California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT
April 3, 2018

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. Update from 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)

Background
In July 2017, the board heard and discussed the results of the University of California San Diego (UCSD) experimental study involving the use of ADDS technology to dispense new and refill medications to employees in an area nonadjacent to a pharmacy counter. This study required a waiver of California Code of Regulations Title 16, section 1713, to allow first-time fills to be dispensed via an ADDS machine, not adjacent to a pharmacy counter.

During the July 2017 board meeting, the board approved an extension of the UCSD study for another 12 months (July 26, 2017 – July 25, 2018); additionally, the board requested that data provided to the board include a distinction between new prescriptions (as defined by law) and previously dispensed prescriptions.

During the September 2017 committee meeting, it was recommended that board staff work with UCSD to ensure that changes made to the Institutional Review Board (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 stops)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study.

A recommendation was approved to direct UCSD to provide study updates to the Enforcement Committee every six months.

For Committee Discussion and Consideration
During this meeting, UCSD researchers will provide a presentation on the status and direction of the study.

A copy of UCSD's planned presentation is provided as **Attachment 1**.

4. Presentation, Discussion and Consideration of the Board's Citation and Fine Program

The board has asked staff to provide information about board-issued citations and fines. During this meeting, Board Chief of Enforcement Julia Ansel, will provide general enforcement information on board investigations as well as specific information to citations and fines issued by the board during 2017.

5. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Members

Background
During Board Member Orientation, members are provided with the Department of Consumer Affairs' list of the "Top 10 Traits of an Effective Board Member." One of the traits on the list is being aware of conflicts of interest, whether conflicts could be real or perceived.

One area where board members should be transparent is in enforcement actions involving themselves (whether they are directly or indirectly involved). Board members should determine whether recusal from a vote or discussion should occur based on the real or possible appearance of self- interest. For example, an enforcement matter involving a board member could influence a member's objectivity in future decision making when the case involves fact patterns similar to their enforcement matter.

Prior Committee Discussion
At the December 2017 committee meeting, a motion was made to recommend to the full board that board member involvement in disciplinary or administrative action would be reported in the Organizational Development Report.

Prior Board Discussion
Most recently, during the January 2018 board meeting, the board voted to send this issue back to the committee for further discussion and reconsideration.

For Committee Discussion and Consideration
Provided below are areas of concern addressed by the board members at the January meeting. The committee was advised to consider the following:

- Determine the types of actions that should be reported for disclosure.
- Determine the purpose of such reporting.
- Determine whether there is currently a problem with the current reporting system.

- Determine reporting parameters.

6. Update on the Substance Abuse Coordinating Committee, and the Department of Consumer Affairs' Reconvening of it Pursuant to Business and Professions Code Section 315.

Background

Senate Bill 1441 (Ridley-Thomas, Chapter 548) established in the Department of Consumer Affairs the Substance Abuse Coordination Committee (SACC). The bill required the SACC to formulate uniform and specific standards in specified areas that each healing arts board would be required to use in dealing with the substance-abusing licensees.

Senate Bill 796 (Hill, 2017, Chapter 600) requires the Department of Consumer Affairs to reconvene the SACC to specifically review the existing substance abuse testing criteria (Uniform Standard 4). The committee must determine whether the existing criteria should be updated, and a report is due to the Legislature by January 1, 2019. The first SACC meeting is scheduled for Monday, April 23, 2018 from 10 a.m. – 3 p.m. in the DCA HQ2 Hearing Room.

Uniform Standard 4 is provided as **Attachment 2**.

7. Update on the Status of the Proposed Regulations Undergoing Pre-Review to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Timeline

- Approved by Board: July 25, 2017
- Submitted to DCA Legal Counsel by Board: November 20, 2017
- Board's DCA Legal Counsel completed pre-review of the rulemaking: February 13, 2018
- Board begins the pre-notice review process by submitting 4 copies of rulemaking to DCA Regulations Coordinator: February 14, 2018
- DCA Regulations Coordinator disseminated copies of the rulemaking to DCA Legal and DCA Budget Office: February 15, 2018
- DCA Legal supervisory review completed: March 7, 2018
- DCA Budget Office currently reviewing rulemaking

Summary of Regulation

This regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system.

The board's emergency regulation expires on June 19, 2018. A re-adoption of the emergency regulation will most like be necessary as the permanent regulation package has not been submitted to OAL to initiate the formal rulemaking process.

8. Discussion and Consideration of the Pew Charitable Trusts "State Oversight of Drug Compounding" Report

Background

More than five years have passed since contaminated injections compounded at a single pharmacy caused 76 deaths and 778 illnesses in a nationwide outbreak of fungal meningitis, a tragedy that made clear that the complex, technical practice of drug compounding was not subject to a level of oversight appropriate to its potential risks to patients. Since then, state and federal officials have been re-examining the laws and regulations governing compounding, and working to strengthen them.

Compounded medications pose a higher level of risk to patients than FDA-approved drugs because they have not been tested for safety and efficacy, have not gone through an approval process, and are typically not made under the same quality standards as approved products. The Pew Charitable Trusts' drug safety project has identified more than 50 reported compounding errors or potential errors from 2001 to 2017 linked to 1,227 adverse events—undesirable experiences associated with the use of a medical product—including 99 deaths. Because many such events may go unreported, this number is likely to be an underestimation.

In November 2013, Congress passed, and President Barack Obama signed into law the bipartisan Drug Quality and Security Act (DQSA), which established clear lines of oversight accountability for two categories of businesses that can compound drugs. While the majority of states have taken action to strengthen sterile compounding oversight policies since the outbreak, it is essential to follow through with strong implementation and enforcement of these laws and rules—including the federal DQSA. This report is intended to highlight the significant progress on public health policy that has occurred and to identify the most fruitful opportunities for action to help ensure a safe supply of compounded drugs. This remains a period of flux for drug compounding oversight: A number of states have pending policy changes, and implementation of the federal DQSA is ongoing. This continuing progress is one key finding of this study.

A copy of the report can be found as **Attachment 3**.

9. Discussion and Consideration of the Anticipated Release of Updates to United States Pharmacopeia Chapter (USP) 797, USP 800, and Other USP Chapters and the Impact on the Board's Regulation of Compounding

Background

For several years this committee and the board have discussed the regulation of compounding, both sterile and nonsterile, and most recently hazardous compounding. The results of these discussion were comprehensive regulations promulgated to ensure compounded drug preparations as safe. Although not totally consistent, relevant USP chapters covering compounding served as part of the framework for these regulations.

During the February 2018 board meeting, counsel was directed to research the feasibility of incorporation USP standards into the board's regulation of compounding practice rather than creating its own requirements.

USP is currently working on revisions to several chapters including 795 and 797. Proposed revisions for Chapter 795 are scheduled to be released in the coming week.

For Committee Discussion

One potential solution, if the committee and board determine to accept USP's compounding standards as the appropriate minimum standards: the board could seek a statute requiring the board to adopt or enforce USP standards, but still allowing the board to strengthen the standards by regulation where the board deems appropriate. Taking such an approach would mean the board would not need to update the regulation if the USP is updated.

Alternatively, it appears that the board could also incorporate the USP standards by reference into its regulations. Such an approach would require:

- That the board still explain in its initial statement of reasons (ISR) the substance (purpose) of each rule or standard being adopted, and why. With OAL's close scrutiny of regulations, this will be a fairly detailed review.
- That the standards adopted be specific to that a single USP version. Any updates will have to be readopted through a subsequent rulemaking.
- That the board analyze and address the cost of purchasing the standards in the regulation process. This is similar to OAL's requirement that an agency adopts specific equipment as a minimum standard, this cost impact needs to be reported in the rulemaking file. Thus, the board would need to explain why is it clearer to use USP standards rather than have a parallel set of regulations. To the extent that the board can show that all, or all responsible, compounders already have copies of USP standards, that would significantly minimize that impact. The board can start to lay some groundwork now by asking the public feedback at board or committee meetings if compounders already own the relevant USP standards.

10. Enforcement Statistics

The enforcement statistics for the first three quarters of FY 2017/2018 are provided in **Attachment 4**.

11. Future Committee Meeting Dates

Enforcement Committee dates for 2018:

- June 7, 2018
- September 5, 2018
- December 13, 2018

Minutes of the December 11, 2017, Enforcement and Compounding Committee meeting is provided as **Attachment 5**.

Attachment 1

Study of Expanded Use of an Automated Delivery Device – Extension Update

UPDATE
April 3, 2018

Jan D. Hirsch, BPharm, PhD
UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

UC San Diego
Health Sciences

Outline

- Kiosk Operations
- Study Data Updates
  - Increased number of patients
  - Added “truly new” prescription designation
- Next Steps
- Questions

Kiosk = ScriptCenter

ScriptCenter Kiosk
Sharp Memorial Hospital

First Floor Lobby Sharp Memorial Hospital

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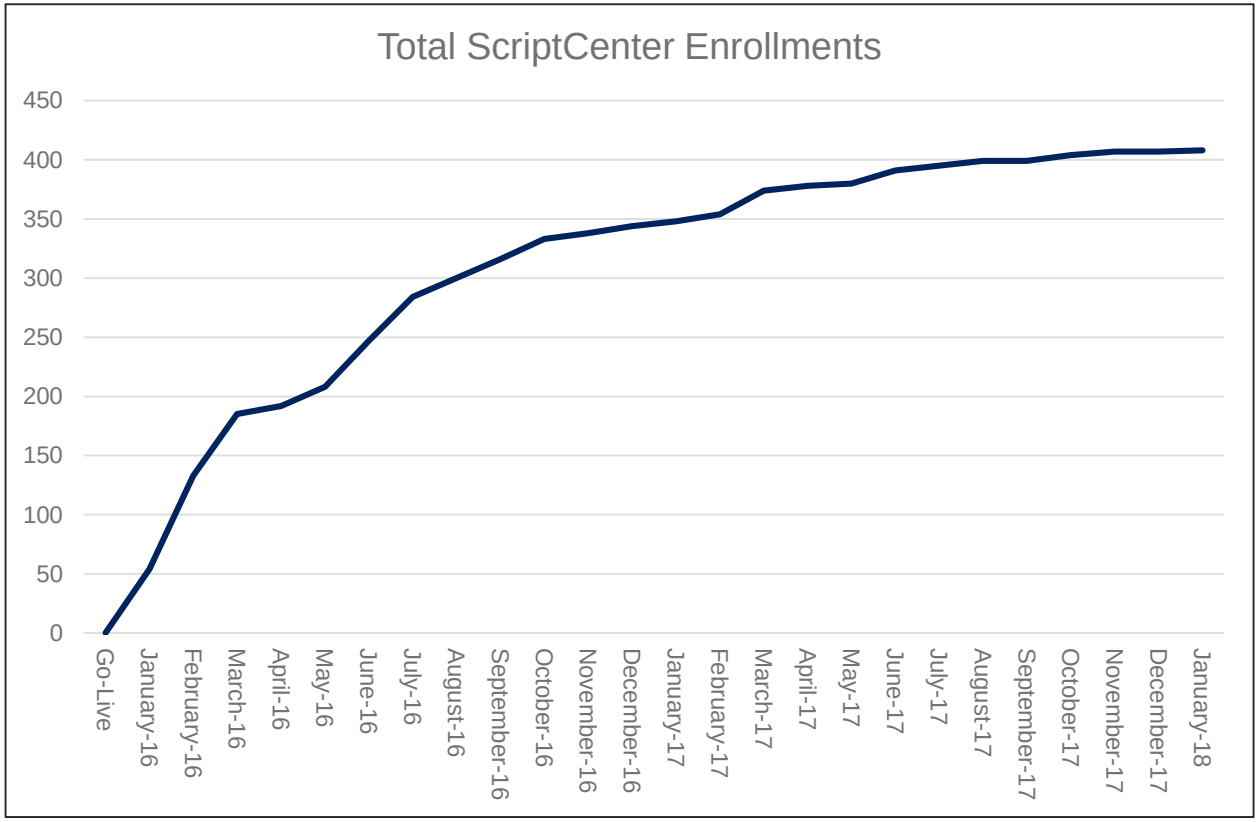
Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

ScriptCenter Kiosk Activity 1/20/16 through 1/31/18

ENROLLMENT



408 users
(*8% Campus Employees)*

Total Campus Employees 4,820
- Day Shift = 2,592
- PM+ Variable = 2,228

If estimate 2 per household = 9,640

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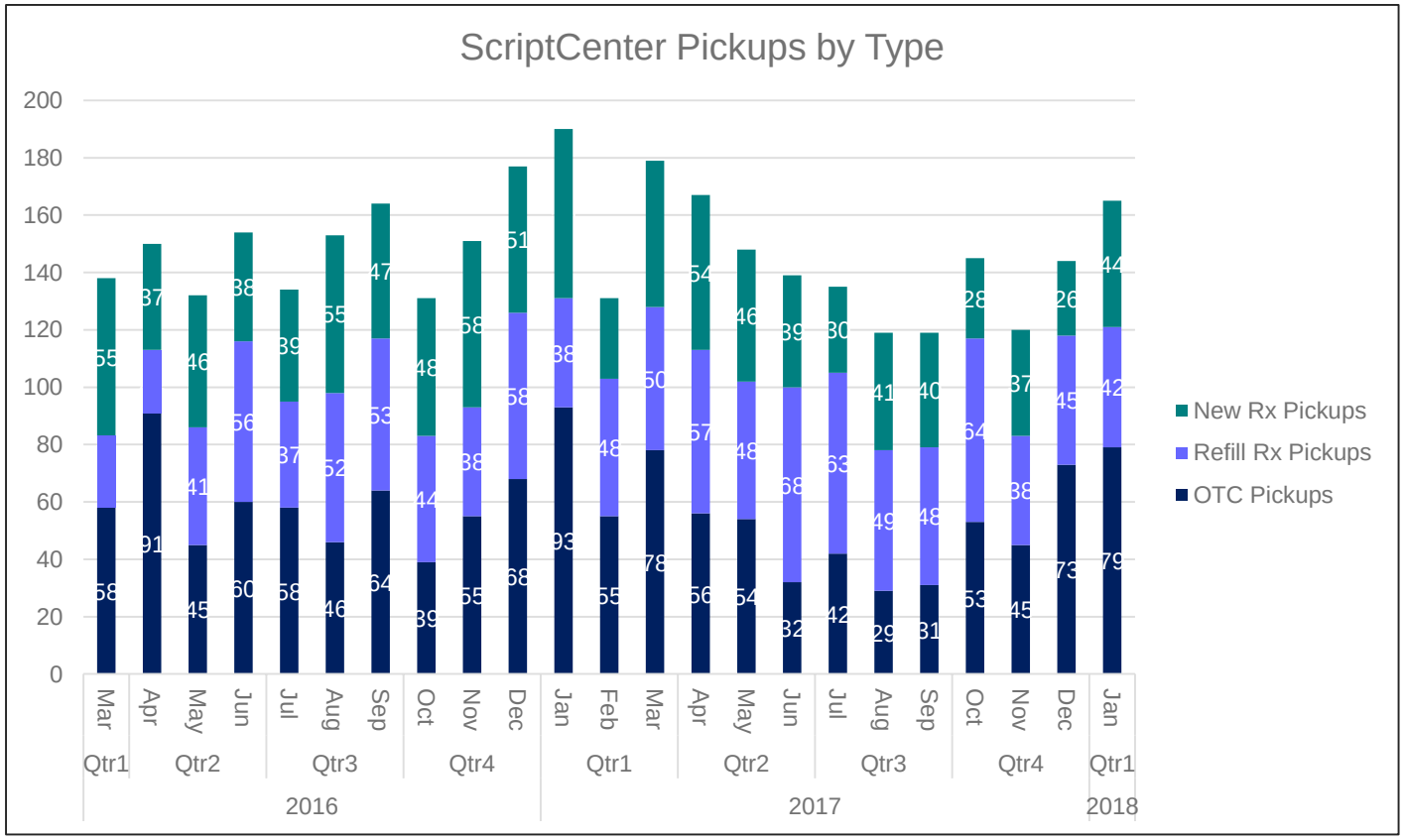
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



Fairly evenly divided among
- New Rxs,
- Refill Rxs
- OTCs

408 Users

New prescription # (number) is ScriptCenter tracking method, some may not be “new” to pharmacy or patient

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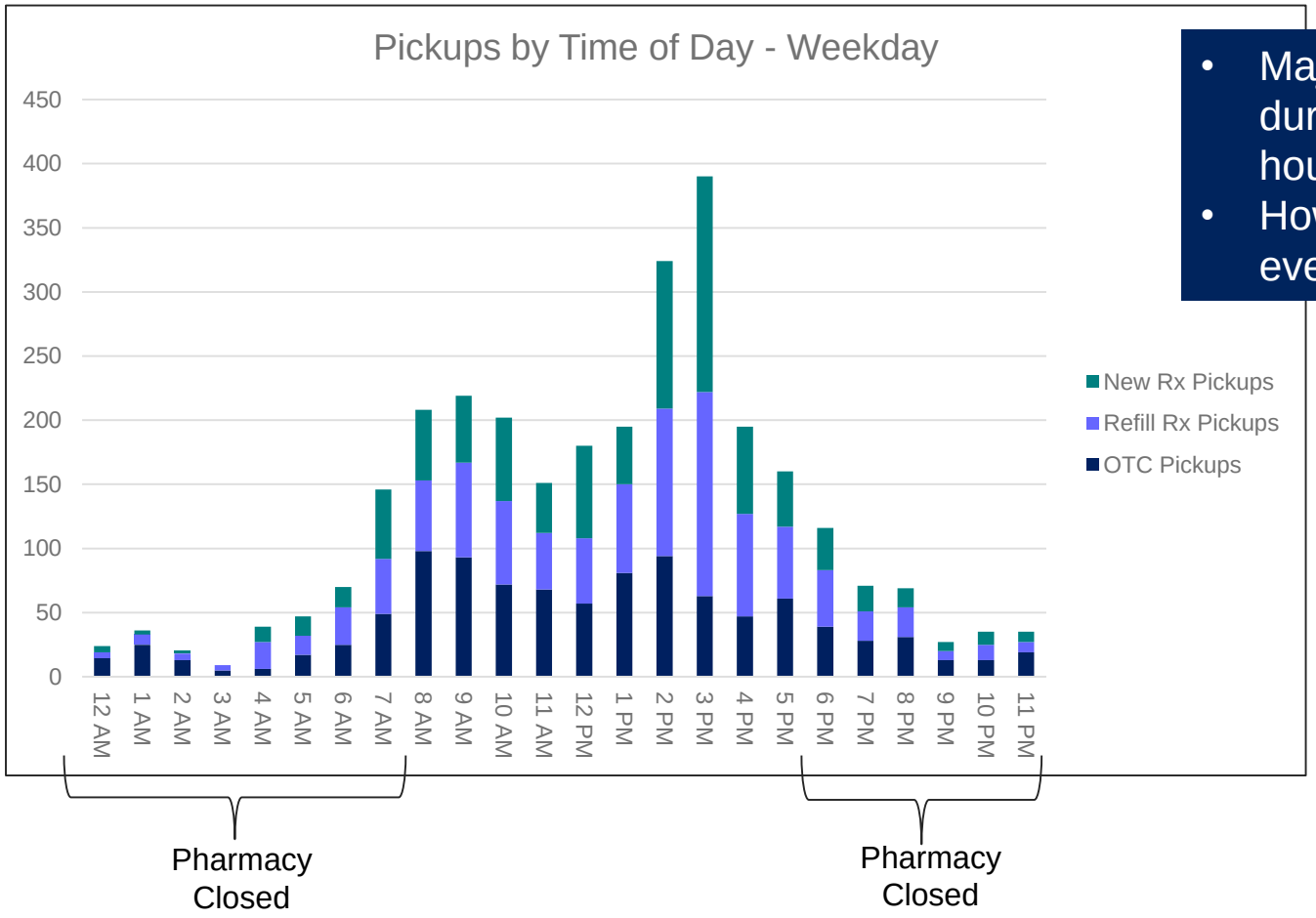
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*



- Majority picked up during pharmacy hours
- However, kiosk used every hour of the day

408 Users

Day Shift = 2,592 PM+ Variable = 2,228

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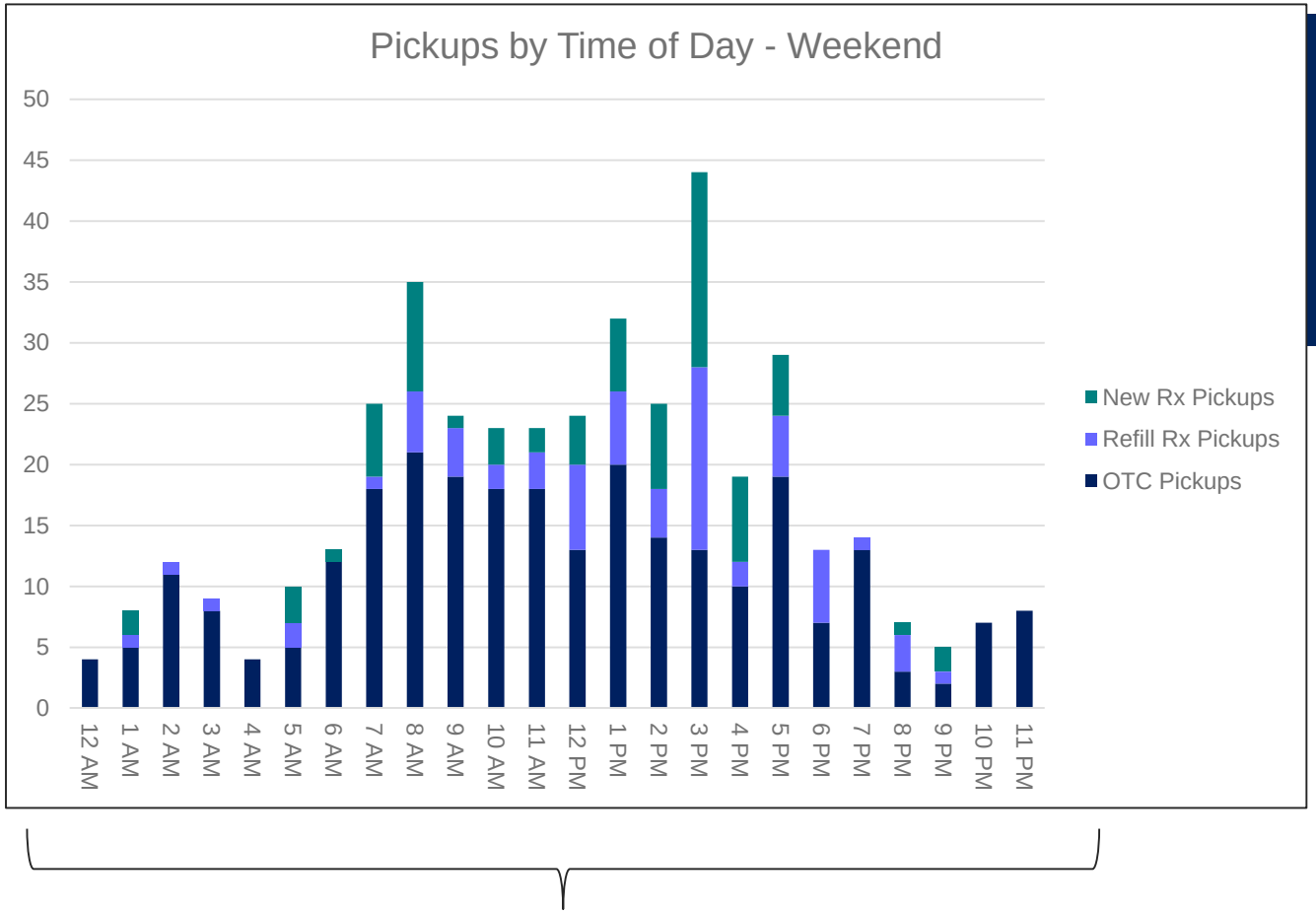
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*



- Lower volume on weekend
- More OTCs
- Kiosk used every hour of the day

408 Users

Pharmacy Closed

Day Shift = 2,592 PM+ Variable = 2,228

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ScriptCenter Kiosk
During vs. After Hours Pickup *(study period: 23 months)*

3,385 Total Pickups

2,302 (68%) During pharmacy hours

1,083 (32%) After pharmacy hours

997 New Rx Pickups

747 (75%) During pharmacy hours

250 (25%) After pharmacy hours

1,084 Refill Rx Pickups

792 (73%) During pharmacy hours

292 (27%) After pharmacy hours

1,304 OTC Pickups

763 (59%) During pharmacy hours

541 (41%) After pharmacy hours

- Majority of Rxs (new and refill) picked up during pharmacy hours
- OTC pickups more evenly split

Day Shift: 2,592

PM + Variable: 2,228

408 Users

After hours includes weekday & weekend times pharmacy is closed.

