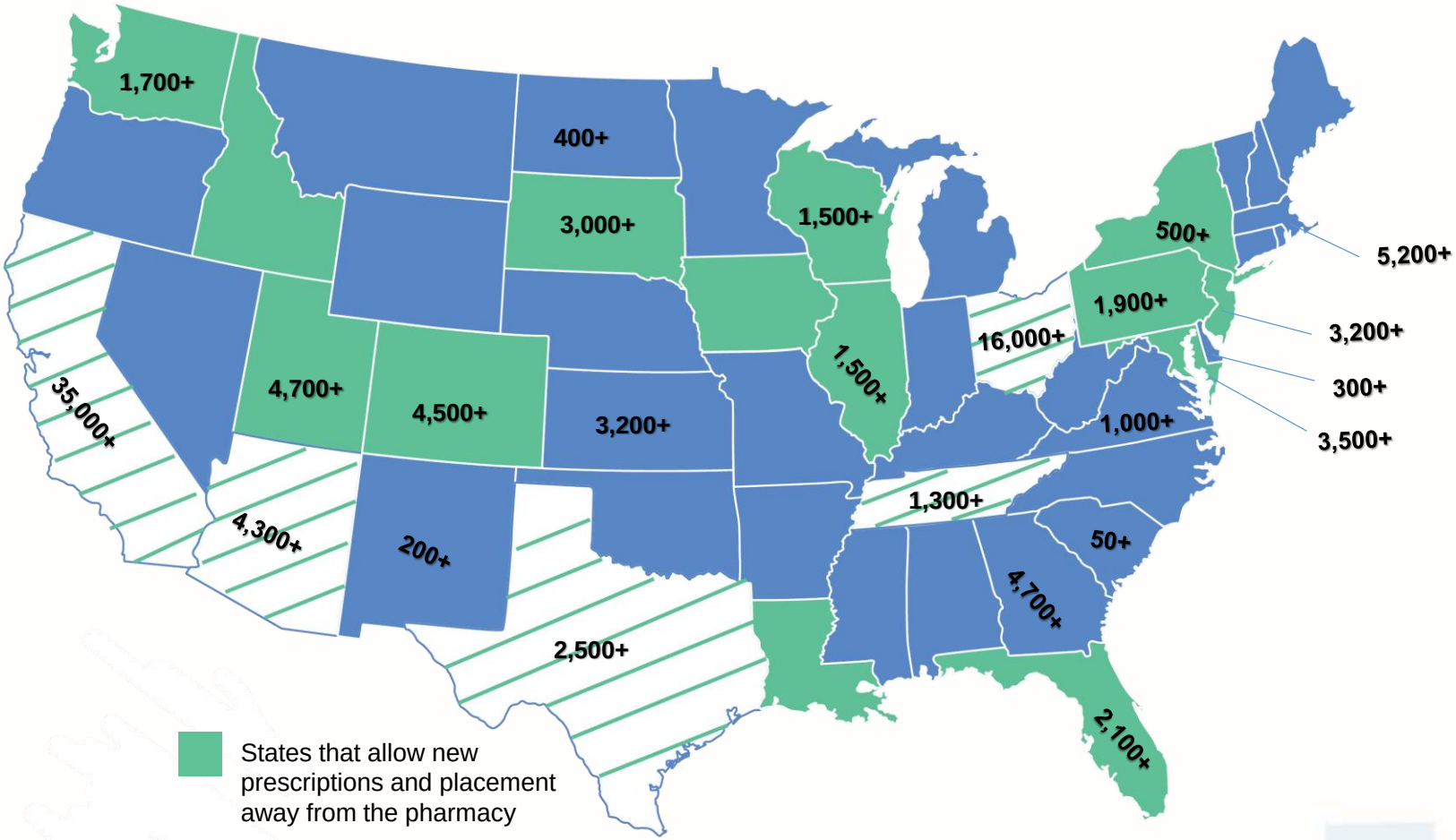
1.5 Million Prescription Pickups



DELIVERED BY ASTERES®

