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

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

DATE:	September 15, 2017
LOCATION:	Northstate Univeristy, School of Pharmacy 9700 West Taron Drive – P3 Classroom Elk Grove, CA 95757
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Amy Gutierrez, PharmD, Licensee Member, Vice Chair Valerie Muñoz, Public Member Gregory Lippe, Public Member
COMMITTEE MEMBERS NOT PRESENT:	Stan Weisser, Licensee Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Laura Hendricks, Staff Analyst

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

President Gutierrez called the meeting to order at 9:30 a.m. Board members present: Amy Gutierrez, Valerie Munoz, Gregory Lippe, and Allen Schaad.

President Gutierrez noted that she would be chairing the meeting for Allen Schaad because he had lost his voice.

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

Note: The committee 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)]

Ms. Herold explained that another Enforcement Committee meeting would be scheduled prior to the February Board Meeting that would focus on sterile compounding issues.

Angie Manetti representing the California Retailers Association and Daniel Rodriguez representing the California Pharmacist Association thanked the board for scheduling another committee meeting to handle sterile compounding. Mr. Rodriguez stated that CPhA would be submitting comments for the sterile compounding committee meeting.

Michael Blair, veterinary compounding pharmacist, stated that in 2010 there was a shortage of diazepam. He explained that compounding pharmacies were able to alleviate the shortage by compounding injectable diazepam. He expressed concern that the board's current requirements for beyond use dating is preventing compounding pharmacies from helping alleviate shortages and is resulting in patient harm.

Corey Meto representing Diamond Back Drugs asked the committee to consider if the same compounding requirements should be applied to research studies. He stated that adding such requirements could slow down important studies that are already underway.

3. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substance Schedules and its Impact on Healthcare Services and Potential Changes to Impact Laws and Regulations

President Gutierrez stated that 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. She added that the federal controlled substances schedules are promulgated federally principally by the DEA and are found the in Code of Federal Regulations.

President Gutierrez explained that Schedule I drugs are generally not intended for medicinal use, except under tightly controlled research studies and are considered "illegal" or "street" drugs. She noted that marijuana is a Schedule I drug federally, and LSD is a Schedule I drug in both federal and state schedules.

President Gutierrez reported that 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. President Gutierrez explained that 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.

President Gutierrez explained that 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). She noted that unlike Schedule II drugs, these medications can be orally ordered for a patient by a prescriber.

President Gutierrez stated that 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.

President Gutierrez explained that 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). President Gutierrez also explained that 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. She noted that Schedule III-V medications can be orally ordered in CA.

President Gutierrez explained that 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. She added that federal law today classifies tramadol as a Schedule IV drug; it is not a scheduled drug under California law.

President Gutierrez stated that 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.

President Gutierrez explained that 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).

President Gutierrez stated that 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.

President Gutierrez stated that 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.

Ms. Herold stated that 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.

Ms. Herold stated that staff is recommending that the schedules be evaluated to determine a way to 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.

Mr. Lippe asked how marijuana would be handled as it is legal in California but is a Schedule I drug federally. He added that this is inconsistent, especially in light of the fact that DCA just created the Bureau of Cannabis Control to regulate its use in California.

President Gutierrez asked Ms. Freedman if California can simply defer to the federal schedule. Ms. Freedman stated that the California schedule is in statute so a statutory change would be required. President Gutierrez asked if the statutory change could be simply stating the California follows the federal schedule so that our statute does not have to be changed each time the federal schedule changes. Ms. Freedman responded that because the California schedule in in the Health and Safety Code, discrepancies such as the scheduling of marijuana must be addressed.

Robert Stein, representing KGI School of Pharmacy, stated that the statutory change would need to be in Health and Safety Code 11056. He recommended against simply following the federal schedule.

President Gutierrez asked how the board would "mesh" the two schedules. Ms. Herold responded that the more stringent of the two schedules would apply with specific exceptions.

Committee Recommendation (Motion): Direct staff to evaluate two schedules and determine a way to 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.

M/S: Munoz/Lippe

Support: 4 Oppose: 0 Abstain: 0

President Gutierrez stated that the proposal will be brought to the full board at its next meeting.

4. <u>Discussion and Consideration of Proposed 2018 Board Sponsored Legislation Regarding CURES</u>

President Gutierrez reported that 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.)

President Gutierrez stated that 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.

President Gutierrez explained that 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.

President Gutierrez stated that 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.

Ms. Herold noted that inspectors are finding that people are purchasing prescription forms online and the doctor has no idea that their name and license information is being used fraudulently.