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RTS Rate: Regular Counter vs. Kiosk (3/1/16-1/31/18: 23 month study period)

	Total Rx Filled	Total Rx Picked Up	Total Rx RTS	Mean* Monthly RTS (%)
Regular Counter+ (6 months prior: 9/1/15- 2/28/16)	4,924	4,668	256	5.2 ± 1.2
Regular Counter+ (23 mo. study period)	70,562	66,746	3,816	5.5 ± 0.8
Kiosk (23 mo. study period)	2,183	2,081	82	4.5 ± 3.3

No significant difference in mean RTS at Kiosk vs. Regular Counter
(p = 0.61 six months prior, p=0.16 23 mo. study period)

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

- Monthly mean over period

Time Verify to Pick Up: Regular Counter vs Kiosk

(3/1/16-1/31/18: 23 month study period)

	Days (Mean* ± SD)	Hours (Mean* ± SD)	Range
Regular Counter+ (22 mo. study period)	1.8 ± 0.2	43.8 ± 5.3	4 sec to 29.0 days
Kiosk (22 mo. study period)	2.8 ± 0.4**	68.0 ± 10.6**	7 min to 19.2 days

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

(p <0.001)

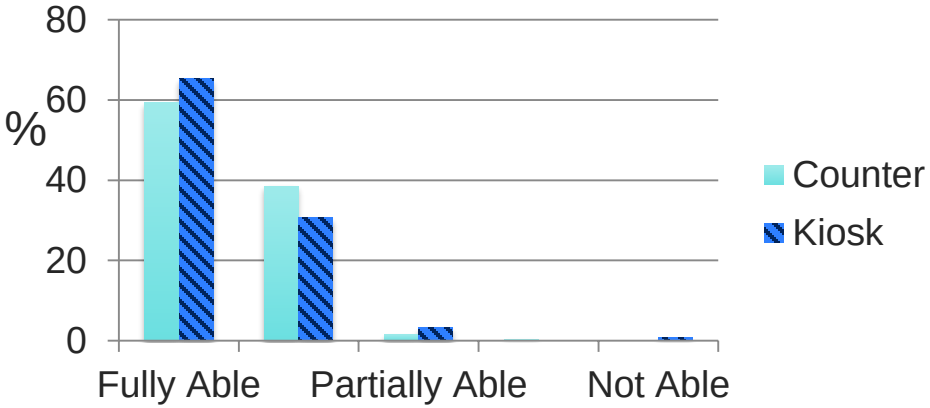
+ Regular Counter = Employees and Dependents only to “match” group using Kiosk

- Monthly mean period

** Significant difference

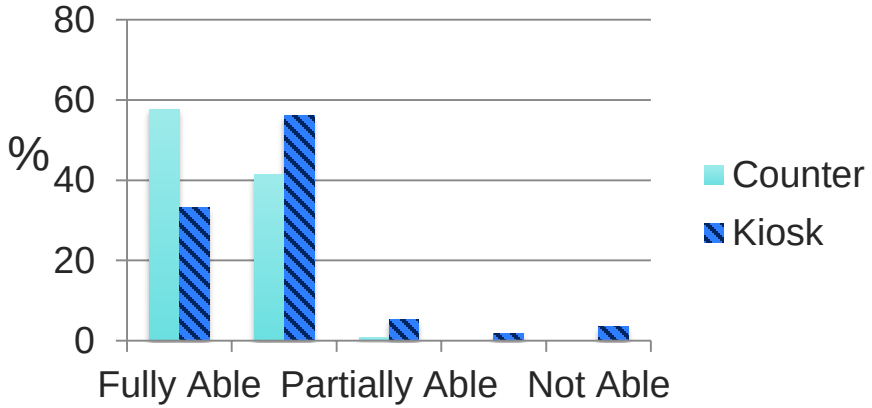
Pharmacist Assessments of Ability to:

Build Therapeutic Relationship



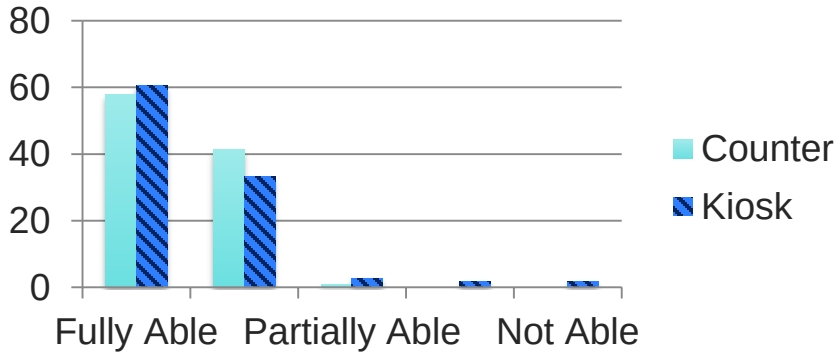
Pharmacist indicated not applicable (N/A):
Counter n=12, Kiosk n=72

Establish Management Plan



Pharmacist indicated not applicable (N/A):
Counter n=38, Kiosk n=122

Negotiate Safety Netting Strategies



Pharmacist indicated not applicable (N/A):
Counter n=54, Kiosk n=106

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Did patients have questions at end of consultation?

	Counter	Kiosk
No	156 (61.2%)	188 (84.3%)
Yes	99 (38.8%)	35 (15.7%)
Total	255	223

Fewer patients had additional questions at kiosk vs. Counter ($p<0.001$)

Counseling logs
- Kiosk = hospital medical staff
- Counter = all patients

- A sampling of counseling sessions at the Regular Counter was conducted during 5 one week periods: May, June, December 2016, November, December 2017
- Kiosk counseling documentation forms collected March-December 2016, October 2017 – February 2018
- Counseling conducted at counter & kiosk for all new prescriptions. Documentation forms for study completed only as above.

Did patients have questions at end of consultation?

Counseling Sessions with Truly New Prescriptions

"Truly New" documentation ***collected only after October 2017***

- Counter: ***104*** of 104 counseling sessions had a truly new prescription (100%)
- Kiosk: ***46*** of 54 counseling sessions had a truly new prescription (85%)

Sessions with Truly New Rxs: % with questions

	Counter	Kiosk
No	56 (53.8%)	43 (93.5%)
Yes	48 (46.2%)	3 (6.5%)
Total	***104***	***46***

Of counseling sessions with a Truly New Rx

- Counter: 46% had a question
- Kiosk: 7% had a question

Counseling logs

- Kiosk = hospital medical staff
- Counter = all patients

- A sampling of counseling sessions at the Regular Counter was conducted during 5 one week periods: May, June, December 2016, November, December 2017
- Kiosk counseling documentation forms collected March-December 2016, October 2017 – February 2018
- Counseling conducted at counter & kiosk for all new prescriptions. Documentation forms for study completed only as above.

Consultations: Initiated by, Location & Duration

Consult initiated by*	Regular counter**	Kiosk**
Pharmacist	246 (98.8%)	188 (85.1%)
Patient	3 (1.2%)	33 (14.9%)

Kiosk patients received text message: asked to call back for counseling

Consult location	Regular counter	Kiosk
Counter	255 (100%)	3 (1.3%)
Phone	0 (0%)	220 (98.7%)

All but three Kiosk consultations conducted via phone

Consult duration	Regular counter***	Kiosk***
Mean (SD)	3.4 ± 1.9	2.0 ± 1.4
Range	1-10 min	1-10 min

Mean consult duration shorter at Kiosk vs Regular Counter ($p<0.001$)
Subset of sessions with a Truly New prescription: Counter 3.3 ± 1.6, Kiosk 2.6 (1.4) ($p=0.01$)

A sampling of counseling sessions at the Regular Counter was conducted during 5 one week periods: May, June, December 2016, November, December 2017

Counter = 255
Kiosk = 223

* Pharmacist includes Pharmacy Intern
** Missing data = 6 Counter and 3 at Kiosk: Pharmacist did not record.
*** Missing data = 37 Counter and 9 at Kiosk: Pharmacist did not record.

Results Summary – Consistent with July 2017 Report to Board of Pharmacy

Kiosk usage

- Fairly evenly divided among New, Refill and OTCs
- Majority Rxs (new & refill) picked up during pharmacy hours

- 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
  - Fewer patients had additional questions at kiosk (16% vs. 39%)
    - Subset of counseling sessions with a Truly New Rx (7% vs. 46%)
  - Counseling logs
    - Kiosk = hospital medical staff
    - Counter = all patients

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Conclusions - Consistent with July 2017 Report to Board of Pharmacy

- The kiosk was a convenient, safe extension of the SRS pharmacy with similar pick up patterns as the regular counter.
  - *Clinical significance of differences in time to pick up and percentage of patients with fewer questions at the kiosk cannot be determined from this study.*

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

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

- 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
  - Includes consultation of every new prescription
  - 24/7 pharmacist access
- Continue to study the Kiosk with automated data & update BOP
  - Kiosk & Counter
    - RTS rate, Time from verify to pick-up
  - Kiosk
    - Kiosk patient satisfaction
- Discontinue manual data collection
- Pursue publication of results

Questions?

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Attachment 2

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomnicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

TESTING FREQUENCY SCHEDULE

A board may order a licensee to drug test at any time. Additionally, each licensee shall be tested RANDOMLY in accordance with the schedule below:

Level	**Segments of Probation/Diversion**	Minimum Range of Number of Random Tests
I	Year 1	52-104 per year
II*	Year 2+	36-104 per year

*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program or who has committed a Major Violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued.

EXCEPTIONS TO TESTING FREQUENCY SCHEDULE

I. PREVIOUS TESTING/SOBRIETY
In cases where a board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing, prior to being subject to testing by the board, the board may give consideration to that testing in altering the testing

frequency schedule so that it is equivalent to this standard.

II. VIOLATION(S) OUTSIDE OF EMPLOYMENT
An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule.

III. NOT EMPLOYED IN HEALTH CARE FIELD
A board may reduce testing frequency to a minimum of 12 times per year for any person who is not practicing OR working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the licensee's board. Prior to returning to any health care employment, the licensee shall be subject to level I testing frequency for at least 60 days. At such time the person returns to employment (in a health care field), if the licensee has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

IV. TOLLING
A board may postpone all testing for any person whose probation or diversion is placed in a tolling status if the overall length of the probationary or diversion period is also tolled. A licensee shall notify the board upon the licensee's return to California and shall be subject to testing as provided in this standard. If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

V. SUBSTANCE USE DISORDER NOT DIAGNOSED
In cases where no current substance use disorder diagnosis is made, a lesser period of monitoring and toxicology screening may be adopted by the board, but not to be less than 24 times per year.

OTHER DRUG STANDARDS

Drug testing may be required on any day, including weekends and holidays.

The scheduling of drug tests shall be done on a random basis, preferably by a computer program, so that a licensee can make no reasonable assumption of when he/she will be tested again. Boards should be prepared to report data to support back-to-back testing as well as, numerous different intervals of testing.

Licensees shall be required to make daily contact to determine if drug testing is required.

Licensees shall be drug tested on the date of notification as directed by the board.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.

Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.

Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.

Collection of specimens shall be observed.

Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.

Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

A board may use other testing methods in place of, or to supplement biological fluid testing, if the alternate testing method is appropriate.

PETITIONS FOR REINSTATEMENT

Nothing herein shall limit a board's authority to reduce or eliminate the standards specified herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522 or statutes applicable to the board that contains different provisions for reinstatement or reduction of penalty.

OUTCOMES AND AMENDMENTS

For purposes of measuring outcomes and effectiveness, each board shall collect and report historical and post implementation data as follows:

Historical Data - Two Years Prior to Implementation of Standard

Each board should collect the following historical data (as available), for a period of two years, prior to implementation of this standard, for each person subject to testing for banned substances, who has 1) tested positive for a banned substance, 2) failed to

appear or call in, for testing on more than three occasions, 3) failed to pay testing costs, or 4) a person who has given a dilute or invalid specimen.

Post Implementation Data- Three Years

Each board should collect the following data annually, for a period of three years, for every probationer and diversion participant subject to testing for banned substances, following the implementation of this standard.

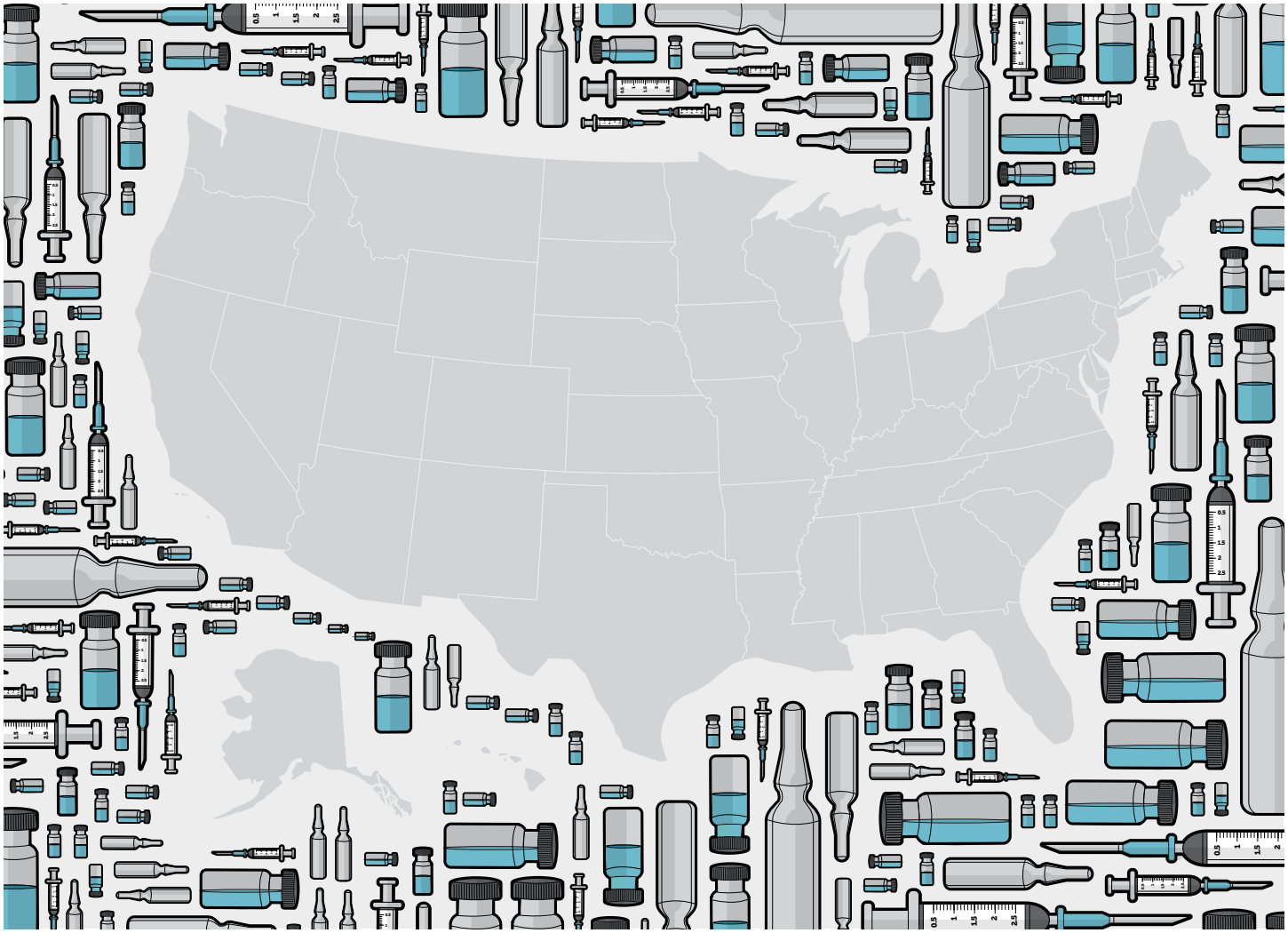
Data Collection

The data to be collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

Probationer/Diversion Participant Unique Identifier
License Type
Probation/Diversion Effective Date
General Range of Testing Frequency by/for Each Probationer/Diversion Participant
Dates Testing Requested
Dates Tested
Identify the Entity that Performed Each Test
Dates Tested Positive
Dates Contractor (if applicable) was informed of Positive Test
Dates Board was informed of Positive Test
Dates of Questionable Tests (e.g. dilute, high levels)
Date Contractor Notified Board of Questionable Test
Identify Substances Detected or Questionably Detected
Dates Failed to Appear
Date Contractor Notified Board of Failed to Appear
Dates Failed to Call In for Testing
Date Contractor Notified Board of Failed to Call In for Testing
Dates Failed to Pay for Testing
Date(s) Removed/Suspended from Practice (identify which)
Final Outcome and Effective Date (if applicable)

Attachment 3

A report from The Pew Charitable Trusts and the National Association of Boards of Pharmacy | Feb 2018



THE PEW CHARITABLE TRUSTS

State Oversight of Drug Compounding

Major progress since 2015, but opportunities remain to better protect patients

Contents

The Pew Charitable Trusts

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Any opinions and conclusions expressed herein are those of The Pew Charitable Trusts and National Association of Boards of Pharmacy, and do not necessarily represent the views of the above individuals.

Acknowledgments

Pew would like to thank the following current and former program staff for their role in this research: Erin Hass, Karen Kavanaugh, Danita Moses, Kathy Pham, Kimberly Smith, Emily Snyder, and Glenn Wright. We would also like to thank the following Pew staff for their contributions: Casey Ehrlich, Elizabeth Hughes, and Alan van der Hilst for their research review and support; Sara Brinda, Kimberly Burge, Matt Mulkey, and Liz Visser for their editorial input; and Erin McNally for her work preparing this report for publication. Finally, we would like to thank our study participants.

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Overview

More than five years have passed since contaminated injections compounded at a single pharmacy caused 76 deaths and 778 illnesses in a nationwide outbreak of fungal meningitis, a tragedy that made clear that the complex, technical practice of drug compounding was not subject to a level of oversight appropriate to its potential risks to patients. Since then, state and federal officials have been re-examining the laws and regulations governing compounding, and working to strengthen them.

Compounding is the creation of medications tailored to patients whose clinical needs cannot be met by U.S. Food and Drug Administration-approved products. Compounded medications pose a higher level of risk to patients than FDA-approved drugs because they have not been tested for safety and efficacy, have not gone through an approval process, and are typically not made under the same quality standards as approved products are. The Pew Charitable Trusts' drug safety project has identified more than 50 reported compounding errors or potential errors from 2001 to 2017 linked to 1,227 adverse events—undesirable experiences associated with the use of a medical product—including 99 deaths. And because many such events may go unreported, this number is likely to be an underestimation.

Scrutiny of compounding policies following the meningitis outbreak in 2012 brought to light weaknesses in state and federal oversight of these potentially risky drugs, prompting reforms at both levels. In November 2013, Congress passed and President Barack Obama signed into law the bipartisan Drug Quality and Security Act (DQSA), which established clear lines of oversight accountability for two categories of businesses that can compound drugs:

- States oversee compounders of patient-specific drugs. They have primary jurisdiction over traditional compounders, who tailor medications to individual patients and include pharmacists practicing in a variety of settings, including community pharmacies and hospitals, as well as physicians who create medications for administration to their patients. These traditional compounders were placed under state jurisdiction in 1997 after Congress introduced new federal policy on compounding as part of the Food and Drug Administration Modernization Act, adding Section 503A to the Federal Food, Drug, and Cosmetic Act (FDCA), and remain so under the DQSA. Both compounding pharmacies and physicians who compound drugs in their offices can be considered traditional compounders, but this report focused on oversight of pharmacies.
- FDA oversees drugs compounded without an individual patient in mind, known as non-patient-specific compounded drugs. FDA is the primary regulator of outsourcing facilities, which can produce "office stock" (bulk supplies of non-patient-specific compounded drugs for hospitals, doctors' offices, and other health care facilities), and are regulated under Section 503B of the FDCA.

The vast majority of compounding is patient-specific; as such, it remained under states' jurisdiction in the federal law. In response to both the outbreak and the subsequent federal law that clarified these regulatory responsibilities, many states also began developing strategies to strengthen their own drug compounding oversight.