Thousands of Users



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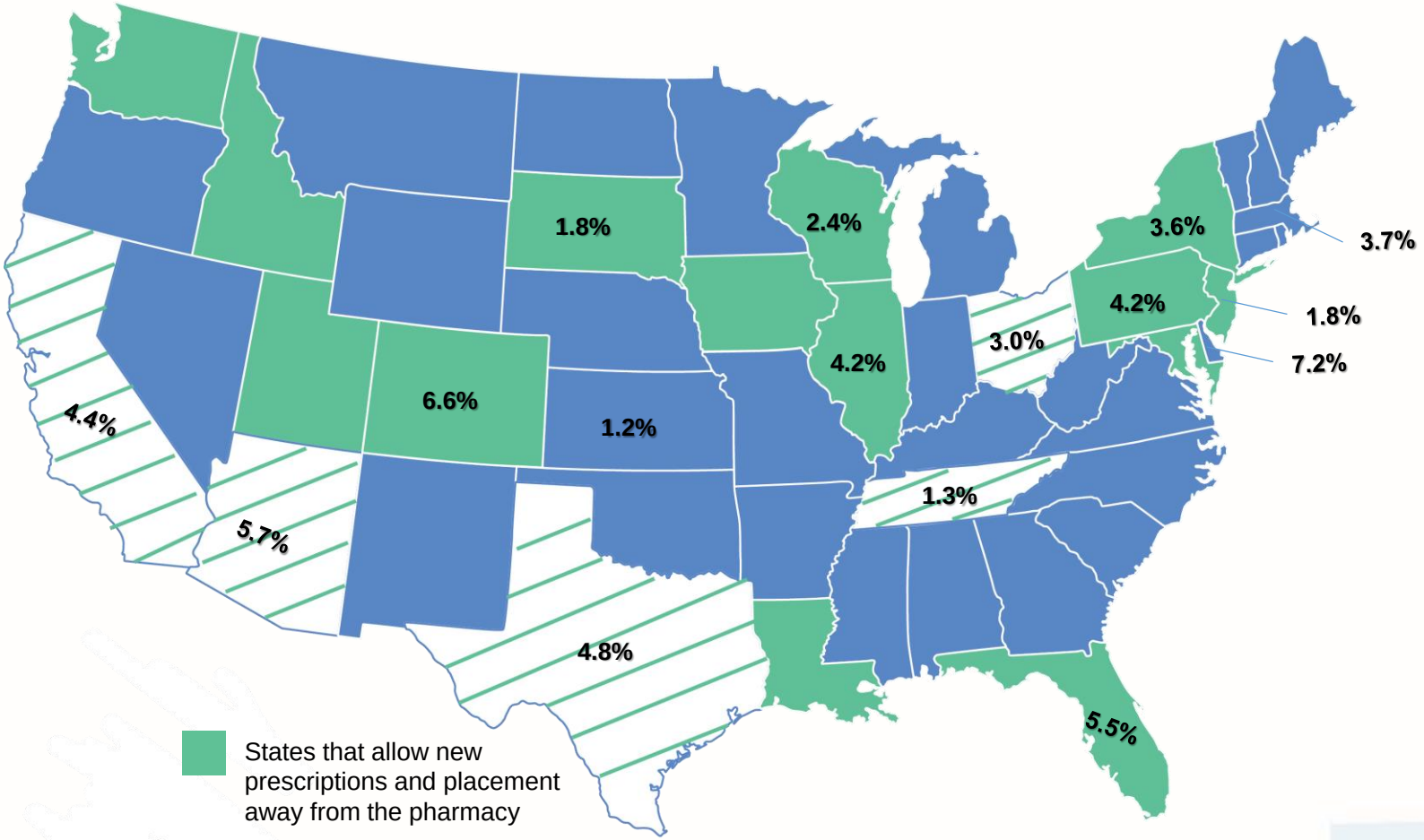
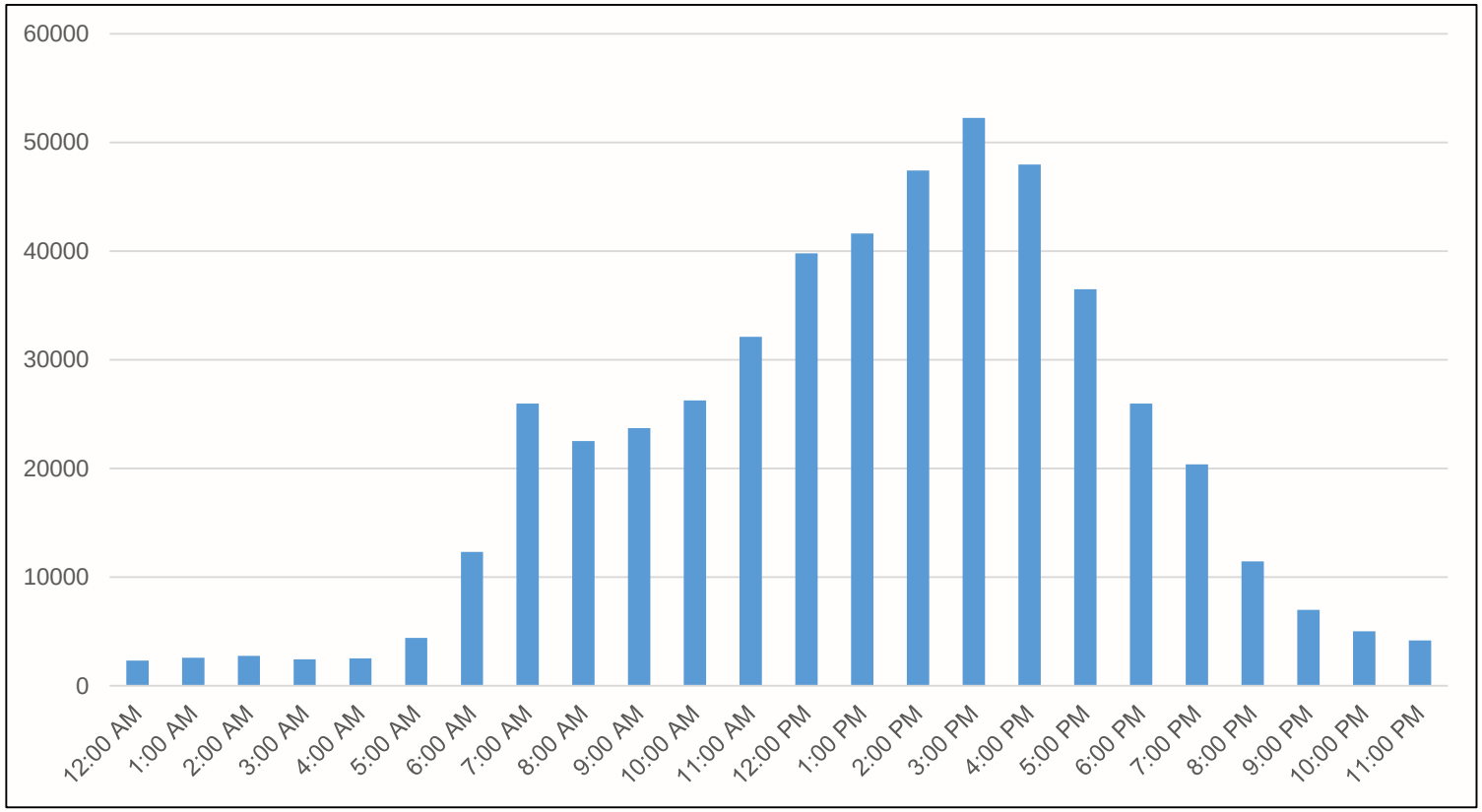
RTS Percentages