President Gutierrez added that California is one of seven states that is not sharing prescription drug monitoring program (PDMP) data across state lines (CURES is California's PDMP). She stated that staff is recommending that the committee also address working with the Department of Justice to secure interstate data exchange of PDMP information. Ms. Herold added that this would require a statutory change.

Robert Stein, representing KGI spoke in support of prescribers being able to see reports on their own patients. He added that the legislation should also address the difference in the federal and state schedules.

Committee Recommendation (Motion): Direct staff to pursue the necessary legislation to address the items below.

a. Make modifications to permit prescribers to view the patients and prescriptions in CURES where they are identified as the prescriber.
b. Require dispensers to report data into CURES within 48 hours of dispensing. (Currently this time frame is no longer than 7 days.)
c. Add the reporting of Schedule V medications dispensed to the CURES system. (Currently federal Schedule II – IV medications are required to be entered.)
d. Secure interstate data exchange of PDMP information. Ms. Herold added that this would require a statutory change.

M/S: Lippe/Schaad

Support: 4 Oppose: 0 Abstain: 0

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

President Gutierrez reported that 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. She added that 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.

President Gutierrez stated that 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**

President Gutierrez noted that while the number of inspectors have increased the number of inspections completed has not increased. Ms. Herold responded that part of that is due to positions being vacant and then needing to train the inspectors once they were hired.

Ms. Herold briefly described the current inspection schedules.

Mr. Schaad requested more information on the duties and productivity of inspectors. President Gutierrez requested that staff graph the number of inspectors versus cases and inspections. She also noted that previously it had been decided by the board that these inspections needed to be done with existing resources.

Ms. Munoz recommended looking at inspection data from other states. She also noted that once the inspections are implemented, staff should look at how it impacts other workload, e.g., a decrease in enforcement action.
President Gutierrez asked staff to research if any other states have regulations requiring a certain number of inspections to be completed in a specific time period.

Ms. Herold stated that these inspections are going to be focused on educating pharmacies and making sure that they are in compliance with pharmacy law. Mr. Schaad recommended that the Communication and Public Education Committee look at ways to more effectively communicate with licensees. A member of the public noted that the board could highlight the information that is available on the board's website in each issue of *The Script*.

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

President Gutierrez stated that 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).

President Gutierrez reported that at a technology summit held by the board earlier this year, various forms of technology were demonstrated.

Note: A summary of the technology was categorized and organized into a table, which was provided in the meeting materials.

President Gutierrez explained that 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.

President Gutierrez stated that these machines benefit patients by increasing their access to pharmaceutical care. She noted that there needs to be appropriate security measures in place, and she directed staff to look at ATM security features (e.g. video cameras). The committee agreed with this recommendation.

Mr. Schaad noted that the board must be notified if any theft or diversion occurs in these machines.

The committee also expressed their desire to ensure that appropriate patient consultation occurs when these machines are used by patients.

Ms. Herold stated that these machines are going to increase in use and the board needs to create requirements now rather than after problems occur.

Ms. Herold noted that the board's requirements also need to address how and where the drugs are being stored before they are put into the machine.

Ms. Herold discussed the need to regulate who can owns the machines. The committee stated that it may be more important to regulate who actually operates the machines.

Ms. Munoz stated that these machines should also be inspected by the board. The committee agreed. President Gutierrez recommended creating a self-assessment form specific to these machines.

Art Whitney cautioned the board against over-regulate these machines. President Gutierrez responded that most of the security features would apply to machines where patients are directly accessing the medications at a location away from a pharmacy. Ms. Herold stated that healthcare professionals divert from the machines being used in healthcare facilities.

The committee recommended creating separate requirements based on who is accessing the medication from the machines (patients vs. healthcare professionals).

Robert Stein, recommended not allowing a machine to be used in a telepharmacy setting.

A member of the public stated that these machines are used extensively in Canada, she recommended that the board look at their requirements and the research they conducted on their use.

President Gutierrez asked Ms. Sodergren if there are any other issues that she feels the committee should address so that staff can draft language. Ms. Sodergren recommended the committee delegate authority to the chair of the committee to work with staff on drafting the language based on the board's discussion and bringing it back to the committee for review. The committee agreed with the is recommendation and Ms. Schaad agreed to work with staff on the language.

Daniel Rodriguez stated that there needs to be a requirement for the machine to verify that the person picking up the medication is actually the patient or their agent. The committee agreed with this recommendation.

7. Discussion and Consideration of the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

President Gutierrez reported that 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.

President Gutierrez stated that 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.