As state officials were seeking to determine which reforms would help them oversee the industry most effectively, Pew convened an advisory committee of state pharmacy regulators and other experts to identify best practices (see the "Best Practices" section below), which were published in its 2016 report "Best Practices for State Oversight of Drug Compounding."

In 2016 Pew also published the report "National Assessment of State Oversight of Sterile Drug Compounding," an evaluation of the national landscape of state policies on compounding of sterile drugs, based on data collected in 2015. The current report provides a targeted update of the prior assessment, focusing on state alignment with three key best practices:

- Application of U.S. Pharmacopeial Convention (USP) quality standards on sterile compounding.
- Harmonization with federal law on compounding without prescriptions.
- Annual inspections of facilities that perform sterile compounding.

This assessment collected data from publicly available sources, which were then verified by the boards of pharmacy in 43 states and the District of Columbia, and through interviews with representatives from four randomly selected boards.

State officials have strengthened sterile compounding oversight laws and rules since the 2015 assessment. The vast majority of states now conform to best practices in two of the three key areas:

- 32 state boards of pharmacy require traditional pharmacies that compound sterile drugs for humans to be in full compliance with the widely recognized quality standards established by the USP in its General Chapter <797>, "Pharmaceutical Compounding—Sterile Preparations." An additional 11 states have strong requirements on sterile compounding practice, which 10 of them characterize as "equivalent to or stricter than" Chapter <797>, even if some elements are less specific. An additional four states have pending policy changes that, if passed, would require full compliance with <797> or other strong quality standards. In 2015, just 26 states required<797> or equivalent quality standards for sterile compounding.
- 39 states and the District of Columbia prohibit traditional pharmacies from compounding for sterile office stock for human use—through their laws, regulations, or state guidance, or by advising compounders to follow the DQSA. However, 11 states have office stock policies (many predating the federal law) that are not aligned with federal statute. In 2015, representatives from nearly two-thirds of state boards of pharmacy that responded to the Pew assessment allowed traditional compounding pharmacies to produce drugs without prescriptions to at least some extent.
- It appears that states may be inspecting traditional pharmacies that do sterile compounding for humans less frequently now than in 2015. Then, 26 states and the District conducted routine inspections at least annually for in-state pharmacies that perform sterile compounding; today, just 22 states and the District do so. Interviews with state officials underscore the need for more financial resources and inspection capacity.

The significant progress in adopting USP Chapter <797> quality standards and aligning with federal law on compounding without prescriptions suggests a key opportunity for jurisdictions that have not yet adopted these best practices. Improvements in rigor and frequency of inspection of facilities that perform sterile compounding will require resources, but interim measures such as harmonizing inspection forms and processes among states may allow for optimal use of existing capacity and enhance efficiencies.

While the majority of states have taken action to strengthen sterile compounding oversight policies since the outbreak, it is essential to follow through with strong implementation and enforcement of these laws and rules—including the federal DQSA. This report is intended to highlight the significant progress on public health policy that has occurred and to identify the most fruitful opportunities for action to help ensure a safe supply of compounded drugs. This remains a period of flux for drug compounding oversight: A number of states have pending policy changes, and implementation of the federal DQSA is ongoing. This continuing progress is one key finding of this study.

Best Practices

In 2014, The Pew Charitable Trusts convened an advisory committee of state regulators and other experts to examine state oversight of compounding and develop best practices. The panel reviewed several regulatory topics, including inspections of compounding pharmacies, requirements for quality, expectations for pharmacist training, and the practice of compounding without a prescription. The committee also discussed how states should harmonize these requirements with federal law and regulations, particularly on issues such as definition and recognition of the "outsourcing facility" category created by the DQSA.

Based on the advisory committee process, Pew produced a report in 2016 that identified the practices that are most meaningful to patient safety and the most achievable—while recognizing that state funding may limit oversight systems. The best practices provide a resource to state regulators, policymakers, and stakeholders who are reviewing oversight practices, and they also support greater harmonization across states—which because of the interstate movement of compounded drugs can help ensure consistent oversight and help discourage businesses from locating in states with less rigorous regulations.

The best practices include:

- Application of U.S. Pharmacopeial Convention (USP) quality standards on compounding.
- Training in sterile compounding for pharmacists who perform or supervise it.
- Annual inspections of facilities that perform sterile compounding.
- State mechanisms, such as separate licensure, to identify and apply specific standards to facilities performing sterile compounding.
- Recognition and definition of outsourcing facilities in a manner aligned with federal law.
- Harmonization of policies on compounding without prescriptions with federal law.
- Meaningful oversight of sterile compounding that occurs in physicians' offices.
- Mechanisms to track the compounding activities conducted by pharmacies within the state.

Whenever the current report refers to best practice recommendations, it means the practices described in detail in Pew's 2016 report "Best Practices for State Oversight of Drug Compounding."

Background

Pharmaceutical compounding is the creation of medications that are tailored to the requirements of patients whose clinical needs cannot be met by FDA-approved products. Like other licensed health care practices, compounding is primarily regulated by the states. Compounded medicines differ from FDA-approved products, which have earned that classification by undergoing a formal drug approval process to demonstrate that their therapeutic benefits outweigh their risks and that they work as intended.

Compounding is an important component of health care in specific circumstances. This process is used, for example, when a child needs a liquid version of a medicine that is approved only in tablet form; when a patient who cannot eat and digest normally must be fed intravenously with a customized mixture of nutrients; or when a patient requires a preservative-free formulation of a sterile drug.

Compounded products pose a higher level of risk to patients than approved products because they have not been tested for safety and efficacy. They are also typically not prepared under the same quality standards—requirements for how drugs are manufactured and stored to prevent contamination or other potentially dangerous problems. Meaningful quality standards are important for all forms of compounded drugs, including tablets, capsules, syrups, and topical creams, but rigorous standards are most critical for drugs that are injected or infused into the body and therefore must be sterile to minimize the risk of infection.

Compounding is as old as the practice of pharmacy itself, and the compounding of sterile injectables and intravenous infusion products by a pharmacist or other practitioner emerged as a practice in the early 20th century, primarily in hospital settings. As the complexity of sterile preparations increased and demand grew, outsourced sterile compounding, conducted off site by a third party, became a viable commercial enterprise.

Dramatic expansion of the outsourced compounding sector in the years before the 2012-13 fungal meningitis outbreak resulted in facilities whose production volumes were in some cases on a scale closer to conventional manufacturing by pharmaceutical companies than traditional compounding done by pharmacists, and it was unclear which regulators were responsible for overseeing these operations. In general, states regulate pharmacists and licensed pharmacies, while the federal government regulates conventional manufacturing—but the compounding of stock supplies of medications fell into a gray area between these oversight systems. A series of conflicting judicial opinions in 2001, 2002, and 2008 led to further confusion about which specific compounding activities were subject to federal oversight and which were the domain of states. Moreover, some states were not prepared to regulate this industry appropriately or had too few resources to do so meaningfully. Thus, this complex, technical practice was not consistently overseen at a level commensurate with its potential risks to patients.

Those were the conditions when the fungal meningitis outbreak occurred after one pharmacy shipped contaminated injectable medications across the country, killing dozens and injuring hundreds more. While this outbreak is the most extensive known example of harm to patients from compounded drugs, many other cases of serious illness, injury, and death associated with such medications have occurred.[1]

In the aftermath of the outbreak, federal and state policymakers, as well as other groups, moved to examine the issues underlying drug compounding and to identify solutions to the systemic shortcomings that allowed the outbreak to occur. Problems highlighted included ways in which state oversight needed to improve, and many state boards of pharmacy responded by re-examining and strengthening their drug compounding oversight laws and rules. Meanwhile, at the federal level, the DQSA was signed into law in November 2013.

The DQSA clarified the distinction between two types of compounders:

- **Pharmacies or physicians** (collectively called "traditional compounders" in this report) that prepare drugs pursuant to individual prescriptions to meet specific patient needs. These compounders are regulated under Section 503A of the FDCA.
- **Companies** selling supplies of compounded drugs without patient-specific prescriptions. They are now regulated as part of a new "outsourcing facility" sector under the FDCA's Section 503B and are required to meet accordingly stricter quality controls.

The DQSA clarified that FDA has primary oversight of the outsourcing facility compounding sector, while states are primarily responsible for regulating the practice of pharmacy, including compounding in traditional pharmacies to fill individual patient prescriptions. (Section 503A of the FDCA authorizes compounding by pharmacists and physicians. This report focuses on compounding as a pharmacy practice, and physician compounding is addressed only briefly, in the "Physician's Office or Clinic Compounding" section below. Compounding by other types of practitioners is beyond the scope of this research.)

Current landscape of sterile compounding oversight

Quality standards

Conforming to scientifically sound standards, such as those established by USP, is critical to preventing contamination, especially for sterile compounding. Deficiencies in sterile compounding practices can cause patient harm and death. Best practice recommendations include state application of USP quality standards on compounding.[2]

For compounding sterile preparations, the widely recognized quality standards in USP Chapter <797> describe specific procedures, conditions, and other requirements that, when followed, are designed to prevent patient harm resulting from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations. Specifically, Chapter <797> describes practices such as appropriate sterile garbing (putting on protective gear such as face masks, shoe covers, and eye shields), cleaning procedures, environmental controls such as airflow, monitoring practices to detect and remediate unacceptable levels of contaminants in the air and on equipment and surfaces, and tests and checks to ensure product quality before drugs are released.

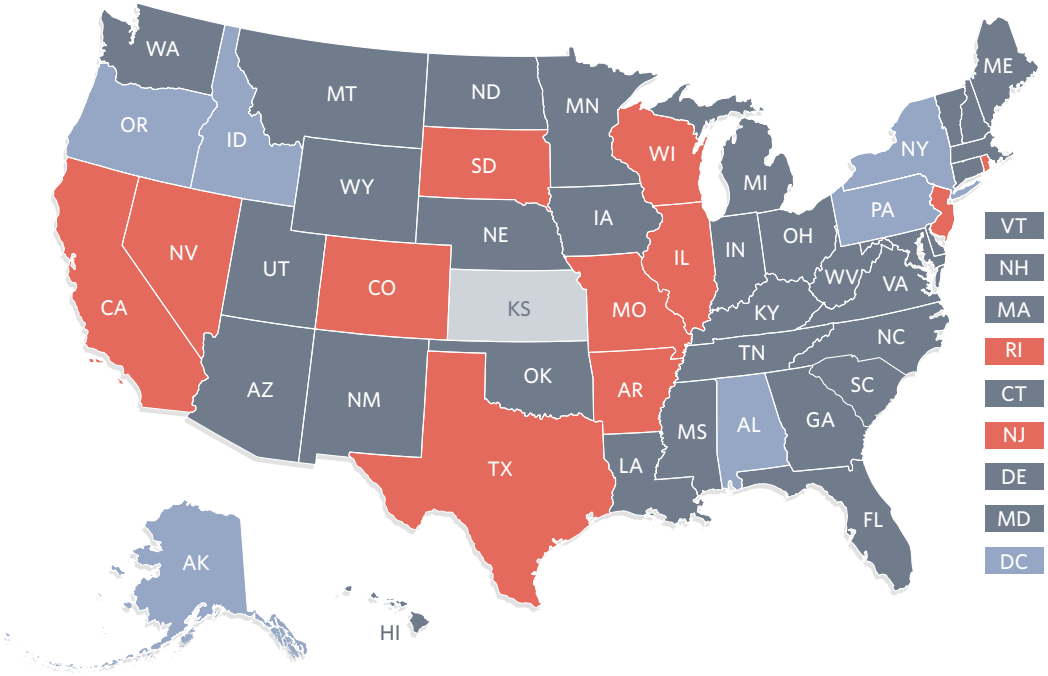
Our study found that 32 state boards of pharmacy require traditional pharmacies that compound sterile drugs for humans to be in full compliance with Chapter <797>. An additional 11 states have strong standards for sterile compounding practice, which 10 states characterize as "equivalent to or stricter than" <797>, even if some elements are less specific.

Six states and the District of Columbia require other compounding quality standards. In Pennsylvania, for example, traditional pharmacies must adhere to compounding quality standards, though the standards do not specify minimum equipment or facility requirements for compounding, a key component of Chapter <797>.[3] As of this writing, just one state, Kansas, does not impose any particular compounding quality standards. However, its board of pharmacy has been directed by statute to "adopt rules and regulations governing proper compounding practices and distribution of compounded drugs by pharmacists and pharmacies."[4] Kansas and three other states have pending policy changes that, if passed, would require full compliance with <797> or other strong quality standards.

Figure 1

Compliance With Sterile Compounding Standards

32 states require full compliance with USP Chapter <797> quality standards



Require full compliance with USP <797>

Require compliance with strong requirements on sterile compounding practice, including the 10 states reporting standards "equivalent to or stricter than" USP Chapter <797>, even if some elements were less specific.

Require other quality standards

Does not require quality standards

The widespread adoption of strong quality standards represents significant progress made by states in recent years. The 2015 assessment found that 26 states mandated Chapter <797> or equivalent quality standards for sterile compounding. (We caution against direct comparisons between these numbers, because there were slight methodological differences between how this question was assessed in each report. For the earlier report, based on data from 2015 and published in 2016, researchers asked boards of pharmacy whether their state mandated <797> or equivalent quality standards for sterile compounding, but that questionnaire, unlike the present study, did not explicitly define what could be considered equivalent quality standards. The current study's methodology was slightly different: First, a licensed pharmacist on Pew's staff compared the state's requirements to USP's to determine whether the state standards for sterile compounding were as strong or stronger than the correlating requirements of <797>, even if some elements were less specific. States were then asked to verify whether Pew's determination was accurate.) Despite the differences in research methodology between the two assessments, it is evident that policy shifts have occurred in many states.

Challenges for states requiring USP Chapter <797>

Chapter <797> describes conditions and procedures that, if followed while compounding sterile drugs, help ensure the drugs' quality and prevent them from harming patients. Although the chapter is incorporated into or referenced by many states' laws and regulations, state boards of pharmacy have cited challenges in using it as an enforceable set of rules. For example, the standards' generally descriptive language and use of the words "should" and "shall" can lead to ambiguity as to what is required versus what is recommended.[5] To mitigate any confusion, some states have created tools that help pharmacies determine whether they are in compliance with <797>. In Washington state, for instance, the Pharmacy Quality Assurance Commission created a Sterile Compounding [USP <797>] Self-Assessment Compliance Checklist that "includes the reported 'principal competencies, conditions, practices, and quality assurance that are required' ('shalls') in U.S. Pharmacopeial (USP) <797>" and "is designed to be a tool to guide and aid you [compounders] to assess your compliance with USP <797>."[6]

Enforcement challenges result not only from the way Chapter <797> is written, but also because it is constantly updated to reflect new research and evidence-based best practices, respond to stakeholder input, and clarify aspects of the standards. Recognizing this, some states have rewritten (or are rewriting) their regulations to exceed the requirements of the current version of <797>. For example, the Massachusetts Board of Registration in Pharmacy reports that a pending state regulation would clarify certain <797> standards, provide greater instruction for state-licensed compounders, and in some cases go above and beyond <797> standards. In New Jersey, regulations fully comply with the intent of the chapter, according to the state Board of Pharmacy, which also reports that, in some cases, its quality standards are more stringent than <797>. For instance, the board requires pharmacies to report any test results indicating possible contaminants in or around the compounding facility and any confirmed incidents of product contamination to the board within 48 hours, while the current version of <797> simply requires compounders to create an actionable plan in such instances.

What the upcoming revision of USP Chapter <797> means for states

USP is revising its standards for sterile compounding. A draft published in September 2015 received more than 8,000 comments from 2,500 stakeholders. Because USP received so many comments, the next draft of the revised edition of <797> will be open for another public comment period before it is finalized. In September 2017, the USP Compounding Expert Committee, which is charged with creating and revising compounding-related chapters and developing compounded preparation monographs, announced that it anticipates this second public comment period to open in September 2018. The committee expects that the revised <797> will become official in December 2019, though USP may allow more time for adoption of certain components of the new standards.[7]

Some states will immediately require full compliance with the updated <797> because their pharmacy laws or rules require compliance with whatever version of <797> is current at the time. For example, New Hampshire administrative rules state that "[t]he board shall require all compounders engaging in compounding in all situations to adhere to and comply with the current edition of the United States Pharmacopeia including but not limited to Chapters 795 (USP 795) and 797 (USP 797), following those guidelines that apply to their practice setting."[8] (Chapter <795> contains quality standards for the preparation of nonsterile compounded medications.)

Other states that require full compliance with a specific version of Chapter <797> will need to make legislative or regulatory changes to mandate compliance with the revised version when it is finished. For example, Wyoming recently passed regulations that require full compliance with <797> "as [it existed] on May 1, 2017-July 31, 2017 including amendments adopted by USP as of that date,"[9] and therefore would need to revise these regulations to require full compliance with the updated <797>.

Pharmacist Education and Training

State rules for pharmacist education and training on compounding vary. Some states, such as New York and Georgia, require pharmacists to pass a hands-on practical examination before becoming licensed; Massachusetts has stringent continuing education requirements. As previously mentioned, some state boards of pharmacy, such as Washington's, developed educational tools to assist pharmacies in complying with USP Chapter <797>. However, most pharmacists obtain their sterile compounding training and experience on the job.

The best practice recommendation published in 2016 is that states require training in sterile compounding for pharmacists who perform or supervise it. To be effective, such training must include classroom and practical components, and must cover core elements of <797>.[10]

Physician's Office or Clinic Compounding

Sterile compounding typically occurs in pharmacies but may also take place in doctors' offices or clinics. Some research suggests that the frequency of contamination of parenteral drug preparations (a category that includes drugs administered through higher-risk routes, such as intravenously or through injection) is higher in clinical environments than in controlled pharmacy environments.[11] Serious adverse events occurring as a result of physicians' office compounding include a case in 2016 in which 17 people developed fungal bloodstream infections after they received contaminated compounded intravenous medications that were prepared at an outpatient oncology clinic in New York.[12]

States generally do not track physician compounding, so the extent of the practice is unclear. Typically, compounding that occurs in doctors' offices is subject to oversight by state boards of medicine rather than pharmacy boards. While a few states have regulations governing compounding in those settings, most do not.[13] The best practice recommendation published in 2016 is that states develop meaningful oversight for compounding in physicians' practices, which includes adopting the same quality standards as other compounding facilities to ensure patient safety. The advisory committee of state regulators and other experts recommended that this issue also be addressed through collaboration between the Federation of State Medical Boards and the National Association of Boards of Pharmacy.[14]

Compounding without prescriptions

State-licensed compounders who seek to produce drugs that qualify for the exemptions under Section 503A of the federal FDCA are prohibited from compounding drugs for human use without a prescription outside of the limited quantities of anticipatory compounding permitted under Section 503A and FDA's prescription requirement guidance for industry. (Anticipatory compounding occurs in circumstances where a pharmacist can anticipate receiving repeated prescriptions for the same compounded drug—for instance, if the pharmacist has a relationship with a practitioner who commonly prescribes a particular product—and can compound a supply of that drug in advance of that need and dispense or distribute it as the prescription orders come in.)

Dispensing supplies of drugs without a prescription for office use (also called office stock) is allowed only for a facility that has registered with FDA as an outsourcing facility under Section 503B of the FDCA, which must meet Current Good Manufacturing Practice (CGMP) standards, which are similar to those that conventional manufacturers must meet. The majority of states also require outsourcing facilities to be separately licensed or registered. Best practice recommendations include harmonizing state policies on compounding without prescriptions with federal law, and recognizing and defining outsourcing facilities in a manner aligned with federal law.[15]

Section 503A created a regulatory framework for pharmacists to produce medicines for specific patients without having to go through the drug approval process to demonstrate safety and effectiveness, while section 503B addressed the need of hospitals and other health care providers to attain bulk supplies of drugs that are otherwise not available to meet patients' medical needs. The DQSA was explicitly written to ensure that sterile drugs that were being produced without a prescription would be held to more robust quality standards than those that apply to traditional compounding.

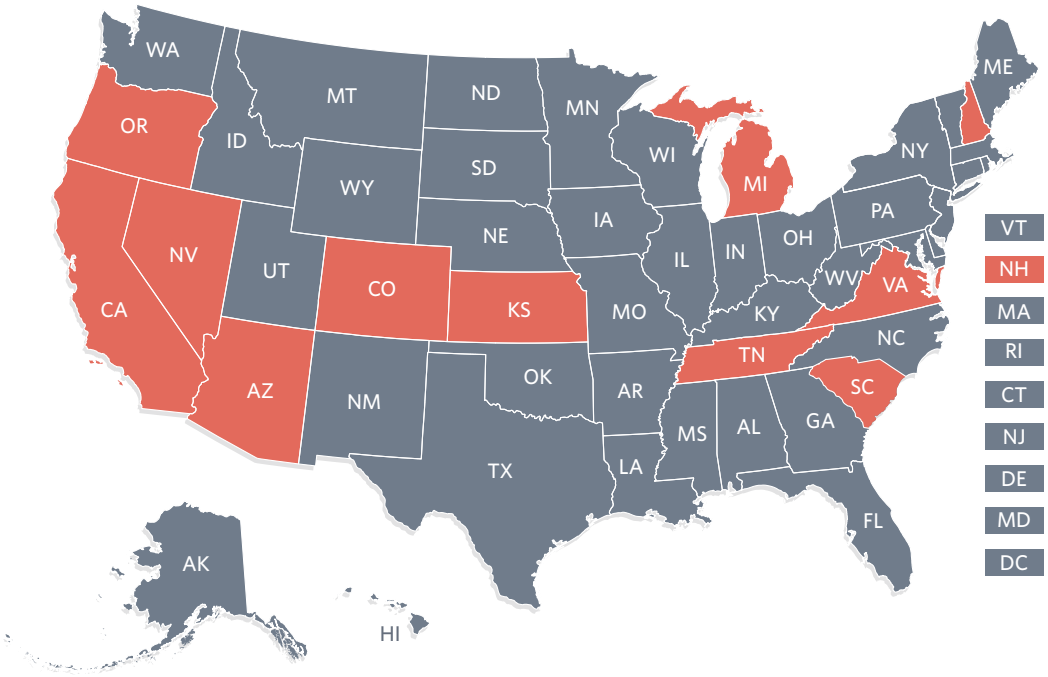
FDA finalized its prescription requirement guidance for industry in December 2016, an important step toward fully implementing the DQSA. The document clarifies the law's requirement that traditional compounders dispense or distribute compounded products only upon receipt of a valid prescription. Because outsourcing facilities can produce and distribute drugs without a prescription, while traditional compounders cannot, FDA calls the prescription requirement a "critical mechanism" for distinguishing traditional compounders from drugmakers that must comply with higher manufacturing standards.[16]

Most states prohibit traditional pharmacies from compounding for office stock, but some states have office stock policies (many predating the federal law) that are not aligned with federal statute. This study found that 39 states and the District of Columbia prohibit traditional pharmacies from compounding sterile drugs for humans in the absence of patient-specific prescriptions outside of anticipatory compounding permitted under FDA's prescription requirement guidance for industry through various mechanisms: state laws or regulations (30 states and the District), state guidance (five states), or advice to compounders to follow the more restrictive federal law (four states). All 11 of the states that allow traditional pharmacies to compound sterile office stock for humans place limitations on this practice.