Sharp RTS Rate 5.0%



DELIVERED BY ASTERES®

Pickups by Time of Day



30% of ScriptCenter pickups after pharmacy has closed (28% at Sharp)

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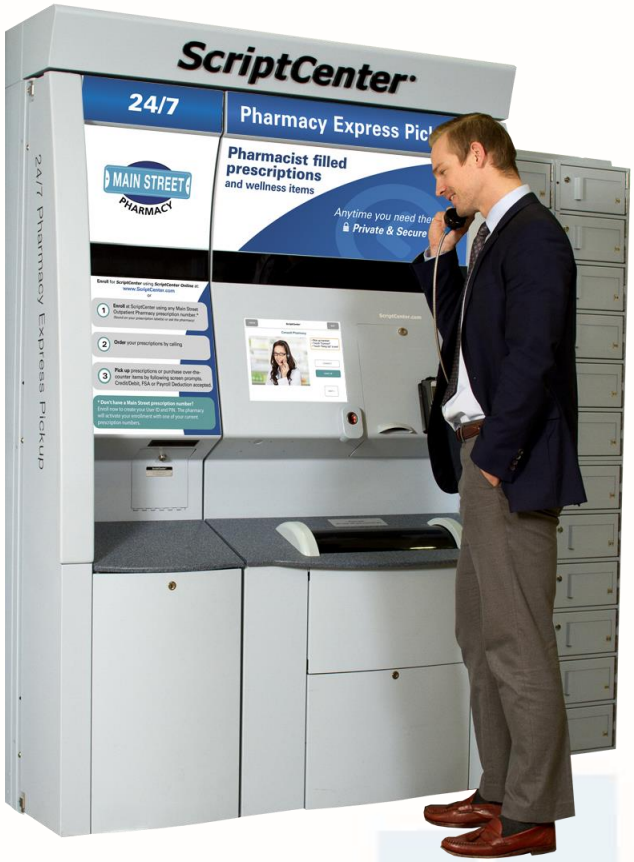
ScriptCenter Supports Counseling

- All required counseling* takes place prior to prescription pickup.
- Some states require an audio AND video connection be available to the patient (IL, TN, TX)
- 1,358 total ScriptCenter Video Consults conducted
- Average duration of a Video Consult is 1.0 minute (Sharp data – 3.5 min at counter and 2.6 min over the phone).



* Counseling requirements vary by state

Pharmacist and Patient Video

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Sample of states allowing remote use & delivery of new Rx's from ScriptCenter

State	Notes
Arizona	For ScriptCenter locations further than 20' from the filling pharmacy, requires notification letter to Board and sometimes presentation.
Colorado	ScriptCenter falls under existing ADS regulations.
Idaho	ScriptCenter falls under existing ADS regulations. Requires installation notification within 30 days post go-live.
Florida	Specific kiosk regulation. Current draft regulations under review by legal to allow for remote placement of ScriptCenter. Expected to be enacted November, 2017.
Illinois	Audio/visual link required on ScriptCenter to be available to patient for counseling.
Louisiana	ScriptCenter falls under existing ADS regulations.
New York	Existing Automated Pharmacy System regulations. Only licensed healthcare facilities. Apply for Satellite Pharmacy Location.
Texas	Separate kiosk regulations – current pilot with Baylor to expand regulation.
Washington	Must notify the Board of any automation installation within 30 days post go-live.
Washington DC	Location must send in notification letter prior to installation.

California

South Dakota

Arizona

Massachusetts

Tennessee

Ohio

Florida

Wisconsin

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Texas

Pennsylvania

Illinois

Arizona

New Jersey

Colorado

New York

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Study of Expanded Use of an Automated Delivery Device

STUDY *EXTENSION AMENDMENT*
September 15th, 2017

Jan D. Hirsch, BPharm, PhD

UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

UC San Diego
HEALTH SCIENCES

Outline

- Reminder of Kiosk vs. Regular Counter Study Results
- IRB Amendment to Extend Waiver Study
  - Based on results of 7/26/17 Board of Pharmacy meeting
    - Continue study
    - Collect data on “truly new” Rxs
- Length of study

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Kiosk vs. Regular Counter Results

Per Study Report 7/17/17

- No Differences
  - Return to Stock (RTS) rate
  - Pharmacists' assessment of their ability to counsel
- Differences
  - Mean time to pick up was about one day greater at Kiosk
  - Percentage consultations with *no more questions* greater at Kiosk (81% vs 66%)

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Add: Kiosk “Truly New” Prescriptions