President Gutierrez explained that after 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.

President Gutierrez stated that at this meeting two presentations would be provided to update the committee on the extended study.

Sara Lake and Dr. Allen provided a presentation on the use of the ScriptsCenter machines in the United States. The presentation provided statistics on the number of prescriptions dispensed by the machines in each state, the number of patients using the machines in each state, and the return to stock percentages in each state. The presentation also highlighted how consultations are provided at the machines and how a patient's identity is verified by the machine.

Note: a copy of the entire presentation is provided following these minutes.

President Gutierrez asked if the Department of Veterans Affairs use the ScriptCenter machines. Ms. Lake confirmed that the V.A. does use the machines.

Dr. Jan Hirsch, from the UCSD Skaggs School of Pharmacy provided a presentation on the proposal to modify the study.

Note: the entire presentation is provided following these minutes.

Dr. Hirsch reviewed the results of the initial study which included the fact that there was no difference in the return to stock rate between the machine and the traditional pharmacy and that it took patients an average of one day longer to pick their prescriptions up from the machine.

Dr. Hirsch noted that at the last meeting the board had requested that they collect data on "truly new" prescriptions. She explained that that UCSD did an analysis for a 10-month period (March – December 2016) and the average percentage of "truly new" prescriptions per month was about 55%. Dr. Hirsch explained that the automated system would not allow them to collect data on the truly new prescriptions, however, the pharmacists will manually collect the data. All prescriptions will be categorized as either: new to patient, new to pharmacy, or re-write.

Dr. Hirsch stated that they would like the committee to approve the removal of "therapeutic categories" from the data collection.

Dr. Hirsch provided an overview of the requested data collection parameters for the study moving forward.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Dr. Hirsch asked is it would be appropriate to extend the study from 12 months to 18 months in order to allow for enough time for the board to complete the regulation process allowing the use of the machines in locations outside of pharmacies. The committee agreed that the study timeframe should be extended to allow for time to complete the regulation process and discussed extending it to 24 months.

Ms. Freedman requested that the amended IRB (even if it is just the draft) be provided to the full board before they approve the proposed amendments to the data collection and the extension of the study.

President Gutierrez asked if it would be possible to expand the study to include not only employees, but other patients as well. Dr. Allen explained that they could expand it, but there would be no way to differentiate between employees and regular patients.

Ms. Freedman explained that if the study is extended to 24 months and if it is opened to all patients it would need to be approved by the full board. However, upon further discussion UCSD decided to keep the study time period to 12 months and to not open it to additional patients. Ms. Freedman stated that the full board would still need to approve the removal of the therapeutic class and the additional data collection on truly new prescriptions.

President Gutierrez noted that if the board passes a regulation allowing these machines to be used outside of pharmacies then the study would end at that time. Ms. Freedman stated that it is important to understand that it is not guaranteed that the regulation will go through.

Ms. Freedman stated that if the committee is comfortable with the proposed changes staff can work directly with UCSD to determine the best way accomplish the changes logistically.

The committee asked that they receive reports on the study every six months. Ms. Lake asked if the first report to the committee would occur at its March meeting. Ms. Herold confirmed that the first report to the committee would occur at its March meeting.

Committee Recommendation (Motion): Approve the changes to the study as provided below and direct staff to work with UCSD to ensure that the changes made to the IRB are consistent with the committee's discussion.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data

- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

M/S: Lippe/Schaad

Support: 4 Oppose: 0 Abstain: 0

Committee Recommendation (Motion): Direct UCSD to provide study updates to the Enforcement Committee every six months.

M/S: Lippe/Schaad

Support: 4 Oppose: 0 Abstain: 0

Counsel again advised that the draft of the revised IRB should be provided to the board at its next meeting so that they can review it prior to approving the changes to the study parameters.

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

President Gutierrez explained that 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. She added that there is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

President Gutierrez explained that 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. She noted that the board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver.

President Gutierrez reported that the 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. She explained that 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. Ms. Herold stated that so far there have been no requests for appeals.

Ms. Herold stated that 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.

Ms. Herold noted that most request waiver sections are 1735.6(e) and 1751.4(g) for the external venting requirement.

Ms. Herold reported that in the next few weeks, the board will add to its website the pharmacies which have been given waivers.

President Gutierrez reviewed the waiver request statistics as provided below.

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

Mr. Lippe asked why most of waiver requests were denied. Ms. Herold responded that most of them provided incomplete information or provided a completion date after July 1, 2018. President Gutierrez stated that the board needs to create a plan as to how it will handle hospitals who cannot complete their construction by July 1, 2018. Ms. Herold responded that staff agrees that there is a risk to patients, but the board does not have the authority to waive the federal implementation date of USP <800> on July 1, 2018.