Figure 2

Restrictions on Sterile Office Stock Compounding for Humans

39 states and the District of Columbia prohibit the practice through laws and other measures



Prohibit sterile office stock compounding for humans through their laws or regulations, state guidance, or by advising compounders to follow the more restrictive federal law

Allow sterile office stock compounding for humans with limitations

State boards of pharmacy have been leaders in protecting patient safety by strengthening sterile compounding oversight policies to help ensure a safe supply of compounded medications. Pew's 2015 state-by-state assessment found that representatives from nearly two-thirds of the boards that responded allowed traditional compounding pharmacies to produce drugs without prescriptions, at least to some extent. That assessment categorized anticipatory compounding as a state limitation on office stock compounding and noted that states appeared in some cases to conflate anticipatory compounding with compounding a supply of a drug without a prescription to be stocked by a doctor's office or clinic. Other limitations on office stock that states identified in the earlier assessment included volume restrictions, limiting the practice to veterinary use, and confining the practice to outsourcing facilities.

In the current study, 39 states and the District of Columbia do not permit traditional pharmacies to compound sterile drugs for humans in the absence of patient-specific prescriptions outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry. (In the present assessment, the research team verified with states whether they allow traditional pharmacies to compound sterile drugs for humans in the absence of patient-specific prescriptions outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry.) Under the DQSA, 503B outsourcing facilities are now the only entities allowed to distribute compounded drugs without prescriptions—in exchange for submitting to more stringent oversight.

Some states, such as New York, prohibited traditional pharmacies from doing sterile office stock compounding for human use before passage of the DQSA. Others moved to prohibit the practice in light of the DQSA and FDA's prescription requirement guidance for industry. For example, New Jersey requires pharmacies to comply with the FDCA (the law that the DQSA amended) and therefore prohibits traditional pharmacies from compounding sterile drugs for humans in the absence of patient-specific prescriptions. However, the New Jersey Board of Pharmacy is currently rewriting its rules to clarify this regulation. Still other states with laws that permit compounding for office stock nevertheless advise the pharmacies they oversee that federal law prohibiting the practice prevails.

Limitations on sterile office stock compounding

Although the federal DQSA prohibits traditional compounders from compounding drugs for humans in the absence of patient-specific prescriptions (outside of anticipatory compounding), 11 state boards of pharmacy allow the practice. In those states, traditional compounders that comply with state requirements may nevertheless be in conflict with federal law. The best practices recommendation is that states harmonize their prescription requirements with federal law. States that choose not to do so may create a confusing regulatory environment for traditional compounders in their state and risk that pharmacies that comply with state compounding requirements are nevertheless subject to federal enforcement.

However, all 11 states that permit compounding sterile drugs for office stock place limitations on it, the most common being that traditional pharmacies may prepare office stock only in limited quantities and may prepare it only for physicians to administer in their offices. One state restricts the distribution of office stock to practitioners in the state, and two states allow traditional pharmacies to produce office stock only if they have a special agreement approved by the board of pharmacy. Four states place more than one of these limitations on office stock compounding. Whether these constraints are meaningful will be affected by state interpretation and enforcement. For example, "limited quantities" is not always defined, which may create challenges for compliance and enforcement. And because some products are always physician-administered, requiring that any office stock be administered by a physician may not meaningfully affect the volume of office stock of such products that a compounder could produce.

States that allow traditional pharmacies to compound sterile drugs for humans without patient-specific prescriptions (outside of anticipatory compounding) blur the clear line the DQSA drew between traditional pharmacies and outsourcing facilities. Even states that place strict limitations on the practice create a gray area with unclear lines of accountability for compounders—one of the problems that led to the meningitis outbreak and that the DQSA solved.

Despite this concern, the California State Board of Pharmacy believes it serves public health to allow traditional pharmacies to compound office stock under specific limitations because the state considers it safer for pharmacists overseen by the board to compound office-use drugs than for prescribers (or prescribers' personnel) to do so in their offices. The concern is that a prohibition on office stock could drive compounding into physicians' offices. California draws its own line between traditional pharmacies and outsourcing facilities: The latter are not allowed to compound patient-specific prescriptions. For California, and potentially other states that may permit office stock for the same reasons, enhanced oversight of compounding in prescribers' offices could make it more feasible for the state to adopt the best practice recommendation published in 2016 to follow federal law requiring prescriptions.

Nonsterile office stock compounding

While 39 states and the District of Columbia prohibit traditional pharmacies from compounding sterile drugs for humans in the absence of patient-specific prescriptions, five fewer jurisdictions (34 states and the District of Columbia) apply that same prescription requirement to nonsterile compounding.

Nonsterile products pose risks that can result in serious patient harm, as was tragically illustrated in 2009, when a patient in North Carolina died after taking compounded capsules of thyroid medication that were 18 times stronger than ordered,[17] and years earlier when two patients died after topical anesthetics they received were too potent.[18]

As with other state regulations of compounded products, this is a time of change, and states may still be moving toward prohibiting nonsterile office stock compounding for humans. For example, Oklahoma removed regulations in 2017 that allow nonsterile office stock compounding. Oklahoma pharmacists are expected to comply with federal law on office use compounding.

It is worth noting that outsourcing facilities—the only entities permitted by federal law to dispense or distribute compounded drugs without patient-specific prescriptions—are required to compound at least some sterile drugs. At present, there is no legal way for an outsourcing facility to produce only nonsterile drugs, potentially creating problems when office stock of such products is necessary.

Outsourcing facilities

FDA has primary oversight of the outsourcing facility sector. However, many states also separately license or register outsourcing facilities. Our study found that 38 states license or register facilities that also register with FDA under the federal outsourcing facility category.

Federal law neither prohibits nor requires state pharmacy licensure for outsourcing facilities, and until recently there was no statutory or other guidance to states on how they should oversee outsourcing facilities. In 2016, FDA developed preliminary recommendations for state licensure of outsourcing facilities, which includes the recommendation that states create a separate state licensure category specific to outsourcing facilities.[19]

States are not required to follow this recommendation, and their approaches to recognizing this category of compounders vary. Among the 38 states that license or register 503B facilities, the most common practice is to license or register them as outsourcing facilities. Other states license or register these facilities as manufacturers or wholesale distributers. Colorado registers in-state outsourcing facilities as manufacturers but out-of-state outsourcing facilities as wholesalers. New Hampshire issues permits for outsourcing facilities in a category it calls bulk sterile and nonsterile compounders, and Mississippi issues a sterile product outsourcing permit.

States also vary on whether they allow a facility to act as both a traditional compounder and an outsourcing facility. Some states allow outsourcing facilities to also compound patient-specific prescriptions as long as all of the facility's compounding adheres to CGMP standards, while at least one state prohibits outsourcing facilities from compounding any patient-specific prescriptions. At least one state requires outsourcing facilities to register as pharmacies even if they do not compound patient-specific prescriptions, at least one state prohibits outsourcing facilities from registering as pharmacies, and still others require only that outsourcing facilities be registered as pharmacies if they compound patient-specific prescriptions. These differing and even contradictory requirements can be a hurdle for outsourcing facilities seeking to do business in multiple states with conflicting requirements.

In the majority of states that recognize outsourcing facilities, they are overseen by the state board of pharmacy. However, in some other states, outsourcing facilities are regulated by another entity. For example, outsourcing facilities in Louisiana are overseen by the state Board of Drug and Device Distributors.

Outsourcing facilities must pay to register with FDA, and the states that separately license or register these facilities also charge for licensure or registration. State fees range from about $50 to $2,270 per year. Some states require outsourcing facility renewal annually, while others require renewal biennially or triennially.

In-state pharmacy inspections

Facility inspection is a key instrument that regulatory bodies use to assess pharmacy compliance with laws and regulations on compounding. Inspections protect the public by ensuring that appropriate quality standards are met.

The frequency of inspections for traditional pharmacies located in a given state is not typically dictated by that state's laws or regulations, but is instead often based on resources. Best practice recommendations include annual inspections of facilities that perform sterile compounding.[20]

Our study found that 22 states and the District of Columbia conduct routine inspections of traditional pharmacies that perform sterile compounding for humans in their respective states at least annually. Four states conduct routine inspections of in-state facilities at least every 18 months, eight states at least every two years, one state at least every three years, and another state at least every five years. Nine states inspect with no specific stated frequency. North Carolina conducts routine inspections based on sterile compounding risk level: annually for high risk, biennially for medium risk, and at least every four years for low risk, although the state's board of pharmacy reports that the frequency of routine inspections for pharmacies engaged in low-risk sterile compounding is typically more often than every four years. Colorado conducts routine inspections at least annually but inspects pharmacies engaged in high-risk sterile compounding at least every six months.

It appears that states may be inspecting traditional pharmacies less frequently now than in 2015. Then, 26 states and the District of Columbia conducted routine inspections at least annually for in-state pharmacies that perform sterile compounding; now just 22 states and the District do so. This may be due to resource constraints. Representatives from all four state boards of pharmacy interviewed for this report described the need for more resources and inspection capacity.

The circumstances that state boards of pharmacy report most commonly trigger state pharmacy inspections are initial licensure, when a pharmacy remodels or moves, and when a complaint or incident occurs. Other circumstances include licensure renewal and random inspections. Missouri may inspect pharmacies if the risk level of activity changes.

Inspector education and training

Sterile compounding is a complex technical practice. To effectively identify areas of concern, best practice recommendations detail inspector qualifications: State and third-party inspectors of sterile compounding pharmacies should be educated and trained to examine the type of facility they are reviewing.[21]

Some states have turned to the National Association of Boards of Pharmacy (NABP) for inspection assistance. For example, after the 2012-13 fungal meningitis outbreak, New Jersey thoroughly reviewed all of its pharmacies and subsequently requested that NABP provide assistance with training and inspections. A New Jersey inspector accompanied NABP representatives on an inspection of every pharmacy in the state. Many states have used training provided by CriticalPoint LLC, a company that offers a hands-on training program tailored for state inspectors.[22]

In some states, pharmacy inspectors are not specialists in compounding or even in the practice of pharmacy. In such states, the same staff members may investigate compliance in several professions.

Out-of-state pharmacies

State boards of pharmacy also regulate compounders shipping drugs into their respective states, often referred to as out-of-state or nonresident pharmacies. Oversight of out-of-state pharmacies varies. Many state boards of pharmacy are concerned about nonresident pharmacies, especially those shipping in large quantities of compounded drugs, and have taken, or are taking, action to strengthen oversight of out-of-state facilities.

Best practice recommendations published in 2016 instruct states to hold out-of-state traditional compounding pharmacies that ship into the state to USP quality standards at a minimum and subject out-of-state pharmacies to the same frequency of inspections as in-state pharmacies, whether conducted by the state or a third party.[23]

Quality standards for nonresident pharmacies

Twenty-four states require out-of-state pharmacies that ship products into their states to comply with their own state's sterile compounding quality standards. In other words, if the state requires in-state pharmacies to comply with USP Chapter <797>, the state also requires out-of-state pharmacies to comply with it. Ten states and the District of Columbia require out-of-state pharmacies to comply with the quality standards of the jurisdiction where the pharmacy is located. Four states require nonresident pharmacies to comply with both their state's quality standards and the quality standards of the state where the pharmacy is located. The Idaho State Board of Pharmacy will permit an out-of-state pharmacy to ship compounded drugs to Idaho if the board determines, evidenced by an inspection report, that the other state's standards are comparable to Idaho's and acceptable to the board.[24]

Inspections of nonresident pharmacies

Forty-one states and the District of Columbia require out-of-state traditional pharmacies that perform sterile compounding for humans to be inspected, though the frequency of required inspections varies. Fourteen states said they do not specify the frequency with which out-of-state traditional pharmacies must be inspected. Fourteen states require inspections at least every two years, two states require inspections at least every year, two states at least every 18 months, and one state at least every five years. Arizona, North Carolina, and Washington report requiring nonresident traditional pharmacies that perform sterile compounding for humans to be inspected based on their respective home state's inspection schedule.

Responsibility for conducting inspections of out-of-state traditional pharmacies varies by state. The majority of state boards of pharmacy that require nonresident pharmacies to be inspected report that they rely on inspections conducted by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located. However, California reports that it conducts its own inspections of out-of-state pharmacies. Some states said they rely on third parties to conduct these inspections. For example, Texas requires out-of-state pharmacies to be inspected by either the Texas State Board of Pharmacy or one of three third-party organizations: Accreditation Commission for Health Care Inc., NABP, or Superior Laboratory Services Inc.

Even without formal inspection authority, state boards may employ mechanisms to learn more about nonresident pharmacies shipping into the state. For example, the New Jersey State Board of Pharmacy does not have legal authority to inspect out-of-state pharmacies. In an effort to collect the same information about the policies and procedures of both in-state and out-of-state traditional pharmacies that perform sterile compounding, the board requires all pharmacies engaging in sterile compounding to fill out a comprehensive questionnaire before licensure.

Representatives from all four state boards of pharmacy interviewed for this report identified concerns about interstate shipment of compounded drugs. Lack of harmonization of inspection forms and processes is a challenge for state boards trying to assess sterile compounding oversight in sister states.

NABP is spearheading an effort to standardize pharmacy inspections across states. After seeking input from state boards of pharmacy, the organization created the multistate pharmacy inspection blueprint program. Its goal is to bring uniformity to sterile compounding pharmacy inspections while also allowing state boards of pharmacy to ensure compliance with their own state-specific requirements.[25]

The blueprint program helps state regulators make decisions about licensure of out-of-state pharmacies. Pharmacies in "blueprint states" are inspected at least every 18 months and meet minimum standards that aim to ensure a safe supply of compounded medications. To become a blueprint state, a state board of pharmacy can have NABP compare its inspection forms to the blueprint to ensure that it covers minimum standards, or it can use NABP's universal inspection form. NABP began enlisting participation in the blueprint program in December 2016. Ten states have signed on, and more than 20 others are actively considering participation.

Recommendations

Across states, policy implementation and enforcement efforts are underway to better ensure a safe supply of compounded drugs. However, additional efforts could accomplish even more.

In general, states should continue to examine existing systems closely and address any gaps to align with the best practices identified in concert with Pew's advisory committee of state regulators and other experts and published in 2016.[26] Specific recommended emphasis areas arising from this research include the following:

- Regardless of where sterile compounding occurs, quality assurance is critical. States should require traditional compounders to comply, at minimum, with all applicable USP standards. States should ensure that any future revisions of USP standards are reflected in state requirements.
- States that permit traditional compounders to produce office stock should align their policies with federal law and guidance on dispensing/distributing without prescriptions. To facilitate alignment with this best practice without driving compounding activity into settings with less oversight, states should move toward meaningful regulation of sterile compounding that occurs in physicians' offices. (While compounding by practitioners other than pharmacists and physicians is outside of the scope of Section 503A of the FDCA and thus not addressed in this report, consistent oversight in all settings where compounding occurs would mitigate the risk of pushing compounding activity into settings that may not meet appropriate quality standards.)
- States whose inspectors have not been able to inspect sterile compounding facilities annually should ensure that oversight boards effectively utilize personnel and resources. In any situation, but particularly when resources are limited, states should prioritize inspections using a risk-based approach in which oversight of higher-risk activities, such as preparing sterile drugs using nonsterile starting ingredients, are subject to more frequent inspection. Mechanisms to harmonize inspections of out-of-state pharmacies, such as the multistate pharmacy inspection blueprint program, can also help states use resources more efficiently by facilitating reliance on other states' inspections.
- Since the last assessment, new options for inspector training have been developed. Through these or other means, best practices we published in 2016 recommend that states require inspectors of sterile compounding pharmacies to be educated and trained to examine the type of facility they are reviewing.

Conclusion

The 2016 best practices document—developed in 2014 by an advisory committee of state regulators and other experts, and published alongside Pew's first assessment of state policy in 2016—identified the most important state practices in the regulation of compounding. Although 2013 federal legislation created a new role for FDA to oversee compounding facilities that produce stock supplies of drugs without prescriptions, states remain the primary regulators of traditional pharmacy compounding. As such, states are responsible for establishing appropriate oversight systems to protect patients from the risk of contaminated or substandard compounded products.

The significant progress in adoption of USP Chapter <797> quality standards and harmonizing policies on compounding without prescriptions with federal law suggest a key opportunity for jurisdictions that have not yet adopted those best practices to come into line with the majority that have. Improvements in inspection frequency for facilities that perform sterile compounding will require resources, but interim measures such as harmonizing inspection forms and processes among states may enhance efficiencies and allow states to optimize use of existing resources.

Appendix A: Methodology and characteristics of participating states

Methodology

The research team used publicly available sources, such as websites for state boards of pharmacy, to assess state policies regarding oversight of sterile drug compounding. The team then developed a questionnaire (see Appendix B) to standardize the format of information it collected. After pre-populating the questionnaire with the data it had collected, the team asked each state board of pharmacy to verify or correct the pre-populated answers.

To determine whether a state's quality standards that did not explicitly require compliance with USP Chapter <797> were potentially equivalent to USP's requirements and should be indicated as such on the pre-populated questionnaire, a licensed pharmacist on Pew's staff compared the state requirements to USP. If the state's requirements were judged to be at least as restrictive as those in Chapter <797>—even if they were different from, less specific than, or missing certain provisions from <797>—that state was identified as potentially having equivalent quality standards. States were then asked to verify whether Pew's determination was accurate. Ten of the 11 states identified as having standards potentially equivalent to USP verified that their policies were indeed equivalent to or stricter than the correlating requirements of USP; one state did not respond. In this report, each of these 11 states is characterized as having strong standards.

When reviewing the states' data verification responses, the research team discovered that a question about office stock policies had been interpreted differently by similarly situated states. Specifically, several states with laws permitting compounding for office stock—but which prohibit the practice in accordance with federal law—responded in different ways. Some indicated that office stock was allowed, and others indicated that it was not. Consequently, to ensure that the results accurately reflected state policy, the research team added a step to its data verification process. It followed up with states to clarify whether they prohibit traditional pharmacies from office stock compounding for human use under state law or because they consider the federal law to override state law.

The research team also interviewed personnel from four state boards of pharmacy to gain a qualitative understanding of state oversight of drug compounding, including any oversight gaps or other issues that may create ongoing risks to patient safety. The research team had randomly selected 10 states from which it would request interviews, and officials from the four states interviewed were those that agreed to participate.

Characteristics of participating states

Boards of pharmacy from 43 states and the District of Columbia responded to the research team's request to verify or correct the data collected about their oversight of sterile drug compounding. The respondents were generally representative of the main U.S. census regions: Northeast (six of nine states, or 67 percent), Midwest (11 of 12 states, or 92 percent), South (13 states and the District of Columbia, of the region comprising 16 states and the District of Columbia, or 82 percent), and West (all 13 states, or 100 percent). According to 2016 census data, the states that responded represented the majority of the population in each region: Northeast (69 percent), Midwest (81 percent), South (78 percent), and West (100 percent). Four state boards of pharmacy agreed to be interviewed for this report: those in California, Iowa, New Jersey, and New York. States in three of

the four main census regions were represented in the interviews (Northeast, Midwest, and West). Three state boards of pharmacy from the South were randomly selected for interviews but either declined to participate or did not respond to a request for an interview.

Results from data collection and subsequent verification by state boards of pharmacy, as well as from interviews with officials from the four states, are described and discussed in this report. Data from all states are available in Appendix C.

Study limitations

This study had a couple of limitations. First, although it achieved a state verification rate of more than 85 percent from the 50 states and the District of Columbia, seven states did not respond to the research team's request to verify or correct the data collected about their state's oversight of sterile drug compounding.

Second, state boards of pharmacy are responsible for defining state oversight of pharmacy compounding practice, and representatives from these regulatory bodies should thus be authorities on the most current status in their jurisdictions. The authors are therefore confident that respondents participating in this study were among the most appropriate and knowledgeable sources to verify information on current state oversight practices. Nonetheless, it is possible that another authority could interpret the policies differently from the state boards of pharmacy.

Appendix B: Questionnaire

Instructions: Please verify the answers to the questions below. If an answer is not accurate, please correct it and return this form with the correct answers.

U.S. Pharmacopeia (USP) Chapter <797>

- Does your state require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP Chapter <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP Chapter <797>)?

☐ Full compliance with USP Chapter <797>
☐Equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP Chapter <797>)
☐No

- If yes, what is the legislation or regulation that mandates full compliance with USP Chapter <797> or equivalent quality standards?

☐ Name of legislation or regulation _____
☐N/A

- If yes, will legislative or regulatory change be needed to require compliance with the updated version of USP Chapter <797> when it is finished? *(Please note that if the answer to this question was unclear or ambiguous to us based on reading the legislation or regulation that mandates full compliance with USP Chapter <797> or equivalent quality standards in your state, we defaulted to no.)*

☐Yes
☐No
☐N/A

- If no, does your state require 503A pharmacies that compound sterile drugs for humans to comply with quality standards?

☐ Yes
☐No
☐N/A

- If yes, what is the legislation or regulation that mandates these standards?

☐Name of legislation or regulation _____
☐N/A

Office stock

- Does your state allow 503A pharmacies (pharmacies that are not registered with the U.S. Food and Drug Administration (FDA) as outsourcing facilities) to compound sterile drugs for humans in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's **prescription requirement guidance for industry**)?

  ☐Yes
  ☐No

  - If no, what is the legislation, regulation, or board of pharmacy or state document that prohibits 503A pharmacies from compounding sterile drugs for humans in the absence of patient-specific prescriptions?