- Prescriptions new to the patient or new to pharmacy
  - That is, not re-writes
- Not able to determine via an automated process
- Did conduct a manual analysis for the 10 month study period (March – December 2016)
  - Average percentage of “truly new” prescriptions per month was about 55% of the new prescriptions (range 33% to 71%)
- Adding: Collection via a prospective log at pharmacy when kiosk prescription verified
  - Categorize new prescriptions as
    - New to patient
    - New to pharmacy (but not to patient)
    - Re-write

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Delete: Therapeutic Categories

- Was an amendment to original protocol
- Unable to draw conclusions due to:
  - Small number of prescriptions per category at kiosk volume
  - Available software categorized 41% of prescriptions as “Other”
    - Labor intensive process to further delineate
    - Interpretation is limited and may be misleading without other information
- Will not include moving forward

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IRB Amendment to Extend Study

- RTS rate: Continue
- Time from verify to pickup: Continue
- Kiosk patient survey data: Continue
- Counseling logs: Continue through end of 2017
  - Note: All required counseling occurs, log is only for study data collection
- Truly new kiosk prescription identification: Add
- Therapeutic class: Delete

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Length of Study

- Need to include realistic study duration in IRB amendment
  - 18 months would end about May 2019
- Will a waiver, and accompanying study, likely still be required then?
  - Does waiver expire 07/2018?

Questions?

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Attachment 5

Board of Pharmacy Enforcement Statistics
Fiscal Year 2017/2018

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 17/18
Complaints/Investigations					
Received	460				460
Closed	444				444
4301 letters	5				5
Pending (at the end of quarter)	2258				2258
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	989				989
Drug Diversion/Fraud	391				391
RX Abuse	164				164
Compounding	117				117
Outsourcing	55				55
Probation/PRP	62				62
Mediation/Enforcement **	191				191
Criminal Conviction	289				289
Application Investigations					
Received	128				128
Closed					
Approved	64				64
Denied	12				12
Total ***	88				88
Pending (at the end of quarter)	131				131
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	14				14
Citations Issued	269				269
Total Fines Collected ****	$349,975.00				$349,975.00

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 8/31/2017 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2017/2018

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 17/18
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	54				54
Accusations Filed	53				53
Statement of Issues Filed	7				7
Petitions to Revoke Filed	2				2
Pending					
Pre-accusation	215				215
Post Accusation	240				240
Total*	486				486
Closed					
Revocation					
Pharmacist	5				5
Intern Pharmacist	1				1
Pharmacy Technician	14				14
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	1				1
Pharmacy	2				2
Revocation,stayed; suspension/probation					
Pharmacist	1				1
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	1				1
Revocation,stayed; probation					
Pharmacist	7				7
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	1				1
Wholesaler	0				0
Sterile Compounding	2				2
Pharmacy	8				8
Surrender/Voluntary Surrender					
Pharmacist	2				18
Intern Pharmacist	0				0
Pharmacy Technician	4				4
Designated Representative	0				0
Wholesaler	1				1
Sterile Compounding	1				1
Pharmacy	5				5

Board of Pharmacy Enforcement Statistics
Fiscal Year 2017/2018

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 17/18
Public Reproval/Reprimand					
Pharmacist	2				2
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	1				1
Pharmacy	3				3
Licenses Granted					
Pharmacist	1				1
Intern Pharmacist	0				0
Pharmacy Technician	1				1
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0
Licenses Denied					
Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Wholesaler	0				0
Sterile Compounding	0				0
Pharmacy	0				0
Cost Recovery Requested**	$391,752				$391,752.00
Cost Recovery Collected**	$177,199				$177,199.00

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	0				0
Automatic Suspension / Based on Conviction	2				2
Penal Code 23 Restriction	3				3
Cease & Desist - Sterile Compounding	0				0

Board of Pharmacy Enforcement Statistics
Fiscal Year 2017/2018

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 17/18
Probation Statistics					
Licenses on Probation					
Pharmacist	193				193
Intern Pharmacist	4				4
Pharmacy Technician	31				31
Designated Representative	1				1
Pharmacy	69				69
Sterile Compounding	15				15
Wholesaler	3				3
Probation Office Conferences	16				16
Probation Site Inspections	91				91
Successful Completion	6				6
Probationers Referred to AG for non-compliance	0				0

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of August 31, 2017.