The committee asked staff to work with counsel to consider possible solutions for facilities who cannot complete construction by July 1, 2018. Ms. Herold stated that a lot will depend on if the facility has made any good faith efforts to come into compliance by the deadline.

A member of the public expressed frustration that the board is implementing regulations that are difficult for hospitals to comply with and are expensive to implement, especially for rural hospitals. Ms. Herold responded that Medicare and Medicaid are tying reimbursements to compliance with the federal USP 800 requirements. President Gutierrez added that even if the board repealed its regulations hospitals would still have to make modifications to comply with USP 800.

Daniel Rodriguez asked when the sterile compounding regulations will be discussed. President Gutierrez stated that they would be discussed at the next Enforcement Committee meeting which will be scheduled prior to the February Board Meeting.

9. Enforcement Statistics

President Gutierrez stated that the meeting materials contains the enforcement statistics for the first two-and-a-half months of FY 2017/2018 for anyone who wishes to review them in detail.

Ms. Herold highlighted the drastic increase that the board has seen in controlled substance losses.

10. Future Committee Meeting Dates

President Gutierrez again stated that the committee is in the process of scheduling an additional committee meeting prior to the February 2018 board meeting. She added that when the meeting date is finalized, the board's website will be updated and a subscriber alert will be sent.

President Gutierrez reported that scheduled committee dates for 2018 as provided below:

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

President Gutierrez adjourned the meeting at 12:30 p.m.

ScriptCenter®

CA Board of Pharmacy

Enforcement Committee Meeting

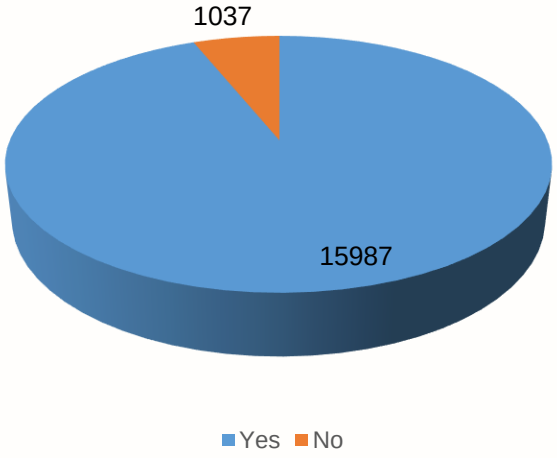
September 15, 2017

ScriptCenter Patient Survey Data

23,000 surveys offered* – 76% answer rate

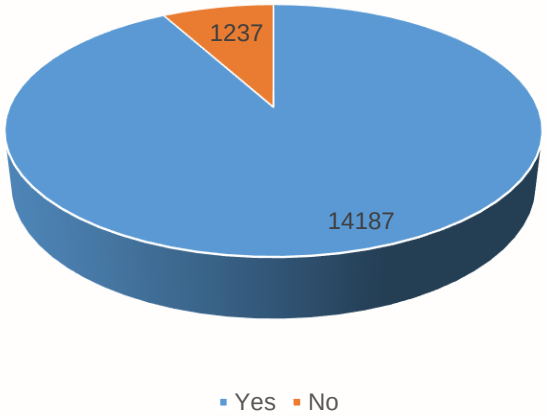
** Survey offered one time at second pickup with offer to skip.*

Would you recommend ScriptCenter to a friend or colleague?



94% Said Yes

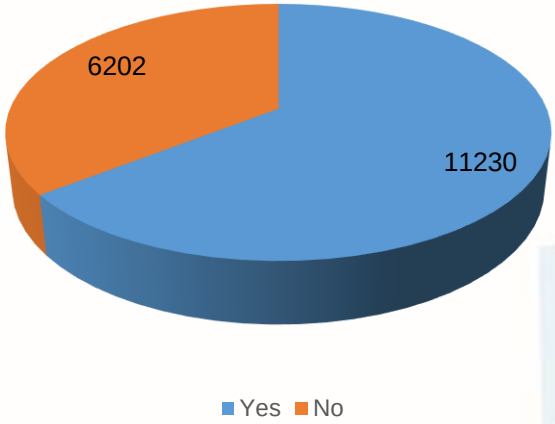
Is the convenience of after hours prescription pick-up an important reason to use this pharmacy?