    ☐ Name of legislation, regulation, or board of pharmacy or state document _____
    ☐N/A

  - If no, does your state allow 503A pharmacies to compound nonsterile drugs for humans in the absence of patient-specific prescriptions (outside of anticipatory compounding)?

    ☐ Yes
    ☐No
    ☐N/A

  - If yes, does your state apply specific limits on 503A pharmacies compounding sterile drugs for humans in the absence of patient-specific prescriptions?

    ☐ Yes
    ☐No
    ☐N/A

    - If yes, what are the limits? Check all that apply.

      ☐Limited quantities, specify _____
      ☐Limited distribution, specify _____
      ☐For in-office administration only, specify _____
      ☐With special agreement approved by the board of pharmacy, specify _____
      ☐Other, specify _____
      ☐N/A

    - If yes, what is the legislation or regulation that specifies these limits?

      ☐ Name of legislation or regulation _____
      ☐N/A

Outsourcing facilities

- Does your state license or register facilities that register with the FDA under the new federal outsourcing facility category of drug compounders?

  ☐Yes
  ☐No

  - If yes, how does your state license or register these facilities? Check all that apply.

    ☐ License or register as pharmacy (if facility compounds patient-specific prescriptions)
    ☐ License or register as outsourcing facility
    ☐License or register as manufacturer
    ☐License or register as wholesale distributor
    ☐Other, specify _____
    ☐N/A

  - If yes, what is the legislation, regulation, or board of pharmacy or state document that requires such licensure or registration?

    ☐ Name of legislation, regulation, or board of pharmacy or state document _____
    ☐N/A

  - If yes, is there a fee for licensure or registration?

    ☐ Yes
    ☐No
    ☐N/A

    - If yes, what is the fee for initial licensure or registration?

      ☐ $_____
      ☐N/A

    - If yes, what is the fee for licensure or registration renewal?
      ☐$_____
      ☐N/A

In-state inspections

- How frequently does your state conduct routine inspections for in-state 503A pharmacies that perform sterile compounding for humans? *(Please note that we answered this question with the answer reported in the National Assessment of State Oversight of Sterile Drug Compounding.)*

☐ At least every year
☐At least every 18 months
☐At least every two years
☐No specific frequency
☐Other, specify _____

- What specific circumstances trigger your state to conduct inspections for in-state 503A pharmacies that perform sterile compounding for humans? Check all that apply. *(Please note that we answered this question with the answer reported in the National Assessment of State Oversight of Sterile Drug Compounding.)*

☐ Initial licensure
☐Licensure renewal
☐When a pharmacy remodels or moves location
☐When a complaint or incident occurs
☐Other, specify _____

Out-of-state inspections

- For out-of-state 503A pharmacies that perform sterile compounding for humans, which quality standards does your state require?

☐ Your state requires an out-of-state 503A pharmacy to comply with your state's sterile compounding quality standards
☐Your state requires an out-of-state 503A pharmacy to comply with the sterile compounding quality standards of the state where the pharmacy is located
☐Other, specify _____

- Does your state require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected?

☐ Yes
☐No

- If yes, how frequently?

☐ At least every year
☐At least every 18 months
☐At least every two years
☐No specific frequency
☐Other, specify _____
☐N/A

- If yes, who performs the inspections? Check all that apply.

☐ Your state
☐The regulatory or licensing agency of the jurisdiction in which the pharmacy is located
☐Third party, specify _____
☐Other, specify _____
☐N/A

Pending policy changes

- Does your state have pending legislation or regulations related to oversight of sterile compounding for humans?

☐Yes
☐No

- If yes, what would the pending legislation or regulation do if passed? Check all that apply.

☐ Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP Chapter <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP Chapter <797>)
☐Prohibit 503A pharmacies (pharmacies that are not registered with FDA as outsourcing facilities) from compounding sterile drugs for humans in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's **prescription requirement guidance for industry**)
☐Prohibit 503A pharmacies from compounding nonsterile drugs for humans in the absence of patient-specific prescriptions (outside of anticipatory compounding)
☐License or register facilities that register with the FDA under the new federal outsourcing facility category of drug compounders

- If so, how would your state license or register these facilities? Check all that apply.

☐ License or register as pharmacy (if facility compounds patient-specific prescriptions)
☐License or register as outsourcing facility
☐License or register as manufacturer
☐License or register as wholesale distributor
☐Other, specify _____

☐Require out-of-state 503A pharmacies that perform sterile compounding for humans to comply with your state's sterile compounding quality standards

☐Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected

- If so, how frequently?

☐ At least every year
☐At least every 18 months
☐At least every two years
☐No specific frequency
☐Other, specify _____

- If so, who would perform the inspections? Check all that apply.

☐ Your state
☐The regulatory or licensing agency of the jurisdiction in which the pharmacy is located
☐Third party, specify _____
☐Other, specify _____

☐Other, specify_____
☐N/A

Appendix C: Complete tables of state oversight of sterile compounding

Forty-three state boards of pharmacy and the District of Columbia Board of Pharmacy responded to the research team's request to verify that the data collected about their respective state's oversight of sterile drug compounding were accurate, and/or to correct any inaccurate information. Seven states (Alabama, Connecticut, Delaware, Florida, Illinois, Maine, and Pennsylvania) did not verify that the data collected were accurate.

Table C.1

Quality Standards for 503A Pharmacies That Compound Sterile Drugs for Humans

	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	**Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished**	**Requires compliance with other quality standards** (Source of requirement)	**Pending legislation or regulation and what it would do if passed**
Alabama	No	N/A	Yes (Code of Alabama, Title 34, Chapter 23, Practice of Pharmacy Act 205, Pharmacists and Pharmacies, Article 7. Compounding of Drugs)	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Alaska	No	N/A	Yes (12 Alaska Administrative Code, Chapter 52. Board of Pharmacy, Article 4. Guidelines for Pharmacies and Pharmacists, 440. Guidelines Relating to Compounding Practices)	N/A
Arizona	Full compliance with USP <797> (Arizona Revised Statutes, Pharmacy Act: Title 32—Chapter 18, Article 1 Board of Pharmacy: 32-1901. Definitions)	No	N/A	N/A
Arkansas	Equivalent quality standards (Arkansas State Board of Pharmacy, Regulation 7: Drug Products/ Prescriptions, 07-02 Compounding)	Yes	N/A	N/A
California	Equivalent quality standards (California Code of Regulations, Division 17, Title 16, Article 7. Sterile Compounding)	Yes	N/A	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Colorado	Equivalent quality standards (Department of Regulatory Agencies, State Board of Pharmacy Rules, Rule 21.00.00, Compounding, Code of Colorado Regulations 719-1, 21.00.00 Compounding)	No	N/A	N/A

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	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished	Requires compliance with other quality standards (Source of requirement)	Pending legislation or regulation and what it would do if passed
Connecticut	Full compliance with USP <797> (Connecticut General Statutes Annotated, Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration. Examining Boards, Chapter 400J. Pharmacy, Part III. Practice of Pharmacy, § 20-633b. Sterile compounding pharmacies. Requirements. Regulations)	No	N/A	N/A
Delaware	Full compliance with USP <797> (Delaware Regulations, Administrative Code, Title 24, 2500 Board of Pharmacy, 10.0 Pharmaceutical Compounding, 10.1 Non-Sterile and Sterile Preparations)	No	N/A	N/A
District of Columbia	No	N/A	Yes (Title 22 District of Columbia Municipal Regulation, Chapter 19. Pharmacies)	N/A
Florida	Full compliance with USP <797> (Rule Chapter: 64B16-27: Pharmacy Practice, 64B16-27.797 The Standards of Practice for Compounding Sterile Products)	Yes	N/A	N/A
Georgia	Full compliance with USP <797> (Rules and Regulations of the State of Georgia, Chapter 480-11-.02(5) and (8) Pharmaceutical Compounding)	No	N/A	N/A
Hawaii	Full compliance with USP <797> (Hawaii Administrative Rules, Title 16 Department of Commerce and Consumer Affairs, Chapter 95 Pharmacists and Pharmacies, Subchapter 13 Disciplinary Sanctions, Application Denial, Hearings, Administrative Practice and Procedure, §16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit)	No	N/A	N/A
Idaho	No	N/A	Yes (Idaho Administrative Code, Idaho Administrative Procedures Act, 27—Board of Pharmacy, 27.01.01.—Rules of the Idaho State Board of Pharmacy, Subchapter C—General Practice Standards, 239. Compounding Drug Products)	N/A
Illinois	Equivalent quality standards (Administrative Code, Title 68: Professions and Occupations, Chapter VII: Department of Financial and Professional Regulation, Subchapter b: Professions and Occupations, Part 1330 Pharmacy Practice Act, Section 1330.670 Compounded Sterile Preparation Standards)	Yes	N/A	N/A
Indiana	Full compliance with USP <797> (Title 856 Indiana Board of Pharmacy, Article 1. Pharmacies and Pharmacists, Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing)	Yes	N/A	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards

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	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished	Requires compliance with other quality standards (Source of requirement)	Pending legislation or regulation and what it would do if passed
Iowa	Full compliance with USP <797> (Iowa Administrative Code, Pharmacy Board [657], Chapter 20 Compounding Practices, 657—20.4(124,126,155A) Sterile compounding)	No	N/A	N/A
Kansas	No	N/A	No	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Kentucky	Full compliance with USP <797> (Kentucky Revised Statutes Chapter 217.015 Definitions for KRS 217.005 to 217.215; 201 KAR 2:076)	Yes	N/A	N/A
Louisiana	Full compliance with USP <797> (Louisiana Administrative Code, Title 46—Professional and Occupational Standards, Part LIII: Pharmacists, Chapter 25. Prescriptions, Drugs, and Devices, Subchapter C. Compounding of Drugs, §2535. General Standards)	Yes	N/A	N/A
Maine	Full compliance with USP <797> (State of Maine Rules for the Department of Professional and Financial Regulation, Chapter 02-392: Maine Board of Pharmacy, Chapter 37: Licensure of Sterile Compounding Pharmacies)	Yes	N/A	N/A
Maryland	Full compliance with USP <797> (Code of Maryland Regulations, Title 10 Department of Health and Mental Hygiene, Subtitle 34 Board of Pharmacy, Chapter 19 Sterile Pharmaceutical Compounding)	No	N/A	N/A
Massachusetts	Full compliance with USP <797> (M.G.L. c 112, § 39G and 247 CMR 9.01(3))	No	N/A	The Board of Registration in Pharmacy has pending regulations in the form of 247 CMR 17.00: Sterile Compounding. This pending regulation will clarify USP <797> standards, provide greater instruction for licensees, and in some cases go above and beyond USP <797>.
Michigan	Full compliance with USP <797> (Public Health Code, Act 368 of 1978, Part 177 Pharmacy Practice and Drug Control, Section 333.17748a Compounding services for sterile pharmaceuticals; accreditation; notification of complaint; maintenance and retention of records; resale of excess compounded pharmaceuticals prohibited; distribution of samples or complimentary starter doses; advertisement or promotion of compounding services; compounding pharmaceutical that is unavailable in marketplace; compounding and manufacturing at same location; rules)	No	N/A	N/A
Minnesota	Full compliance with USP <797> (Minnesota Administrative Rules, 6800.3300 Compounding Standards, Subp. 2. Standards for sterile compounding)	No	N/A	N/A

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	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished	Requires compliance with other quality standards (Source of requirement)	Pending legislation or regulation and what it would do if passed
Mississippi	Full compliance with USP <797> (Title 30: Professions and Occupations, Part 3001: Mississippi Pharmacy Practice Regulations, Article XXVIII Regulations for Preparation of Sterile Pharmaceuticals)	No	N/A	N/A
Missouri	Equivalent quality standards (Rules of Department of Insurance, Financial Institutions and Professional Registration, Division 2220—State Board of Pharmacy, Chapter 2—General Rules, 20 Code of State Regulations 2220-2.200 Sterile Compounding)	Yes	N/A	N/A
Montana	Full compliance with USP <797> (Rule Chapter: 24.174: Board of Pharmacy, Subchapter 8 Pharmacies, 24.174.841 Sterile Products)	Yes	N/A	N/A
Nebraska	Full compliance with USP <797> (State of Nebraska, Statutes Relating to Pharmacy Practice Act, 38-2867. Pharmacy; scope of practice; prohibited acts; violation; penalty, 38-2867.01. Authority to compound; standards; labeling; prohibited acts)	Yes	N/A	N/A
Nevada	Equivalent quality standards (Nevada Administrative Code, Chapter 639—Pharmacists and Pharmacy, Compounding and Dispensing Drug Products)	Yes	N/A	N/A
New Hampshire	Full compliance with USP <797> (Administrative Rules, Chapter Ph 100 Organizational Rules, Part Ph 404 Standards for Compounding and Dispensing Sterile and Non-Sterile Pharmaceuticals)	No	N/A	N/A
New Jersey	Equivalent quality standards (New Jersey Administrative Code, Title 13 Law and Public Safety, Chapter 39 State Board of Pharmacy, Subchapter 11. Compounding Sterile Preparations in Retail and Institutional Pharmacies; Regulations also address Hazardous Compounding in New Jersey Administrative Code, Title 13 Law and Public Safety, Chapter 39 State Board of Pharmacy, Subchapter 11B Compounding of antineoplastic agents and other hazardous substances)	Yes	N/A	N/A
New Mexico	Full compliance with USP <797> (New Mexico Statutes Annotated, Chapter 26 Drugs and Cosmetics, Article 1 General Provisions, Section 26-1-2. Definitions)	No	N/A	N/A
New York	No	N/A	Yes (Title 8 NYCRR in 29.1 and 29.2 A14 and Education Law, Article 137)	N/A

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	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished	Requires compliance with other quality standards (Source of requirement)	Pending legislation or regulation and what it would do if passed
North Carolina	Full compliance with USP <797> (North Carolina Administrative Code, Board of Pharmacy—Pharmacy Rules, Section .2800—Compounding, 21 NCAC 46 .2801 Compounding)	No	N/A	N/A
North Dakota	Full compliance with USP <797> (Administrative Code (Rules/Regulations), Chapter 61-02-01 Pharmacy Permits, Section 61-02-01-03. Pharmaceutical compounding standards)	Yes	N/A	N/A
Ohio	Full compliance with USP <797> (Ohio Administrative Code, 4729 State Board of Pharmacy, Chapter 4729-16 Drug Compounding, 4729-16-03 Drugs compounded in a pharmacy)	Yes	N/A	N/A
Oklahoma	Full compliance with USP <797> (Oklahoma Administrative Code, Title 535. Oklahoma State Board of Pharmacy, Chapter 15. Pharmacies, Subchapter 10. Good Compounding Practices, Part 3. Good Compounding Practices for Sterile Products)	Yes	N/A	N/A
Oregon	No	N/A	Yes (Oregon Administrative Rules, Board of Pharmacy, Division 45 Sterile and Non-Sterile Compounding)	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Pennsylvania	No	N/A	Yes (The Pennsylvania Code, Chapter 27. State Board of Pharmacy)	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Rhode Island	Equivalent quality standards (Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19.1-PHAR], Part IV Specialized Pharmacy Practice, Section 19.0 Compounding of Pharmaceuticals)	Yes	N/A	N/A
South Carolina	Full compliance with USP <797> (South Carolina Board of Pharmacy Policies & Procedures, Sterile Compounding Policy and Procedure #137)	No	N/A	N/A
South Dakota	Equivalent quality standards (Administrative Rules of South Dakota, Article 20:51 Pharmacists, Chapter 20:51:31, Sterile Compounding Practices)	Yes	N/A	Require 503A pharmacies that compound sterile drugs for humans to be in full compliance with USP <797> or equivalent quality standards
Tennessee	Full compliance with USP <797> (Rules of the Tennessee Board of Pharmacy, Chapter 1140-07 Sterile Product Preparation in Pharmacy Practice)	No	N/A	N/A

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	Requires full compliance with USP <797> or equivalent quality standards (i.e., state requirements on sterile compounding practice are equivalent to or stricter than the correlating requirements of USP <797>) (Source of requirement)	Legislative or regulatory change will be needed to require compliance with the updated version of USP <797> when it is finished	Requires compliance with other quality standards (Source of requirement)	Pending legislation or regulation and what it would do if passed
Texas	Equivalent quality standards (Texas Administrative Code, Title 22 Examining Boards, Part 15 Texas State Board of Pharmacy, Chapter 291 Pharmacies, Subchapter G Services Provided by Pharmacies, Rule §291.133 Pharmacies Compounding Sterile Preparations)	Yes	N/A	N/A
Utah	Full compliance with USP <797> (R156. Commerce, Occupational and Professional Licensing, R156-17b. Pharmacy Practice Act Rule, R156-17b-614a. Operating Standards—General Operating Standards, Class A and B Pharmacy)	No	N/A	N/A
Vermont	Full compliance with USP <797> (Administrative Rules of the Board of Pharmacy, Part 13 Sterile Pharmaceuticals, 13.22 USP 797 Compliance for Compounded Sterile Products)	No	N/A	N/A
Virginia	Full compliance with USP <797> (Commonwealth of Virginia, Chapter 20 Regulations Governing the Practice of Pharmacy, Part VII. Prescription Order And Dispensing Standards, 18VAC110-20-321. Compounding and Chapter 34 of Title 54.1 of the Code of Virginia, The Drug Control Act, §54.1-3410.2 Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements)	No	N/A	N/A
Washington	Full compliance with USP <797> (Revised Code of Washington, Chapter 18.64 Pharmacists, Section 18.64.270 Responsibility for drug purity—Compounding—Adulteration—Penalty)	Yes	N/A	N/A
West Virginia	Full compliance with USP <797> (Title 15 Legislative Rule West Virginia Board of Pharmacy, Series 1 Licensure and Practice of Pharmacy, § 15-1-16. Sterile Pharmaceutical Compounding)	No	N/A	N/A
Wisconsin	Equivalent quality standards (Wisconsin Administrative Code, Pharmacy Examining Board, Chapter Phar 15 Sterile Pharmaceuticals)	Yes	N/A	N/A
Wyoming	Full compliance with USP <797> (State of Wyoming Pharmacy Act Rules and Regulations, Chapter 17 Sterile Compounding)	Yes	N/A	N/A

Table C.2

Policies on 503A Pharmacies Compounding Drugs for Humans in the Absence of Patient-Specific Prescriptions

	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Alabama	No, restricts through state guidance (Alabama Board of Pharmacy Sterile Compounding Frequently Asked Questions)	No	N/A	N/A
Alaska	No, restricts through state law or regulation (AS 08.80 Pharmacists and Pharmacies Statutes)	No	N/A	N/A
Arizona	Yes	N/A	Limited quantities: Not to exceed five percent of the pharmacy's gross sales (Article 3.1 Regulation of Full Service Wholesale Permittees, 32-1981. Definitions)	N/A
Arkansas	No, advises pharmacies to follow federal law through informal state board of pharmacy communication (Board advises all 503A facilities that to do non-patient-specific human compounding without a 503B permit would be a violation of FDA rules so they cannot do so.)	No	N/A	N/A
California	Yes	N/A	Limited quantities: A reasonable quantity, which means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and is sufficient for administration or application to patients solely in the prescriber's office; and that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and with regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with 241 pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and does not exceed an amount the pharmacy can reasonably and safely compound For in-office administration only: Administration or application to patients solely in the prescriber's office (California Code of Regulations, Division 17, Title 16, Article 4.5 Compounding, Section 1735.2. Compounding Limitations and Requirements; Self-Assessment)	N/A
Colorado	Yes	N/A	Limited quantities: For in-state pharmacies only—10 percent of the total number of dosage units dispensed and distributed in a calendar year (Section 12-42.5-118(6), C.R.S. and Board Rule 21.00.00)	N/A

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Connecticut	No, restricts through state law or regulation (Connecticut General Statutes Annotated, Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration. Examining Boards, Chapter 400J. Pharmacy, Part III. Practice of Pharmacy, § 20-633b. Sterile compounding pharmacies. Requirements. Regulations)	Yes	N/A	N/A
Delaware	No, restricts through state law or regulation (Delaware Regulations, Administrative Code, Title 24, 2500 Board of Pharmacy, 5.0 Dispensing)	No	N/A	N/A
District of Columbia	No, restricts through state law or regulation (Title 22 District of Columbia Municipal Regulation, Chapter 19. Pharmacies, Sec 1999 Definitions)	No	N/A	N/A
Florida	No, restricts through state law or regulation (Rule Chapter: 64B16-27: Pharmacy Practice, 64B16-27.700 Definition of Compounding)	Yes	N/A	N/A
Georgia	No, restricts through state guidance (State of Georgia Drugs and Narcotics Agency 2016 letter)	No	N/A	N/A
Hawaii	No, restricts through state law or regulation (Board of Pharmacy interpretation of various pharmacy laws/rules that a valid prescription that is patient-specific is required for any pharmacies to dispense a prescription drug)	No	N/A	N/A
Idaho	No, restricts through state law or regulation (Idaho Administrative Code, Idaho Administrative Procedures Act, 27—Board of Pharmacy, 27.01.01.—Rules of the Idaho State Board of Pharmacy, Subchapter E—Drug Outlet Practice Standards, 615. Drug Distribution)	Yes	N/A	N/A
Illinois	No, restricts through state law or regulation (Title 68: Professions and Occupations Chapter VII: Department of Financial and Professional Regulation Subchapter B: Professions and Occupations Part 1330 Pharmacy Practice Act Section 1330.640 Pharmaceutical Compounding Standards)	No	N/A	N/A
Indiana	No, restricts through state law or regulation (Title 856 Indiana Board of Pharmacy, Article 1. Pharmacies and Pharmacists, Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing)	Yes	N/A	N/A
Iowa	No, restricts through state law or regulation (Iowa Administrative Code, Pharmacy Board [657], Chapter 20 Compounding Practices, 657—20.15(124,126,155A) Compounding for office use)	No	N/A	N/A

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Kansas	Yes	N/A	Limited quantities: Minimal quantities of drugs (Pharmacy Practice Act—Statutes, Chapter 65.—Public Health, Article 16.—Regulation of Pharmacists, 65-1626. Definitions)	N/A
Kentucky	No, restricts through state guidance (Kentucky Board of Pharmacy Compounding FAQs)	No	N/A	N/A
Louisiana	No, restricts through state law or regulation (Louisiana Administrative Code, Title 46—Professional and Occupational Standards, Part LIII: Pharmacists, Chapter 25. Prescriptions, Drugs, and Devices, Subchapter C. Compounding of Drugs, §2535. General Standards)	No	N/A	N/A
Maine	No, restricts through state law or regulation (32 MRS § 13702-A(4))	No	N/A	N/A
Maryland	No, restricts through state law or regulation (Code of Maryland Regulations, Title 10 Department of Health and Mental Hygiene, Subtitle 34 Board of Pharmacy, Chapter 19 Sterile Pharmaceutical Compounding, .19 Office Use)	Yes	N/A	N/A
Massachusetts	No, restricts through state law or regulation (M.G.L. c 112, § 39F; M.G.L. c. 94C §17)	No	N/A	N/A
Michigan	Yes	N/A	Limited quantities: Limited quantities For in-office administration only: For a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients With special agreement approved by the board of pharmacy: Upon application by a pharmacist or compounding pharmacy, the department may authorize the pharmacist or compounding pharmacy (Public Health Code, Act 368 of 1978, Part 177 Pharmacy Practice and Drug Control, Section 333.17748b Compounding nonsterile or sterile pharmaceuticals for prescriber or health facility or agency to administer to patients without prescription; authorization; report of adverse event; list of authorized pharmacies and pharmacists; selling or redispensing to prescriber or health facility or agency)	N/A
Minnesota	No, restricts through state law or regulation (Minnesota Statute §151.01, subd. 35, definition of Compounding, and Minnesota Administrative rules, 6800.3100 Compounding and Dispensing)	No	N/A	N/A
Mississippi	No, restricts through state law or regulation (Title 30: Professions and Occupations, Part 3001: Mississippi Pharmacy Practice Regulations, Article XXXI Compounding Guidelines)	No	N/A	N/A

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Missouri	No, restricts through state law or regulation (Rules of Department of Insurance, Financial Institutions and Professional Registration, Division 2220—State Board of Pharmacy, Chapter 2—General Rules, 20 Code of State Regulations 2220-2.400 Compounding Standards of Practice)	No	N/A	N/A
Montana	No, restricts through state law or regulation (Statute: 37-7-101(9), MCA, 37-7-101(39), MCA; Rule: ARM 24.174.831)	No	N/A	N/A
Nebraska	No, restricts through state guidance (Pharmacies should be FDA-registered outsourcing facilities to comply with federal regulations per Board meeting minutes)	No	N/A	N/A
Nevada	Yes	N/A	For in-office administration only: A pharmacy may compound for administration by a practitioner (office use) (Nevada Administrative Code, Chapter 639—Pharmacists and Pharmacy, Compounding and Dispensing Drug Products)	N/A
New Hampshire	Yes	N/A	Limited quantities: A batch with 50 or less dosage units For in-office administration only: Compounding includes preparation of drugs and devices on the order of a practitioner, which may be sold to the practitioner for use in his or her office to administer to a specific patient, but not for resale (Administrative Rules, Chapter Ph 100 Organizational Rules, Part Ph 404 Standards for Compounding and Dispensing Sterile and Non-Sterile Pharmaceuticals)	N/A
New Jersey	No, restricts through state law or regulation (New Jersey Administrative Code, Title 13 Law and Public Safety, Chapter 39 State Board of Pharmacy, Subchapter 11. Compounding Sterile Preparations in Retail and Institutional Pharmacies 13:39-11.18 Compounded Sterile Preparations for Prescriber Practice Use)	No	N/A	N/A
New Mexico	No, restricts through state law or regulation (16.19.36 NMAC)	No	N/A	N/A
New York	No, restricts through state law or regulation (Education Law, Article 137, Pharmacy)	No	N/A	N/A
North Carolina	No, restricts through state law or regulation (North Carolina Administrative Code, Board of Pharmacy—Pharmacy Rules, Section .2800—Compounding, 21 NCAC 46 .2801 Compounding; federal Drug Quality and Security Act)	No	N/A	N/A
North Dakota	No, advises pharmacies to follow federal law through informal state board of pharmacy communication (Federal law pre-empts our state law and communicating through multiple channels)	No	N/A	N/A

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Ohio	No, restricts through state law or regulation (Rule 4729-16-03)	No	N/A	N/A
Oklahoma	No, restricts through state law or regulation (Oklahoma Administrative Code, Title 535. Oklahoma State Board of Pharmacy, Chapter 15. Pharmacies, Subchapter 10. Good Compounding Practices, Part 3. Good Compounding Practices for Sterile Products)	No	N/A	N/A
Oregon	Yes	N/A	Limited distribution: For a practitioner or dispenser located in Oregon With special agreement approved by the board of pharmacy: Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005 Other: Compounding by a pharmacy located in Oregon (Oregon Administrative Rules, Board of Pharmacy, Division 45 Sterile and Non-Sterile Compounding)	(POSSIBLY) Prohibit 503A pharmacies from compounding sterile drugs for humans in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry)
Pennsylvania	No, restricts through state law or regulation (The Pennsylvania Code, Chapter 27. State Board of Pharmacy, § 27.18. Standards of practice)	No	N/A	Allow 503A pharmacies to compound sterile and nonsterile drugs for humans in the absence of patient-specific prescriptions only for distribution to a medical practitioner to administer to an individual patient if the medical practitioner has an administrative system whereby the product can be tracked through the medical practitioner to the individual patient
Rhode Island	No, restricts through state law or regulation (Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors [R5-19.1-PHAR], Part IV Specialized Pharmacy Practice, Section 19.0 Compounding of Pharmaceuticals)	No	N/A	N/A
South Carolina	Yes	N/A	For in-office administration only: The minimum expected compliance for a pharmacist selling compounded products to a physician or licensed practitioner is that the pharmacist have a contract with the physician or licensed practitioner specifying that the compounded medications are for office administration only, and that lot numbers and expiration dates shall be maintained and readily retrievable on patient's records/charts (South Carolina Board of Pharmacy Policies & Procedures, Compounding Pharmacies Policy and Procedure #132)	N/A
South Dakota	No, restricts through state guidance (No state document, refer to federal Drug Supply Chain Security Act per Board newsletter)	No	N/A	Prohibit 503A pharmacies from compounding sterile and nonsterile drugs for humans in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry)

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Tennessee	Yes	N/A	For in-office administration only: For use in a licensed prescribing practitioner's office for administration to the prescribing practitioner's patient or patients when the product is not commercially available upon receipt of an order from the prescriber; for use in a health care facility for administration to a patient or patients receiving treatment or services provided by that facility when the product is not commercially available upon receipt of an order from an authorized licensed medical practitioner of the facility; for use by emergency medical services for administration to a patient or patients receiving services from them under authorized medical control when the product is not commercially available upon receipt of an order from a licensed prescriber authorized to provide medical control (Tennessee Code Annotated, Title 63 Professions Of The Healing Arts, Chapter 10 Pharmacy, Part 2 Pharmacy Practice, 63-10-204. Definitions)	N/A
Texas	No, advises pharmacies to follow federal law through informal state board of pharmacy communication (During inspections, if an inspector notices compounding only for outsourcing facilities and not pursuant to prescription or if the pharmacy is compounding inordinate quantities that exceed the amount needed for anticipatory prescriptions, Board office will advise the pharmacy to become licensed as an outsourcer by FDA, licensed with the Department of State Health Services [DSHS], and notify DSHS.)	No	N/A	N/A
Utah	No, restricts through state law or regulation (R156. Commerce, Occupational and Professional Licensing, R156-17b. Pharmacy Practice Act Rule, R156-17b-624. Operating Standards. Repackaged or Compounded Prescription Drugs—Sale to a Practitioner for Office Use)	No	N/A	N/A
Vermont	No, restricts through state law or regulation (Administrative Rules of the Board of Pharmacy, Part 10 Pharmacy Practice, 10.23 Drugs Compounded in a Pharmacy)	No	N/A	N/A
Virginia	Yes	N/A	For in-office administration only: A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. (§54.1-3410.2 (C) of The Drug Control Act)	N/A
Washington	No, restricts through state law or regulation (Washington Administrative Code, Title 246, Chapter 246-878)	No	N/A	N/A
West Virginia	No, restricts through state law or regulation (West Virginia Code, Chapter 30. Professions and Occupations, Article 5. Pharmacists, Pharmacy Technicians, Pharmacy Interns and Pharmacies, §30-5-4. Definitions)	No	N/A	N/A

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	Allow compounding sterile drugs in the absence of patient-specific prescriptions (outside of the limited quantities of anticipatory compounding permitted under FDA's prescription requirement guidance for industry) (Source of requirement)	Allow compounding nonsterile drugs in the absence of patient-specific prescriptions (outside of anticipatory compounding)	Limits on compounding sterile drugs in the absence of patient specific prescriptions (Source of requirement)	Pending legislation or regulation and what it would do if passed
Wisconsin	No, restricts through state law or regulation (Wisconsin Administrative Code, Pharmacy Examining Board, Chapter Phar 7 Pharmacy Practice)	No	N/A	Allow 503A pharmacies to compound sterile and nonsterile drugs for humans in the absence of patient-specific prescriptions for in-office administration only
Wyoming	No, advises pharmacies to follow federal law through informal state board of pharmacy communication (The more strict federal law must be followed.)	No	N/A	N/A

Table C.3

State Licensure/Registration of Outsourcing Facilities

	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Alabama	Yes (Alabama Board of Pharmacy 2016 licenses for pharmacies and facilities renewal letter)	As outsourcing facility	Unspecified	Unspecified	N/A
Alaska	Yes (Unspecified)	As pharmacy (if facility compounds patient-specific prescriptions)	Unspecified	Unspecified	N/A
Arizona	Yes (Application for Manufacturer Permit)	As manufacturer	$1,000	$1,000 biennially	N/A
Arkansas	Yes (Pharmacy Practice Act, 17-92-108. Fees)	As outsourcing facility	$300	$150 annually	N/A
California	Yes (Business & Professions Code, Chapter 9, Division 2, Article 7.7. Outsourcing Facilities, 4129. Outsourcing Facility—License Required)	As outsourcing facility	$2,270 for in-state; $2,380 for nonresident	$1,325 annually for in-state; $2,270 annually for nonresident	N/A
Colorado	Yes (Section 12-42.5-117, C.R.S.)	Other: In-state as manufacturers, out-of-state as out-of-state wholesalers	Varies from year to year as set by the Division of Professions and Occupations	Varies from year to year as set by the Division of Professions and Occupations	N/A
Connecticut	No	N/A	N/A	N/A	N/A
Delaware	Yes (Delaware Regulations, Administrative Code, Title 24, 2500 Board of Pharmacy, 5.0 Dispensing)	As outsourcing facility Other: Must hold current Delaware in-state pharmacy, nonresident pharmacy, or distributor license or apply for one of these licenses concurrently with the application for an Outsourcing Facility permit	$145 for outsourcing facility—retail (in-state) pharmacy; $145 for outsourcing facility—nonresident pharmacy; $365 for outsourcing facility—wholesale (distributor)	Unspecified	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
District of Columbia	No	N/A	N/A	N/A	N/A
Florida	Yes (The 2016 Florida Statutes, Title XXXII Regulation of Professions and Occupations, Chapter 465 Pharmacy, 465.0158 Nonresident sterile compounding permit; Rule Chapter: 64B16-27: Pharmacy Practice, 64B16-27.700 Definition of Compounding)	Other: Nonresident as outsourcing facilities. (Outsourcing facilities located in the state must register with FDA.) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, an outsourcing facility must also hold a nonresident sterile compounding permit.	$255 for nonresident	Unspecified	N/A
Georgia	Yes (State of Georgia Drugs and Narcotics Agency 2016 letter)	As pharmacy (if facility compounds patient-specific prescriptions) As manufacturer Other: Must hold a Georgia drug manufacturing permit	$500 for resident pharmacies; $1,000 for nonresident pharmacies; $1,000 for all manufacturers	$400 for resident pharmacies; $750 for nonresidents; $750 for all manufacturers biennially	N/A
Hawaii	No	N/A	N/A	N/A	License or register facilities that register with the FDA under the federal outsourcing facility category of drug compounders as outsourcing facilities

Continued on next page

	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Idaho	Yes (Idaho Administrative Code, Idaho Administrative Procedures Act, 27—Board of Pharmacy, 27.01.01.—Rules of the Idaho State Board of Pharmacy, Subchapter B—Professional and Drug Outlet Licensure, 074. Outsourcing Facility Registration)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$250 for resident; $500 for nonresident	$250 annually	N/A
Illinois	No	N/A	N/A	N/A	N/A
Indiana	No	N/A	N/A	N/A	N/A
Iowa	Yes (Iowa Code 2017, Chapter 155A Pharmacy, 155A.13C Outsourcing facility license—renewal, cancellation, denial, discipline)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$135	$135 annually	N/A
Kansas	Yes (Pharmacy Practice Act—Statutes, Chapter 65.—Public Health, Article 16.—Regulation of Pharmacists, 65-1643. Registration or permit required; pharmacies, manufacturers, wholesalers, auctions, sales, distribution or dispensing of samples, retailers, institutional drug rooms, pharmacy students, veterinary medical teaching hospital pharmacies; certain acts declared unlawful)	As pharmacy (if facility compounds patient-specific prescriptions) As manufacturer As wholesale distributor	Not more than $500	Not more than $400 annually	License or register facilities that register with the FDA under the federal outsourcing facility category of drug compounders as outsourcing facilities
Kentucky	Yes (Kentucky Revised Statutes Chapters 315.340 Permit for operation of in-state outsourcing facility doing business in Kentucky—Requirements—Administrative regulations and 315.342 Permit for operation of out-of-state outsourcing facility doing business in Kentucky—Requirements—Administrative regulations)	As outsourcing facility	Not to exceed $500 for in-state; for out-of-state, not to exceed $250 or the current in-state permit	Not to exceed $500 annually for in-state; for out-of-state, not to exceed $250 annually or the current in-state permit	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Louisiana	Yes (responsible agency: LA Board of Drug & Device Distributors) (Distribution is licensed by Board of Drug & Device Distributors (LBDDD), as authorized by La. R.S. 37:3461 et seq. Dispensing is licensed by Board of Pharmacy (LBP), as authorized by La. R.S. 37:1161 et seq.)	As pharmacy (if facility compounds patient-specific prescriptions)—this credential from the La. Board of Pharmacy Other: Standard distributor	LBDDD: $400 LBP: $150	LBDDD: $300 LBP: $125 annually	N/A
Maine	No	N/A	N/A	N/A	N/A
Maryland	No	N/A	N/A	N/A	N/A
Massachusetts	Yes (247 CMR 21.00: Registration of Outsourcing Facilities and M.G.L. c 112, § 36E)	As outsourcing facility	$750	$750 biennially	N/A
Michigan	Yes (Public Health Code, Act 368 of 1978, Part 177 Pharmacy Practice and Drug Control, Section 333.17748 Pharmacy, manufacturer, or wholesale distributor; license required; compounding services; renewal; designation of pharmacist in charge; joint responsibility; exemption; report of change in ownership, management, location, or PIC or facility manager; duties of pharmacist in charge; submission of fingerprints; criminal history check; exception; investigation or inspection of out-of-state applicant or compounding pharmacy; reimbursement for expenses)	Other: Must be licensed as a pharmacy (even if it does not compound patient-specific prescriptions)	Pharmacy / Controlled Substance-Facility—$181.80	Pharmacy—$111.10 biennially; Controlled Substance-Facility—$151.50 biennially	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Minnesota	Yes (Minnesota Board of Pharmacy website, license and registration 503B outsourcing facility page)	As pharmacy (if facility compounds patient-specific prescriptions) As manufacturer Other: 503B outsourcing facilities must be licensed as both a drug manufacturer and a drug wholesaler	$235, see website	Unspecified, see website	N/A
Mississippi	Yes (Title 30: Professions and Occupations, Part 3001: Mississippi Pharmacy Practice Regulations, Article VI Practice of Pharmacy Permits)	Other: Sterile product outsourcing permit	$300	$300 biennially	N/A
Missouri	Yes (338.330, RSMo to 338.340, RSMo)	As wholesale distributor	$300	$300 biennially (However, fee has been reduced by the Board for the last six years to $150)	N/A
Montana	Yes (New 2017 legislation, SB 68, defines outsourcing facility which will allow the Board to make rule changes to add an endorsement for outsourcing facility or sterile compounder to existing facility license types)	As pharmacy (if facility compounds patient-specific prescriptions) As wholesale distributor	Pharmacy (in-state) $240; out-of-state mail-order pharmacy $240; wholesale drug distributor (in-state and out-of-state) $240	Pharmacy (in-state) $150; out-of-state mail-order pharmacy $240; wholesale drug distributor (in-state and out-of-state) $240 annually	N/A
Nebraska	No	N/A	N/A	N/A	N/A
Nevada	Yes (Nevada Administrative Code, Chapter 639—Pharmacists and Pharmacy, Outsourcing Facilities)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$500	$500 biennially	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
New Hampshire	Yes (Title XXX Occupations and Professions, Chapter 318 Pharmacists and Pharmacies, Section 318:51-c Licensing of Outsourcing Facilities Identified as Section 503B Facilities by the United States Food and Drug Administration)	Other: Permit as bulk sterile & nonsterile compounders	$250	$250 annually	N/A
New Jersey	No	N/A	N/A	N/A	N/A
New Mexico	Yes (New Mexico Administrative Code, Title 16 Occupational and Professional Licensing, Chapter 19 Pharmacists, Part 37 Minimum Standards for Outsourcing Facilities)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$2,000	$2,000 biennially	N/A
New York	Yes (Education Law, Article 137, Pharmacy, §6808. Registering and operating establishments and §6831. Special provisions relating to outsourcing facilities)	As outsourcing facility	$825	$520 triennially	N/A
North Carolina	Yes (North Carolina General Statutes, Chapter 106 Agriculture, Article 12. Food, Drugs and Cosmetics, § 106-140.1. Registration of producers of prescription drugs and devices)	As manufacturer	$1,000	$1,000 annually	N/A
North Dakota	Yes (Administrative Code (Rules/ Regulations), Chapter 43-15.3, Wholesale Drug Pedigree, Section 43-15.3.13 Compounding provided by an outsourcing facility)	Other: License under Wholesale Drug Pedigree chapter with an outsourcing facility classification	$200	$200 annually	N/A
Ohio	Yes (Section 4729.52 of the Revised Code)	As outsourcing facility	$1,900 for noncontrolled and $2,000 for controlled	$1,900 for noncontrolled and $2,000 for controlled biennially	N/A

Continued on next page

	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Oklahoma	Yes (Oklahoma Administrative Code, Title 535. Oklahoma State Board of Pharmacy, Chapter 20. Manufacturers, Repackagers, Outsourcing Facilities, Wholesalers, Third-Party Logistics Providers, and Medical Gas Suppliers and Distributors, Subchapter 6. Outsourcing Facilities)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$200	$200 annually	N/A
Oregon	Yes (Oregon Administrative Rules, Board of Pharmacy, Division 60 Pharmaceutical Manufacturers)	As manufacturer	$400	$400 annually	N/A
Pennsylvania	No	N/A	N/A	N/A	N/A
Rhode Island	No	N/A	N/A	N/A	N/A
South Carolina	Yes (Outsourcing Facility Permit Application; Non-Resident Outsourcing Facility Permit Application)	Other: As pharmacy and outsourcing facility or as a pharmacy and wholesale distributor	$200 for in-state; $500 for nonresident	$100 annually for in-state; $500 annually for nonresident	N/A
South Dakota	Yes (South Dakota Codified Law, Chapter 36-11A Wholesale and Other Drug Distributors, 36-11A-4.1. License required for wholesale distributors, outsourcing facilities etc.)	As "503B outsourcing facility" Other: Inspection requirements? Yes. Must be inspected by the FDA prior to licensure in SD.	$200	$200 annually	License or register facilities that register with the FDA under the federal outsourcing facility category of drug compounders as outsourcing facilities
Tennessee	Yes (Rules of the Tennessee Board of Pharmacy, Chapter 1140-01 Introductory Rules, 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/ Distributor Licenses)	As outsourcing facility Other: Must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy	$525	$525 biennially	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Texas	Yes (Health and Safety Code, Chapter 483, Texas Dangerous Drug Act, section 483.041)	Other: In-state as prescription drug manufacturers, and out-of-state as prescription drug distributors	There is a range based on cross annual sales. $1,080-$2,295 for a two-year license	Same	N/A
Utah	Yes (Class C Pharmacy as defined in UCA 58-17b-102)	Other: Must license a Class C Pharmacy as defined in UCA 58-17b-102 (12)	$200 + fingerprinting fee	$103 biennially	N/A
Vermont	No	N/A	N/A	N/A	N/A
Virginia	Yes (Commonwealth of Virginia, Chapter 20 Regulations Governing the Practice of Pharmacy, Part VII. Prescription Order And Dispensing Standards, 18VAC110-20-215. Outsourcing facilities and Chapter 34 of Title 54.1 of the Code of Virginia, The Drug Control Act, § 54.1-3434.05. Permit to act as an outsourcing facility and § 54.1-3434.5. Nonresident outsourcing facilities to register with the Board)	As pharmacy (if facility compounds patient-specific prescriptions) As outsourcing facility	$270	$270 annually	N/A
Washington	Yes (RCW 18.64.045 Manufacturer's license—Fees—Display—Declaration of ownership and location—Penalties. And RCW 18.64.046 Wholesaler's license—Required—Authority of licensee—Penalty—Ephedrine / pseudoephedrine / phenylpropanolamine)	As manufacturer As wholesale distributor	Manufacturer $590	Wholesaler $590	N/A
West Virginia	Yes (Application for License Permit or Renewal as a Manufacturer)	As manufacturer	$500	$500 annually	N/A
Wisconsin	No	N/A	N/A	N/A	N/A

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	License or register facilities that register with FDA under the federal outsourcing facility category of drug compounders (Source of requirement)	Type of licensure or registration	License or registration fee		Pending legislation or regulation and what it would do if passed
			Initial fee	Renewal fee	
Wyoming	Yes (Unspecified)	As pharmacy (if facility compounds patient-specific prescriptions) As manufacturer	Unspecified	Unspecified	License or register facilities that register with the FDA under the federal outsourcing facility category of drug compounders as outsourcing facilities

Table C.4

Inspections of In-State 503A Pharmacies That Perform Sterile Compounding for Humans