92% Said Yes

97% Said Yes at Sharp

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

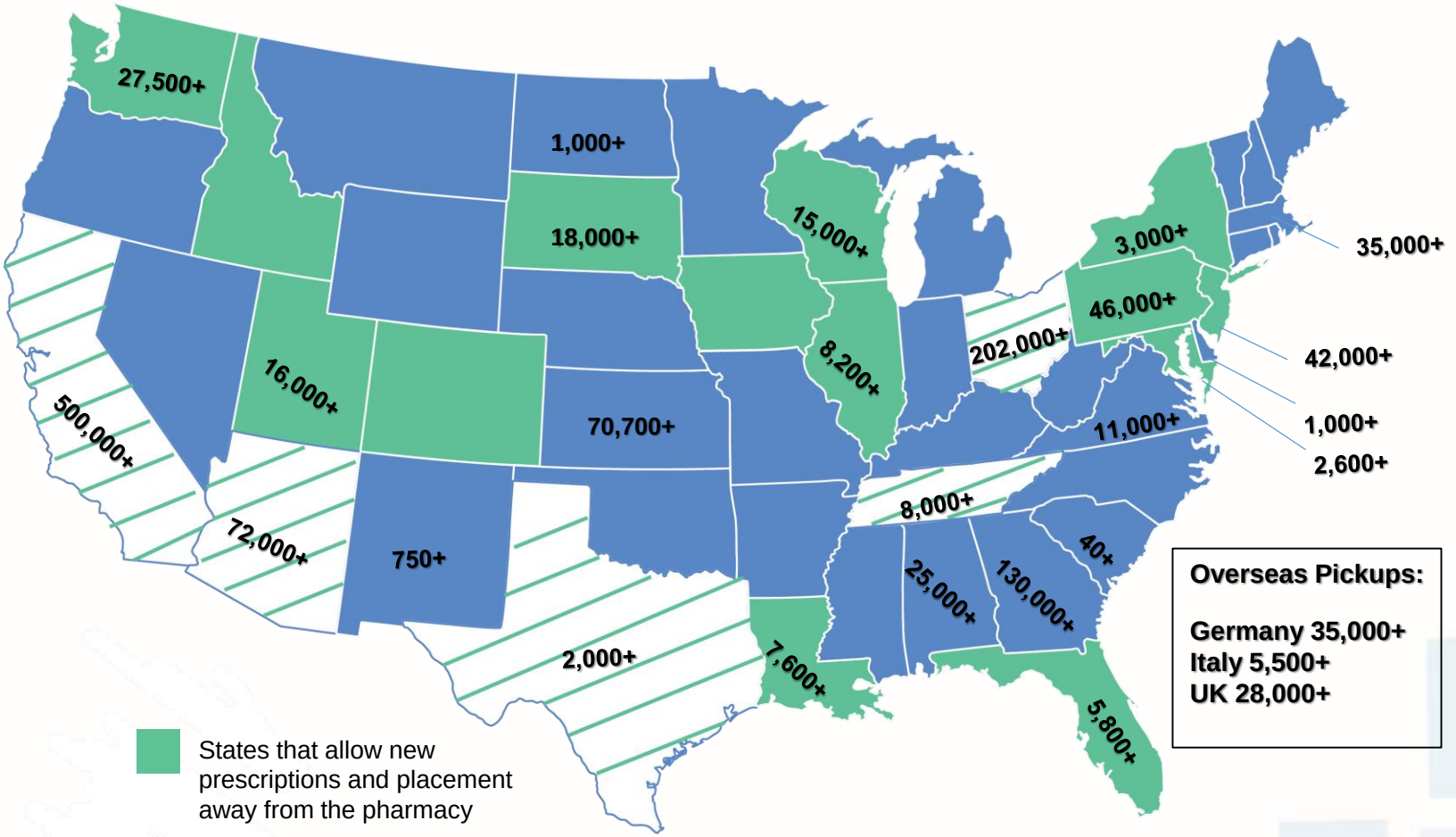


64% Said Yes

73% Said Yes at Sharp

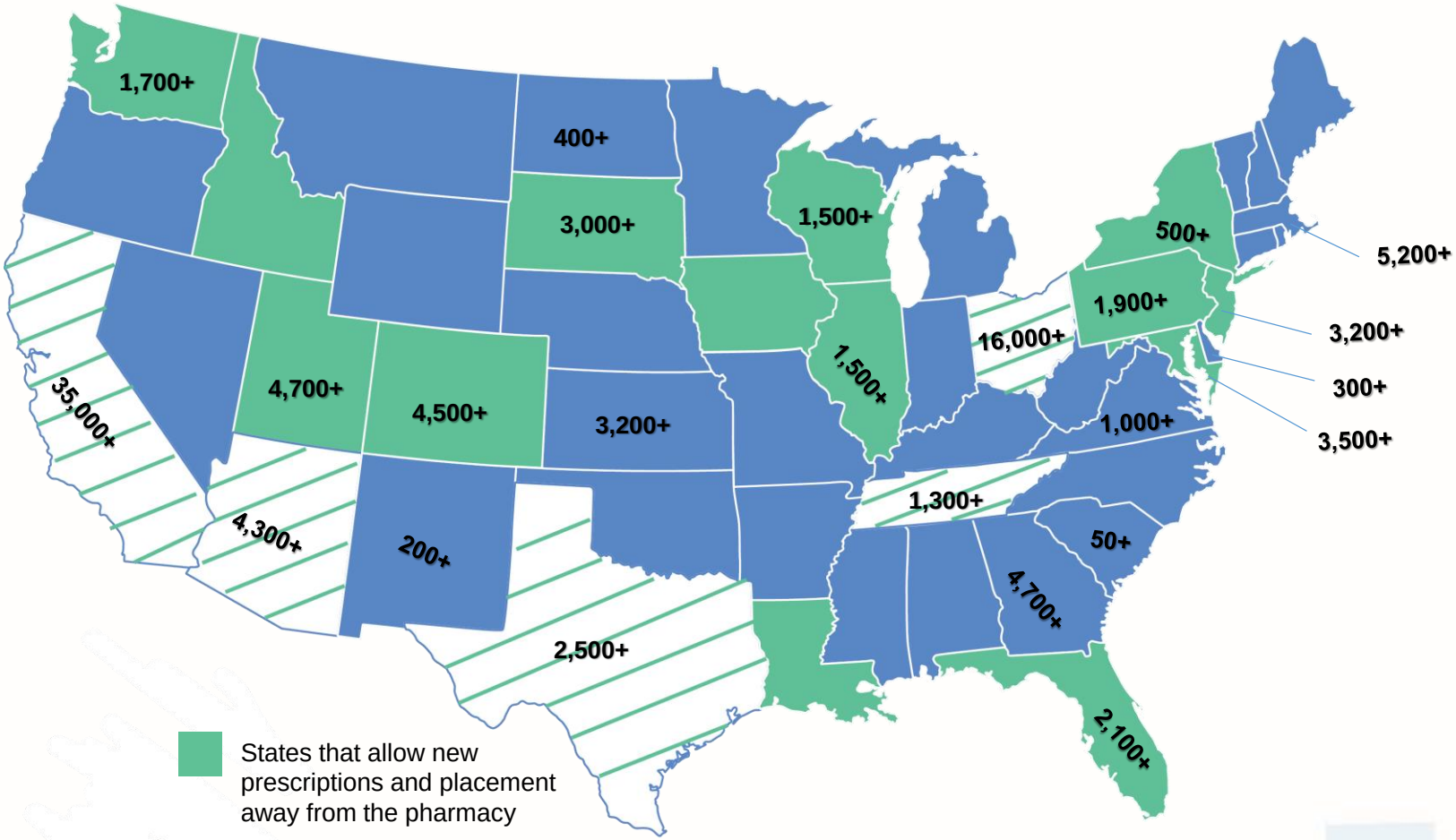
DELIVERED BY ASTERES®

1.5 Million Prescription Pickups



DELIVERED BY ASTERES®

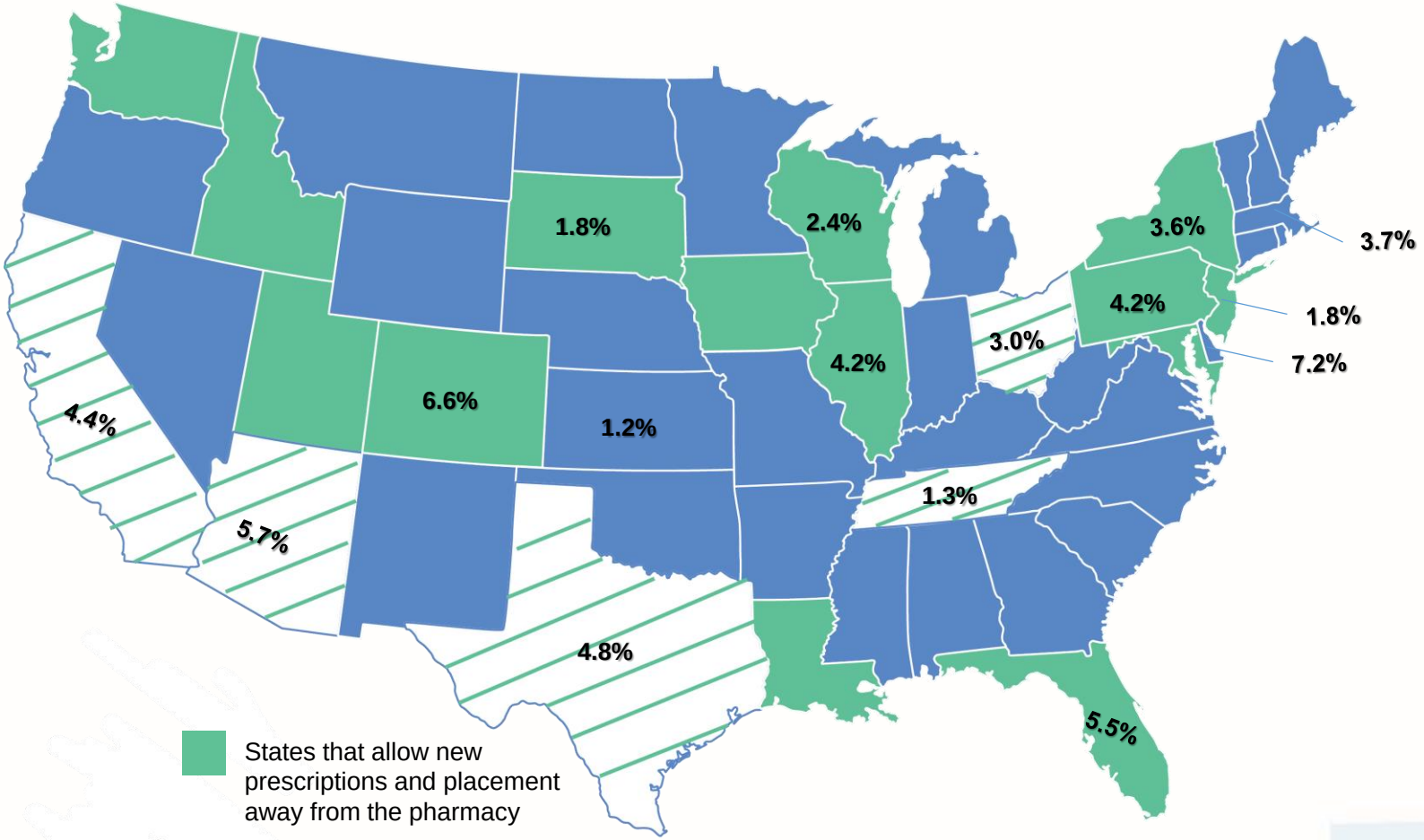
Thousands of Users



DELIVERED BY ASTERES®