	Frequency of routine inspections	Specific circumstances that trigger inspections
Alabama	At least every two years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Alaska	Unsure	Unsure
Arizona	At least every 18 months	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Routine approximately annual inspections
Arkansas	At least every 18 months	Initial licensure Other: Also inspect any new locations if a pharmacy moves
California	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Colorado	At least every year Other: Every six months for high-risk sterile	Initial licensure Other: Unannounced annual and every six months for high-risk sterile
Connecticut	Unsure	Unsure
Delaware	At least every year	Initial licensure Licensure renewal
District of Columbia	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs Other: Damaged premises shall be inspected by the mayor to determine their continued suitability for pharmacy operations
Florida	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location

Continued on next page

	Frequency of routine inspections	Specific circumstances that trigger inspections
Georgia	No specific frequency	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Agents' discretion; registrants' request
Hawaii	No specific frequency	When a complaint or incident occurs Other: Random inspections
Idaho	Other: There is not a rule in which any facility be inspected. However, it is the intent that every drug outlet be inspected every 18 months.	When a pharmacy remodels or moves location When a complaint or incident occurs
Illinois	No specific frequency	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Indiana	At least every three years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Iowa	No specific frequency	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Kansas	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Kentucky	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Louisiana	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Maine	At least every year	Initial licensure Licensure renewal When a complaint or incident occurs

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	Frequency of routine inspections	Specific circumstances that trigger inspections
Maryland	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Massachusetts	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Michigan	No specific frequency Other: Working with the National Association of Boards of Pharmacy (NABP) to look at establishing a plan to inspect on a frequent basis, and using NABP's universal inspection form for sterile compounding.	Initial licensure When a complaint or incident occurs
Minnesota	At least every two years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Mississippi	At least every 18 months	Initial licensure When a complaint or incident occurs
Missouri	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Routine inspections and may inspect if requested by the board or if the risk level of activity changes
Montana	At least every year	Initial licensure When a pharmacy remodels or moves location Other: Change in ownership
Nebraska	At least every five years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Random sample of pharmacies inspected annually

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	Frequency of routine inspections	Specific circumstances that trigger inspections
Nevada	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs Other: Whenever board requests
New Hampshire	At least every year	Other: No specific circumstances (other than annual inspections)
New Jersey	At least every 18 months	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
New Mexico	At least every two years	Initial licensure When a pharmacy remodels or moves location
New York	No specific frequency	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
North Carolina	Other: Depends on the risk level of compounding—annually for high-risk; biennially for medium-risk; at least every four years for low-risk (though frequency typically greater)	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: If the pharmacy is due for an inspection under the inspection policy
North Dakota	At least every year	Other: No specific circumstances (other than annual inspections)
Ohio	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Oklahoma	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Oregon	At least every year	When a pharmacy remodels or moves location When a complaint or incident occurs Other: Routine annual inspections
Pennsylvania	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Random inspections

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	Frequency of routine inspections	Specific circumstances that trigger inspections
Rhode Island	No specific frequency	Initial licensure When a complaint or incident occurs Other: Random inspections
South Carolina	At least every two years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
South Dakota	At least every year	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Yearly inspection schedule
Tennessee	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Texas	At least every two years	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs
Utah	No specific frequency	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Random inspections
Vermont	At least every two years	Initial licensure When a pharmacy remodels or moves location
Virginia	At least every two years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs
Washington	At least every two years	Initial licensure When a pharmacy remodels or moves location When a complaint or incident occurs Other: Every 24 months
West Virginia	Other: For pharmacies shipping out-of-state, every 18 months. All others are inspected every two years.	Initial licensure When a pharmacy remodels or moves location

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	Frequency of routine inspections	Specific circumstances that trigger inspections
Wisconsin	No specific frequency	Initial licensure When a complaint or incident occurs
Wyoming	At least every year	Initial licensure Licensure renewal When a pharmacy remodels or moves location When a complaint or incident occurs

Table C.5

State Oversight of Out-of-State 503A Pharmacies That Perform Sterile Compounding for Humans

	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Alabama	Other: Unspecified	No	N/A	N/A
Alaska	Standards of the state where the pharmacy is located	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party Other: Verified Pharmacy Program inspection	N/A
Arizona	Standards of the state where the pharmacy is located	Yes (Other: Based on home state inspection schedule)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Arkansas	Same standards as in-state pharmacies	No	N/A	N/A
California	Same standards as in-state pharmacies	Yes (At least every year)	California	N/A
Colorado	Same standards as in-state pharmacies and standards of the state where the pharmacy is located	Yes (Other: Applicants are required to submit proof of inspection by resident state pharmacy board)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: A board-approved third-party entity that inspects pharmacy outlets	N/A
Connecticut	Same standards as in-state pharmacies	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: If the state in which the nonresident pharmacy is located does not conduct inspections based on standards required in the most recent USP <797>, as amended from time to time, such nonresident pharmacy shall provide satisfactory proof to the department that it is in compliance with the standards required in the most recent USP <797> as amended from time to time	N/A
Delaware	Other: Unspecified	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
District of Columbia	Standards of the state where the pharmacy is located	Yes (Other: Inspection report required for initial registration and pharmacy is required to report any actions taken by a state regulatory body)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A

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	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Florida	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: If the applicant is unable to submit a current inspection report conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department shall: conduct, or contract with an entity to conduct, an onsite inspection; accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or accept a current inspection report from the FDA	N/A
Georgia	Same standards as in-state pharmacies and standards of the state where the pharmacy is located	No	N/A	N/A
Hawaii	Standards of the state where the pharmacy is located	No	N/A	N/A
Idaho	Other: Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the board, evidenced by an inspection report	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: If the regulatory board or licensing authority of the state in which a nonresident outlet is located fails or refuses to conduct an inspection or fails to obtain records or reports required by the board, upon reasonable notice to the nonresident outlet, the Idaho State Board of Pharmacy may conduct an inspection	N/A
Illinois	Other: Unless there is a direct conflict between Illinois pharmacy law and the pharmacy laws of the state in which the nonresident pharmacy is located, nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents	No	N/A	N/A
Indiana	Standards of the state where the pharmacy is located	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Iowa	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: If the home state licensing authority has not conducted an inspection, the pharmacy may submit an inspection report from NABP's verified pharmacy program, or the pharmacy may submit an inspection report from another qualified entity if preapproved by the board, if the inspection report satisfies all of the other requirements; another option is for the pharmacy to request the inspection be performed by Iowa compliance staff, costs associated with this inspection are assessed to the requesting pharmacy	N/A
Kansas	Other: Unspecified	Yes (Other: Must provide a yearly inspection from their home state on renewal)	Other: Unspecified	Require out-of-state 503A pharmacies that perform sterile compounding for humans to comply with the same standards as in-state pharmacies Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected at least every year by Kansas, the regulatory or licensing agency of the jurisdiction in which the pharmacy is located, third party

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	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Kentucky	Standards of the state where the pharmacy is located	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Louisiana	Same standards as in-state pharmacies	Yes (At least every two years)	Louisiana Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: The nonresident pharmacy must submit inspection reports resulting from inspections conducted by any other state pharmacy licensing agency or any agent thereof, and any inspection reports produced by the FDA or the federal Drug Enforcement Administration	N/A
Maine	Other: Unspecified	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Maryland	Same standards as in-state pharmacies	Yes (At least every two years)	Maryland Other: A designee of the Board; the FDA; or another appropriate state entity which indicates compliance with USP <797>	N/A
Massachusetts	Other: Out-of-state licensure is pending; no requirement at this time	No	N/A	Require out-of-state 503A pharmacies that perform sterile compounding for humans to comply with the same standards as in-state pharmacies Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected at least every year by third party: Proposed plan is to have inspections completed by NABP
Michigan	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: NABP Verified Pharmacy Program	N/A
Minnesota	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: An authorized representative of the board, per MN Statute §151.19, for example NABP Verified Pharmacy Program	N/A
Mississippi	Same standards as in-state pharmacies	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Missouri	Same standards as in-state pharmacies and standards of the state where the pharmacy is located	Yes (Other: Board is in process of promulgating a rule that would require inspections within the last year for new applicants; currently, the board requests inspections within the last year and may request additional information if that timeframe is not met)	Other: The applicant's home state, but the board may perform an inspection if deemed necessary or appropriate	N/A
Montana	Same standards as in-state pharmacies	Yes (Other: At time of initial licensure for an out-of-state mail-order pharmacy)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A

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	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Nebraska	Other: To be qualified to hold a mail service pharmacy license, a person shall be located and operating in a state in which the requirements and qualifications for obtaining and maintaining a pharmacy license or permit are considered by the Department of Health and Human Services, with the approval of the Board of Pharmacy, to be substantially equivalent to the requirements of the Health Care Facility Licensure Act and the Pharmacy Practice Act related to the practice of pharmacy	Yes (Other: At least every five years, based on the most recent inspection conducted by the jurisdiction where the pharmacy is located)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Nevada	Standards of the state where the pharmacy is located	Yes (No specific frequency)	Nevada Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: Drug Enforcement Administration	N/A
New Hampshire	Same standards as in-state pharmacies	Yes (At least every 18 months)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: Other responsible state or national regulatory agency or New Hampshire board of pharmacy-approved third party entity	N/A
New Jersey	Same standards as in-state pharmacies	Yes (No specific frequency Other: Board requests that every nonresident pharmacy on initial application or during renewal submits an inspection report demonstrating compliance with USP <797> that is no more than two years old)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: NABP	N/A
New Mexico	Same standards as in-state pharmacies	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: Party recognized by that agency to perform such inspection, or party recognized by the board	N/A
New York	Same standards as in-state pharmacies	No	N/A	N/A
North Carolina	Same standards as in-state pharmacies and standards of the state where the pharmacy is located	Yes (Other: At intervals as required by the home state. This issue is under discussion at the board, however.)	Other: The facilities and records of an out-of-state pharmacy shall be subject to inspection by the North Carolina Board of Pharmacy; provided however, the board may accept in lieu thereof satisfactory inspection reports by the licensing entity of the state in which the pharmacy is located; board accepts Verified Pharmacy Program (VPP) inspections performed under the auspices of NABP as well because the personnel are board affiliated and the inspection forms and criteria have been developed by, and are monitored by, the state boards of pharmacy	N/A
North Dakota	Same standards as in-state pharmacies	Yes (At least every year)	North Dakota Third party: A duly authorized agent of a third party approved by the board which is the NABP Verified Pharmacy Program	N/A

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	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Ohio	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: A regulatory or licensing agency from another licensing jurisdiction, NABP's verified pharmacy program, Accreditation Commission for Health Care inspection services (a.k.a. ACHC inspection services or AIS), or proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the Accreditation Commission for Health Care (ACHC)	N/A
Oklahoma	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: Any organization approved by the Oklahoma State Board of Pharmacy Other: The Oklahoma State Board of Pharmacy may conduct on-site periodic routine inspections and investigations during reasonable business hours	N/A
Oregon	Other: Unspecified	Yes (Other: When a sterile compounding pharmacy is seeking initial and renewal licensure)	Other: Unspecified	Require out-of-state 503A pharmacies that perform sterile compounding for humans to comply with the same standards as in-state pharmacies Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected
Pennsylvania	Standards of the state where the pharmacy is located	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: NABP's Verified Pharmacy Program	N/A
Rhode Island	Same standards as in-state pharmacies	No	N/A	N/A
South Carolina	Other: Unspecified	Yes (At least every two years)	Third party: Nonresident pharmacy sterile compounding requirements include submitting a copy of last inspection, by qualified individual, of hoods, buffer, clean and ante areas including ISO classification, particle counts and microbiology	N/A
South Dakota	Standards of the state where the pharmacy is located	Yes (No specific frequency Other: Requested within four years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: VPP	Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected within four years for renewals by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located. There must be an inspection before a new application can be approved.
Tennessee	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Texas	Same standards as in-state pharmacies	Yes (At least every two years)	Texas Third party: Accreditation Commission for Health Care Inc. (ACHC), NABP, or Superior Laboratory Services Inc. (SLSI)	N/A

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	Quality standards state requires	Require to be inspected (Frequency)	Who performs the inspections	Pending legislation or regulation and what it would do if passed
Utah	Same standards as in-state pharmacies	Yes (At least every two years)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: Conducted as part of the NABP Verified Pharmacy Program Other: Performed by the state licensing agency of the state in which the applicant is a resident and in accordance with the NABP multistate inspection blueprint program	N/A
Vermont	Same standards as in-state pharmacies	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
Virginia	Same standards as in-state pharmacies	Yes (At least every two years Other: The initial application for a new nonresident pharmacy registration must include a report of inspection conducted within six months of the date the application is received by the board)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Other: If the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Virginia Board of Pharmacy may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent	N/A
Washington	Standards of the state where the pharmacy is located	Yes (Other: Based on the state of residence for the pharmacy)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located	N/A
West Virginia	Other: Every 18 months by NABP Universal Inspection	Yes (At least every 18 months)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party	N/A
Wisconsin	Other: Unspecified	No	N/A	N/A
Wyoming	Standards of the state where the pharmacy is located	Yes (No specific frequency)	Regulatory or licensing agency of the jurisdiction in which the pharmacy is located Third party: NABP blueprint states, NABP VPP inspections, or the FDA	Require out-of-state 503A pharmacies that perform sterile compounding for humans to be inspected by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located; third party: NABP blueprint state inspection, NABP VPP

Table C.6

Other Pending Policy Changes

	Pending legislation or regulation, and what it would do if passed
California	Modify existing regulations
Montana	Changes pursuant to 2017 legislation, SB 68

Endnotes

1 The Pew Charitable Trusts, "U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–17" (2017), http://www.pewtrusts.org/en/multimedia/data-visualizations/2017/us-illnesses-and-deaths-associated-with-compounded-medications-or-repackaged-medications.

2 The Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding" (2016), http://www.pewtrusts.org/~/media/assets/2016/02/best_practices_for-state_oversight_of_drug_compounding.pdf.

3 Pennsylvania Code, "Chapter 27. State Board of Pharmacy," accessed Sept. 19, 2017, http://www.pacode.com/secure/data/049/chapter27/chap27toc.html.

4 Kansas Board of Pharmacy, "Laws and Regulations," accessed Nov. 2, 2017, https://pharmacy.ks.gov/docs/default-source/statues-regulations/full-version-pdf.pdf?sfvrsn=2.

5 Massachusetts Office of Health and Human Services, letter to USP Expert Committee, Jan. 31, 2016, http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/public-comment-memo.pdf.

6 Washington State Pharmacy Quality Assurance Commission, "Sterile Compounding [USP <797>] Self-Assessment Compliance Checklist," accessed Nov. 2, 2017, http://www.doh.wa.gov/Portals/1/Documents/2300/2016/7-2bPharmacyUSP797.pdf.

7 U.S. Pharmacopeial Convention, "General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings" (Sept. 29, 2017), http://www.uspnf.com/notices/gc-800-hazardous-drugs-handling-in-healthcare-settings.

8 New Hampshire General Court, "Chapter Ph 100: Organizational Rules," accessed Aug. 16, 2017, http://www.gencourt.state.nh.us/rules/state_agencies/ph100-2000.html.

9 Wyoming Pharmacy Laws, "Sterile Compounding: Chapter 17," accessed Aug. 16, 2017, https://drive.google.com/file/d/0B8cDfZ_Wrtc8MWxoTEZhRlpYTkk/view.

10 The Pew Charitable Trusts, "Best Practices for State Oversight."

11 Peter D. Austin, Kieran S. Hand, and Marinos Elia, "Systematic Review and Meta-Analysis of the Risk of Microbial Contamination of Parenteral Doses Prepared Under Aseptic Techniques in Clinical and Pharmaceutical Environments: An Update," *Journal of Hospital Infection* 91, no. 4 (2015): 306–18, http://dx.doi.org/10.1016/j.jhin.2015.04.007.

12 Amber Vasquez et al., "Notes From the Field: Fungal Bloodstream Infections Associated With a Compounded Intravenous Medication at an Outpatient Oncology Clinic—New York City, 2016," *Morbidity and Mortality Weekly Report* 65, no. 45 (2016): 1274–75, http://www.cdc.gov/mmwr/volumes/65/wr/mm6545a6.htm?s_cid=mm6545a6_w.

13 U.S. Government Accountability Office, "Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges" (2016), https://www.gao.gov/assets/690/681096.pdf.

14 The Pew Charitable Trusts, "Best Practices for State Oversight."

15 Ibid.

16 U.S. Food and Drug Administration, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry" (2016), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf.

17 North Carolina Board of Pharmacy, "Consent Order: In the Matter of Deep River Drug," April 28, 2011, http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/DeepRiverDrug08944.pdf.

18 Reid Paul, "Despite Court Ruling, FDA Still Warning Compounders," *Drug Topics*, Jan. 8, 2007, http://drugtopics.modernmedicine.com/drug-topics/content/despite-court-ruling-fda-still-warning-compounders.

19 U.S. Food and Drug Administration, "Preliminary Recommendations for Aligning Federal and State Regulation of Compounders Registered as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (2016), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCo%20mpounding/UCM520830.pdf.

20 The Pew Charitable Trusts, "Best Practices for State Oversight."

21 Ibid.

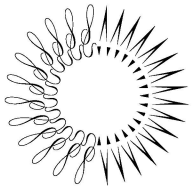
22 NABP and Pew provide some funding for state inspectors to attend the CriticalPoint LLC training program. Additionally, one of the external reviewers of this report is a principal at CriticalPoint, and another external reviewer teaches a portion of a CriticalPoint hazardous drug course.

23 The Pew Charitable Trusts, "Best Practices for State Oversight."

24 Idaho Administrative Procedure Act, IDPAP 27—Board of Pharmacy, 6, 20, accessed Nov. 2, 2017, https://adminrules.idaho.gov/rules/current/27/0101.pdf.

25 National Association of Boards of Pharmacy, "Traning and Resources Support Member Boards' Next Steps to Inspection Blueprint Uniformity and State Collaboration," *Innovations* 46, no. 1 (2017): 8–9, https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations_January_Final.pdf.

26 The Pew Charitable Trusts, "Best Practices for State Oversight."



THE PEW CHARITABLE TRUSTS

Attachment 4

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	676	630	499		1805
Closed	676	783	558		2017
4301 letters	6	5	3		14
Pending (at the end of quarter)	2283	2028	2009		2009
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	992	952	1014		1014
Drug Diversion/Fraud	370	307	302		302
RX Abuse	185	132	118		118
Compounding	130	86	70		70
Outsourcing	43	29	22		22
Probation/PRP	63	49	67		67
Mediation/Enforcement **	190	143	75		75
Criminal Conviction	320	330	341		341
Application Investigations					
Received	228	96	65		389
Closed					
Approved	92	125	42		259
Denied	17	20	20		57
Total ***	126	177	87		390
Pending (at the end of quarter)	192	153	94		94
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	30	73	53		156
Citations Issued	425	610	398		1433
Total Fines Collected ****	$535,944	$501,038	$423,625		$1,460,607

* 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 2/28/2018 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*	83	102	53		238
Accusations Filed	78	43	42		163
Statement of Issues Filed	10	7	5		22
Petitions to Revoke Filed	2	0	2		4
Pending					
Pre-accusation	204	200	229		200
Post Accusation	245	237	240		237
Total*	471	516	514		497
Closed					
Revocation					
Pharmacist	7	2	4		13
Intern Pharmacist	1	0	1		2
Pharmacy Technician	22	17	14		53
Designated Representative	0	0	0		0
Wholesaler	0	1	1		2
Sterile Compounding	1	0	0		1
Pharmacy	2	1	1		4
Revocation,stayed; suspension/probation					
Pharmacist	2	3	1		6
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	0	0		0
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	1	0	2		3
Revocation,stayed; probation					
Pharmacist	9	13	13		35
Intern Pharmacist	1	0	0		1
Pharmacy Technician	0	1	0		1
Designated Representative	1	2	0		3
Wholesaler	0	1	1		2
Sterile Compounding	3	0	0		3
Pharmacy	9	12	4		25
Surrender/Voluntary Surrender					
Pharmacist	2	3	3		8
Intern Pharmacist	0	0	0		0
Pharmacy Technician	4	3	8		15
Designated Representative	0	2	0		2
Wholesaler	1	0	0		1
Sterile Compounding	2	2	1		5
Pharmacy	6	3	5		14

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	5	3	3		11
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	2	3		5
Designated Representative	0	0	1		1
Wholesaler	0	0	0		0
Sterile Compounding	1	0	0		1
Pharmacy	3	2	1		6
Licenses Granted					
Pharmacist	1	1	0		2
Intern Pharmacist	1	3	0		4
Pharmacy Technician	1	2	2		5
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0
Licenses Denied					
Pharmacist	0	0	0		0
Intern Pharmacist	0	0	0		0
Pharmacy Technician	0	4	0		4
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	1	0	0		1
Pharmacy	0	0	0		0
Cost Recovery Requested**	$357,388	$439,458	$274,966		$1,071,811.59
Cost Recovery Collected**	$238,133	$189,505	$90,355		$517,993.07

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	0	3	2		5
Automatic Suspension / Based on Conviction	2	0	0		2
Penal Code 23 Restriction	3	3	2		8
Cease & Desist - Sterile Compounding	1	0	0		1

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	194	211	218		218
Intern Pharmacist	5	8	9		9
Pharmacy Technician	32	29	29		29
Designated Representative	1	3	2		2
Pharmacy	68	75	73		73
Sterile Compounding	15	16	16		16
Wholesaler	3	4	5		5
Probation Office Conferences	27	36	18		81
Probation Site Inspections	145	165	93		403
Successful Completion	6	7	6		19
Probationers Referred to AG for non-compliance	1	5	2		8

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 February 28, 2018.

Attachment 5

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
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ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE:	December 11, 2017
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 North Market Blvd Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, License Member, Chair Amy Gutierrez, PharmD, Licensee Member, Vice Valerie Munoz, Public Member
COMMITTEE MEMBERS NOT PRESENT:	Gregory Lippe, Public Member Stan Weisser, Licensee
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Christine Acosta, MD, Supervising Inspector Laura Freedman, DCA Staff Counsel Joshua Room, DCA Staff Counsel Laura Hendricks, Staff Analyst MaryJo Tobola, Senior Enforcement Manager

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

Chair Allen Schaad called the meeting to order at 9:32 a.m.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

The committee was advised of a current shortage of IV bags and requested that there be discussion on how to alleviate the shortage at a future meeting. The committee was also advised of delays in processing applications within the California Department of Public Health(CDPH) regarding construction in hospitals necessary to comply with board regulations. A request was made for assistance in resolving the CDPH backlog.

A representative from the California Retailers Association (CRA) requested the board to consider future discussion regarding quality assurance testing for simple to moderate compounding products.

3. Discussion and Consideration of Possible Statutory Proposal Relating to the Use of Automated Drug Delivery Systems (ADDS)

Chairperson Schaad provided an overview of the agenda item including a review of relevant law, background and prior committee discussion regarding the use of ADDS. Chairperson Schaad reviewed the basic framework from which a legislative proposal could be secured.

In addition to discussing the outlined proposal parameters, Chairperson Schaad reminded the committee that board staff are seeking input from the committee on the frequency of inspections for the location of the device, as well as if the proposal should include a limit on the number of dispensing systems a pharmacy can operate.

As part of the discussion, the committee asked whether a pharmacy with an ADDS could be located out of state and was advised that the pharmacy operating and owning the ADDS must be licensed in California. Further, the committee was advised that the clinical (for example, patient consultation) may only be performed by a California licensed pharmacist; the pharmacist may reside in another state, but they must be licensed to practice in California. The committee discussed the two types of uses of an ADDS including those systems used to dispense directly to the patient as well as those used for unit dose administration by an authorized person to a patient. The committee discussed the need to maintain safety and the security precautions that may be necessary pertaining to the location of the machine. The committee considered inspection requirements including pre-licensure inspection The committee determined that a limit of five dispensing devices should be incorporated into the program.

The committee heard public comments in support of the expanded use of ADDS.

The committee confirmed that under the proposal, an ADDS could be used for new and refill prescriptions and that consultation requirements need to be consistent with current requirements for any other medication dispensed to a patient in California. The committee agreed to limit the locations of a dispensing system to those locations where healthcare is provided

Motion: Recommend that the committee move forward to direct board staff to draft a proposal that the committee can present to the full board which incorporates all concepts listed identified below.

a. ADDS proposal will apply to new and refill prescriptions.
b. Re-emphasize the requirements for resolving medication errors.
c. Pharmacies have the obligation to correct the issues.
d. Require notification to the board of any security events.
e. Require consultation for only new or changes in prescriptions.
f. Require completion of the Self-Assessment Form on an annual basis, as well as the other triggers.
g. Confirm that Notice to Consumers and language requirements are complied with at the dispensing site.

h. Limit the number of dispensing systems a pharmacy may operate.
i. Pre-licensure inspection for site approval.

M/S: Gutierrez/Munoz

Support: 3 Oppose: 0 Abstain: 0

4. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Members

Chairperson Schaad stated that board members must be aware of conflicts of interest and clarified that such conflicts could be real or perceived.

Chairperson Schaad identified that one area where board members should be transparent is in the area of enforcement actions (whether they are directly or indirectly involved). Board members should determine whether recusal should occur based on the real or possible appearance of self-interest. For example, an enforcement matter involving a board member could influence a member's objectivity in future decision making.

Legal advised that the disclosure of disciplinary or administrative action could be addressed in the Organizational Development Report.

No public comments.

Motion: Board member involvement in disciplinary or administrative action will be reported in the Organizational Development Report.

M/S: Gutierrez/Munoz

Support: 3 Oppose: 0 Abstain: 0

5. Discussion and Consideration of Federal Drug Administration (FDA) Draft Guidance for Industry Relating to *"Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier"*

Chairperson Schaad provided background information on the Drug Supply Security Act (DSSA), signed into law in November 2013, which established the federal track and trace requirements.

The committee was advised that information on the delays in implementation will be included in the board newsletter.

6. Discussion and Consideration of "CURES 2.0 Survey of California Physicians' and Pharmacists' Experience with and Attitudes about CURES 2.0"

Chairperson Schaad provided background information on the survey. As approved by the board at the July 2016 meeting, the board assisted researchers from the University of California, Davis in surveying pharmacists regarding the use of CURES. Questions were designed to learn about their use, access to, likes, dislikes and concerns with CURES. Physicians also participated in a related survey at the same time.

UC Davis researchers partnered with the California Department of Public Health to develop and conduct the survey.

Ms. Herold informed the committee that the board has already agreed to sponsor legislation on upgrading elements in CURES to make the system more valuable, which could include more CURES education/training.

The committee heard public comment which informed the board that legislation has been passed to improve CURES access relative to the electronic medical records within hospital facilities.

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

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

Chairperson Schaad reported that prescription medications may be prescribed on paper, verbally or electronically. Controlled medications, a subset of prescription medication, have special restrictions that specify conditions for oral or written prescriptions, and electronic prescriptions must comply with federal requirements. Additionally, in California, if written, the prescriptions must generally be written on prescription forms printed by DOJ-licensed printers with 14 specific features. He added that Schedule II controlled medications, with rare exceptions, cannot be orally ordered or refilled.

Chairperson Schaad stated that over the past decade, the abuse of pharmaceutical drugs both controlled and noncontrolled has skyrocketed in the United States and has led to the current opioid epidemic throughout the country.

Chairperson Schaad reported that in California criminal organizations have been able to take advantage of weaknesses and lack of oversight of the printing program for prescription pads, resulting in their ability to counterfeit prescriptions. This has led to the diverting of the most dangerous and addictive drugs prescribed. Chairperson Schaad stated that as recently as November 29, 2017, a member of a drug trafficking organization that illegally acquired and distributed at least 50,000 oxycodone tablets valued at $1.5 million using counterfeit security prescription forms during a three-year

span was convicted in federal court in San Diego.

Chairperson Schaad explained that some patients who have become addicted to drugs or simply want to divert drugs alter prescriptions to increase the quantity prescribed, add additional drugs, or add refills. Some steal entire prescription pads from prescribers that are sold to criminal organizations or used by addicts to fill the drugs of their choice. Chairperson Schaad noted that prescribers routinely report losing their pads to the Board of Pharmacy and other agencies.

Chairperson Schaad reported that there are currently seven states that have passed legislation on e-prescribing. Laws already exist in three states (NY, MN, and ME) while the remaining four will become effective in 2018. Of the three states with active laws, Minnesota requires prescribers, pharmacies and health systems to have the capabilities to e-prescribe but does not mandate its use. However, NY and ME mandate the use of e-prescribing as the primary means of prescribing medication.

Chairperson Schaad stated that according to Surescripts data, 98 percent of retail pharmacies were able to accept e-prescriptions and 45.3 million prescriptions for controlled substances were delivered electronically in 2016 – a 254 percent increase from the 12.81 million controlled substance e-prescriptions in 2015.

Chairperson Schaad explained that in New York, which has had a mandate since March 2016 for both controlled and non-controlled prescriptions to be e-prescribed:

- 98.1 percent of pharmacies were EPCS-enabled.
- 72.1 percent of prescribers were EPCS-enabled. (One year ago, only 47% of New York prescribers could use EPCS.)
- 91.9 percent of controlled substance prescriptions were sent electronically, according to Surescripts).

Chairperson Schaad stated that the use of e-prescribing in California is increasing because e-prescribing helps to:

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

Chairperson Schaad reported that board staff recommends sponsoring legislation to require e-prescribing as the primary mode for ordering controlled and other prescription

drugs in CA. Staff notes that the proposal would need to allow for exemptions to the e-prescribing requirements to address some scenarios, e.g., for terminally ill patients or when the electronic system is not available.

Chairperson Schaad added that as part of its discussion the committee may also want to consider when such provisions would take effect. In NY, the mandate to use e-prescribing was three years after enactment of their regulations, and their full implementation date was 2016. (Several other exemptions are still being phased into e-prescribing.)

Dr. Gutierrez and Chairperson Schaad spoke in support of requiring e-prescribing in California.

Dr. Gutierrez stated that there are some circumstances that the board may want to consider exempting. She explained that in New York, e-prescribing in emergency rooms sometimes caused problems for patients. Ms. Herold agreed that switching to 100 percent e-prescribing will not work and added that as part of the legislative process these exemptions (emergency rooms, rural areas, terminally ill patients) will need to be addressed.

Ms. Herold stated that the according to the New York Board of Pharmacy's executive officer, within two years of implementing e-prescribing doctor shopping dropped by 90 percent. Ms. Herold stated that she strongly recommends that the board require e-prescribing with a three-year implementation timeline.

Dr. Gutierrez stated that in her professional career she has found that e-prescribing benefits patients by ensuring prescription accuracy and helps pharmacists ensure that controlled substance prescriptions are valid.

BJ Bartleson from the California Hospital Association spoke in support of e-prescribing and asked that the board allow for an implementation period so that hospitals can get the needed electronic systems in place.

Angie Manetti representing the California Retailers Association also spoke in support of e-prescribing.

Lori Womsly representing Walgreens spoke in support of e-prescribing but stated that a three-year implementation may be too long. Dr. Gutierrez agreed that the board should not specify an implementation timeline as this would probably be determined during the legislative process.

A representative from Kaiser Permanente spoke in support and asked the board to be mindful of areas where e-prescribing may be inappropriate (such as in emergency rooms and in rural areas).

Charlie Hardey from CVS Health spoke in support of e-prescribing and added that currently approximately 30 percent to 40 percent of prescriptions CVS receives are via e-prescription. He added that CVS's data analysis shows that after the implementation of e-prescribing in New York, there has been a significant decrease in pharmacy and prescriber transcription errors. He also noted that according to CVS when a hard-copy prescription is handed to a patient, 1 in 3 patients will not get it filled; e-prescribing helps doctors and pharmacists monitor patient adherence.

A member of the public asked if veterinarians would be exempt. Ms. Herold responded that in some states they are exempted, but the board will have to determine if they should be exempted in California. The board determined that this would need to be researched and addressed as part of the legislative process.

A pharmacist asked if e-prescribing would affect oral prescriptions. Ms. Herold responded that currently the board does not intend to disallow oral prescriptions; however, the preferred method would be e-prescribing.

Motion: Sponsor legislation requiring e-prescribing for all prescriptions in California. Direct staff to work with the chair of the committee to determine settings where e-prescribing my not be clinically appropriate.

M/S: Gutierrez/Munoz

Support: 3 Oppose: 0 Abstain: 0

DynaLabs Stability Studies Presentation

During the meeting, DynaLabs provided the committee with a presentation on stability studies and potency over time. The presentation highlighted, potency over time, what is required in a stability study, stability indicating method creation per USP, linearity and range, accuracy and precision, forced degradation studies, validation extension/specificity, summary of differences between POT vs SIM study, specificity aka validation extension and how cGMP ideology relates to sound scientific principal.

The committee discussed FDA approval, specificity and validation. Chairperson Schaad asked DynaLabs representative if they are FDA approved because the FDA has not disapproved their method. DynaLabs representative confirmed that by FDA not saying their method is wrong there is an inference that their method is correct.

Ms. Sodergren asked if their stability indicating method is consistent with USP for 503(a). DynaLabs representative confirmed that stability indication is required for 503a and/or 503(b).

8. Discussion and Consideration of Noncompliant California Security Prescription Forms

Chairperson Schaad informed the committee that the California Health and Safety Code contains specific provisions for California Security Forms, which are the specialized prescription forms for prescribing controlled substances in California. There are 14 security features that are required to appear on the form. California Department of Justice (DOJ) licenses the printers who are authorized to print these forms.

Chairperson Schaad explained that the board has identified that noncompliant security forms are in use. The board typically cites and fines the pharmacy, and advises the prescribing board that one of its practitioners is using noncompliant form.

Chairperson Schaad, specified that in early November, two pharmacy chains refused to fill non-compliant security forms. The board learned that a DOJ audit of California licensed security printers identified 12 companies that were producing forms that were non-compliant.

Chairperson Schaad informed the committee that the board recently has received complaints from patients or prescribers whose patients have been denied medication from the pharmacy because of the noncompliant forms

Chairperson Schaad confirmed that a Subscriber Alert has been released addressing, in part, Interim Solutions.

The committee was informed by Ms. Herold that there are 33 DOJ licensed security printers. There are four licensed security printers who continue to print noncompliant forms. There are two major areas of noncompliance: no checkoff box for the number of refills and absence of a watermark.

Ms. Herold reminded the committee that initially the board processed the licensure of security printers. In 2006, licensure responsibility was transferred to DOJ, regulations have not yet been promulgated. Ms. Herold suggested that the committee may want to consider working with DOJ to transfer the licensure of security printers back to the Board of Pharmacy, due to our ability to regulate.

The committee heard public comment which recommended a standardized template to ensure that compliance is consistent, an inquiry on how pharmacists would know if a form received from a licensed security printer was valid as well as information that there are prescribers who refuse to buy new forms until they have run out, regardless of warnings.

Motion: Executive Officer will work with Department of Justice to ensure that prescribers are receiving compliant forms.

M/S: Gutierrez/Schaad

Support: 3 Oppose: 0 Abstain: 0

9. Update on Emergency Regulations to Amend California Code of Regulations, Title 16 Section 1735.2, Related to Compounding Beyond Use Dates

Chairperson Schaad informed the committee that during the July 2017 Board Meeting, the board voted to pursue an emergency regulation to amend Section 1735.2.

The committee was informed that emergency regulations were filed on December 11, 2017.

10. Discussion and Consideration of Draft Frequently Asked Questions Relating to Compounding Requirements, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.

Chairperson Schaad stated the committee has considered requested changes to the board's compounding requirements. Some of the requested changes were accepted and are included in the board's emergency rulemaking and/or the permanent rulemaking referenced above.

Chairperson Schaad also stated that when considering some other requested changes, members determined that a change to the regulation was not necessary, but additional guidance should be provided in the form on a FAQ.

Board staff confirmed that a FAQ has been developed, but the committee was encouraged to consider adding other areas that would be helpful in the FAQ.

The committee heard public comment. A member of the public suggested a FAQ topic on the required training and competency requirements (content and frequency) of non-sterile compounding supervising staff pharmacists and PICs. Members of the public were invited to submit additional topics for an FAQ.

11. Discussion and Consideration of Requested Changes to Board Compounding Regulations, California Code of Regulations, Title 16, Sections 1735 et seq. and 1751 et seq.

Chairperson Schaad provided an overview of relevant law, CCR Section 1735 et seq., and CCR section 1751 et seq., which established the requirements for compounding drug preparation.

Chairperson Schaad invited discussion regarding the following proposed regulatory changes.

<u>Proposed change to CCR 1735(b) regarding the use of compounding kits</u>
Chairperson Schaad stated that the committee previously considered a change that would exempt from the definition of compounding the combining of nonhazardous ingredients

from prepackaged kits supplied by an FDA registered manufacturer for nonsterile preparations. In response to public comment, board staff was directed to contact the FDA to determine the level of regulatory oversight these kits have. Staff has been advised that the FDA is not aware of any FDA approved applications for compounding kits and the FDA has not conducted premarket review of any instructions provided with product or any premarket review of the manufacturer's assignment of BUDs. The FDA also advised board staff that it is currently reviewing its policy in this area. Given the review being undertaken by the FDA, rather than exempting compounding kits from the definition of compounding, an alternative approach may be to exempt such compounding from some of the regulation requirements such as the compounding log. Based on the direction from the committee, staff can develop language to facilitate implementation.

A representative from the California Pharmacists Association (CPhA) encouraged the board to maintain consistent with USP in the creation of compounding regulations. Board staff asked if there is an exemption for compounding kits in their suggested language. CPhA representative stated that there is no specific language, but they recommend reference to CCR1735 (a)(3). CPhA recommends that the kits, themselves, be held to the same compounding standards as medications.

As part of its discussion the staff and committee discussed how to determine if a medication in a kit is an FDA approved medication.

The committee stated the goal is to move forward while making sure the kits are available and meet all standards. Board staff will work on a recommendation for the next meeting.

Proposed change to CCR Section 1735.1(r) regarding the board's current definition of "hazardous drug"

Chairperson Schaad stated that the committee previously considered a request to change the board's definition of "hazardous drug" to mirror the definition provided in USP <800>. In late September 2017 USP announced the postponement of the official date of Chapter <800> until December 1, 2019 to coincide with the anticipated update to Chapter <797>.

Consistency between the board's definition of hazardous and USP <800> would be beneficial to the board's regulated public. However, given the postponement of the relevant USP Chapter, it seems appropriate for the committee to provide guidance on its preference for reconciling the two definitions.

Chairperson Schaad presented proposed language that could be used to update the board's definition of hazardous to coincide with the effective date of USP <800>.

The committee was informed by public comment that pharmacists have been complying by performing appropriate risk assessment. A public member recommended that language allows for risk assessment and allows for alternate strategies, in alignment with USP <800>.The committee was informed that CalOSHA is also working on regulations,

therefore, recommendations should be identical.

Board staff confirmed that staff will research USP <800>, in relation to risk assessment.

Proposed Change to CCR Section 1735.2(a), regarding documentation of prescriber's authorization to compound

Chairperson Schaad stated that during prior discussions, the committee considered if it would be appropriate to remove the requirement to document a prescriber's authorization to compound a product. As a result, the committee requested additional research to be conducted by board staff.

Chairperson Schaad explained to the committee that without documentation neither the pharmacy nor the board will have any record that the prescriber authorized use of a compounded product.

Chairperson Schaad informed the committee that public comment previously contemplated that such a requirement could result in a delay in therapy. It was suggested that in order to avoid a delay, a slight revision to the language or an FAQ could be developed to specify that the documentation could be made after the compounded preparation is dispensed.

The committee discussed, in part, whether this change is necessary, explored the need for written documentation at a pharmacy level and the apparent need to clarify what makes a prescription compound.

Public comments supported that this change is unnecessary.

The committee directed the board staff to create language that is not burdensome nor redundant to current requirements in law. Board staff will refine current language and draft language that will focus on consumer protection.

Proposed Change to CCR Section 1735.2(i)(2)-(4), regarding BUDs for sterile drug products

Chairperson Schaad stated that during prior discussions, the committee considered if changes were necessary to the requirements for the establishment of a BUD for sterile products. At the time of its last discussion, the committee was anticipating changes to USP <797> would be in place in 2018. Given the delay in those changes, it may be appropriate consider if board requirements should be updated now and reassessed after USP completes it work.

Chairperson Schaad provided the committee, for consideration, recommended language which may more clearly align with current USP <797> requirements.

The committee was informed by board staff that the presented recommended language was previously brought to the committee; no action has been taken.

Public comment proposed mirroring emergency regulations for non-sterile compounding to apply to sterile compounding. Public comment also encouraged adding language for approved monographs.

The committee asked board staff to research what we are currently doing with patients who need more than one dose and look for alternatives.

Proposed Change to CCR Section 1735.6(e), regarding the venting requirements for hazardous drug compounding

Chairperson Schaad stated the board's current regulations require such compounding must be completed in an externally vented, physically separated room and that each PEC in the room shall also be externally vented.

Chairperson Schaad informed the committee that board staff received questions about the venting requirements and was recently advised that the board's application of the requirement, which allows a single venting system for both the PEC and the room, is consistent with OSHPD's. Specifically, OSHPD advised the board staff that there is nothing in the code or USP that prevents a designer from venting the room through the hood and noted that the key is to ensure that the design would not violate the hood's listing requirements to be able to maintain its ISO-5 environment.

Chairperson Schaad stated that during prior discussions, the committee considered if alternative containment strategies for hazardous drugs could be considered. Given the statements from OSHPD on this item, board staff does not believe such a change is appropriate.

Chairperson Schaad informed the committee that recently, board staff was advised that the board's requirements should be placed in the Building Standards Code. Board staff confirmed that staff will be working with legal counsel to determine if such a change is necessary and if so, the best strategy for implementation.

No public comment.

Proposed Change to CCR Section 1751.4(d) regarding where decontamination requirements and cleaning frequency

Chairperson Schaad stated that in response to questions submitted previously, it was suggested that the board consider detailing contamination requirements as well as reconsider the frequency of cleaning some surfaces and areas that must be cleaned.

Chairperson Schaad provided the committee with proposed language that could be used to update such requirements.

Public comment recommended extending the frequency from 48 to 72 hours, to allow for long weekends. Public comment also recommended using the verbiage, “when open and daily when compounding”.

The committee discussed issues with pharmacists that only open once a month. The committee was informed that board staff could work with staff experts to consider consequences of cleaning once per month for such pharmacies. The committee directed board staff to conduct more research to present to the committee, at a later date.

Proposed Change to CCR Section 1751.7(e)(1) regarding alternative testing methods and end product testing requirements.

Chairperson Schaad stated that the committee has previously considered whether a rapid microbial test method may be appropriate. Such testing, when used and applied appropriately, can provide test results much more quickly than current testing requirements, which could address some concerns raised about delays in therapy.

Chairperson Schaad presented proposed language that could be used to allow for the use of rapid microbial method testing for batch-produced sterile drug programs.

In relation to the proposed language, Chairperson Schaad stated that the committee has previously considered if the board should expand its current exception for end product testing of non-sterile to sterile batch preparations. Given that pharmacies need to provide compounded preparations when a drug is in short supply, a limited exception for such instances may be appropriate.

In response, Chairperson Schaad presented proposed language that could be used to create such an exception.

The committee agreed that they agreed with the concept which includes the use of RMM and FDA.

Public comment suggested taking out RMM and using alternative testing methods per USP <797>. In addition, public comment recommended the board to consider irrigation solutions being exempt from pyrogen testing.

Board staff confirmed that they will research irrigation solution issues. The results of research will be brought directly to the full board.

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

Chairperson Schaad provided an overview of relevant law and an overview of the process. Chairperson Schaad provided the committee with an update, informing them that 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.

Chairperson Schaad reminded the committee During the November 2017 Board Meeting, the recent delay in USP <800> to December 1, 2019, was discussed. The board directed staff to continue to evaluate waivers and monitor progress toward compliance with the board's regulation. The board granted authority to the executive officer to grant waivers through November 30, 2019.The board's continued monitoring of progress is consistent with USP, which is "…encouraging early adoption and implementation of Chapter <800> to help ensure a safe environment and protection of healthcare practitioners and others when handling hazardous drugs."

Chairperson Schaad reported that since the waiver process began, 415 waivers have been approved. Board staff continues to receive a relatively low number of new requests. However, as implementation of the waivers transitions to a monitoring phase, board staff is now undertaking review of status reports that are documenting progress of an entity to achieving compliance

Ms. Herold informed the committee that the last Waiver Appeal meeting was conducted in July 2016.

13. Enforcement Statistics

Enforcement statistics were distributed for two months.

14. Future Committee Meeting Dates

Chairperson Schaad reported that scheduled committee dates for 2018 as provided below:

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

Chairperson Schaad adjourned the meeting at 2:33 PM.