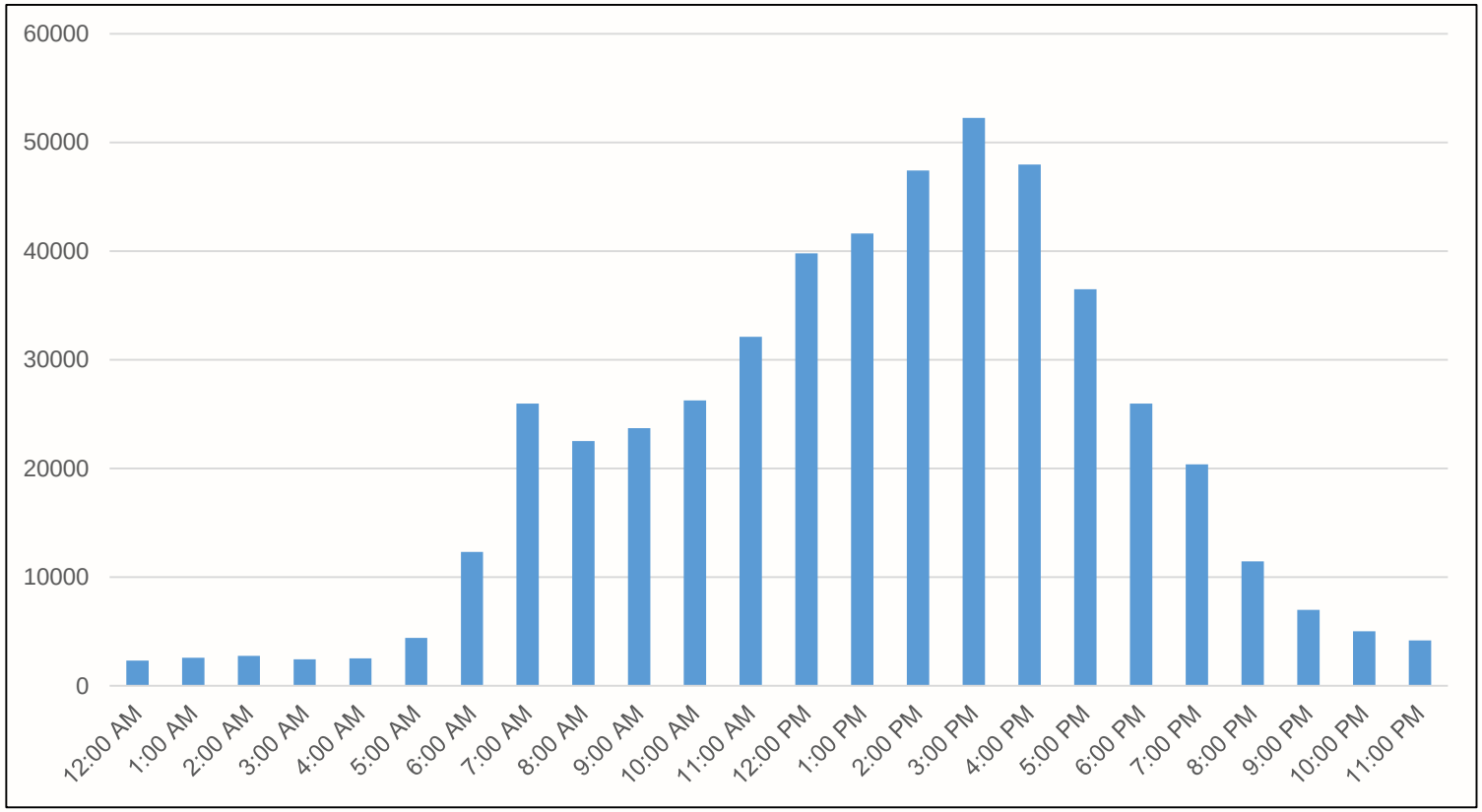
RTS Percentages

Sharp RTS Rate 5.0%



DELIVERED BY ASTERES®

Pickups by Time of Day

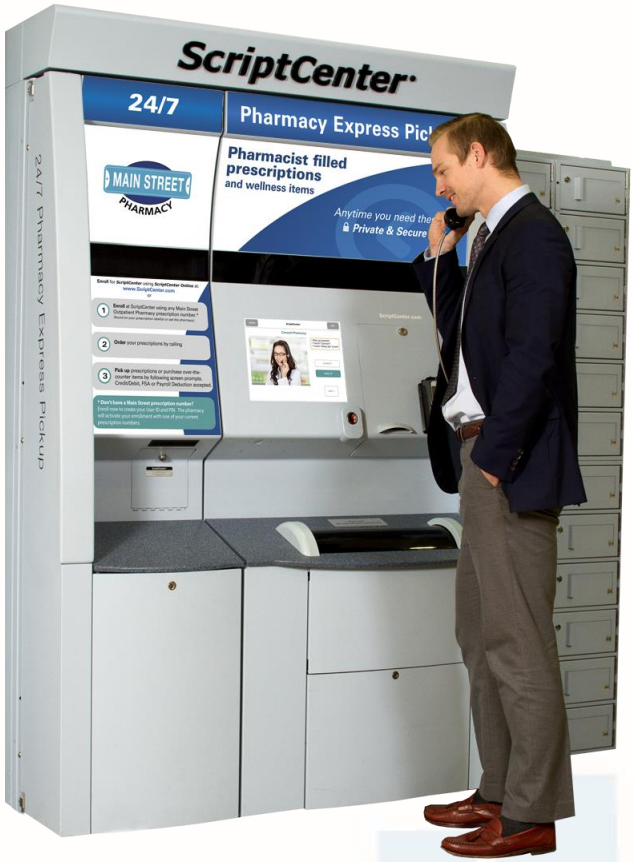


30% of ScriptCenter pickups after pharmacy has closed (28% at Sharp)

DELIVERED BY ASTERES®

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

DELIVERED BY ASTERES®

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

DELIVERED BY ASTERES

Texas

Pennsylvania

Illinois

Arizona

New Jersey

Colorado

New York

DELIVERED BY ASTERES

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

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

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%)

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

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

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

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

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

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

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

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?

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES