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
CHAIR REPORT

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

a. Report on the Presentation by 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)

Attachment 1

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 also 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.

Committee Discussion

Jan Hirsch, BPharm, PhD and UCSD researcher, provided a presentation on the status and direction of UCSD's experimental program regarding access to medications from an ADDS. UCSD provided a PowerPoint presentation, Study of Expanded Use of an Automated Delivery Device Extension Update. The committee was advised that no action was required and that the presentation was being provided consistent with the board's request to receive an update on the study after the extension of study was granted.

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

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

Background

At the request of the committee, Board Chiefs of Enforcement Julia Ansel and Tom Lenox provided general enforcement information on board investigations as well as specific information about citations and fines issued by the board during 2017.

Committee Discussion

Chairperson Schaad noted that the presentation was part of the board's efforts to increase transparency regarding the board's citation and fine program. Further, Chairperson Schaad noted that members of the board's regulated public have a misconception about board member involvement in the issuance of citation and fines.

As part of the discussion, the committee was advised that most programs within the DCA have a citation and fine program. Further, however it was noted that the board's authority to issue the letters of correction and the letters of admonishment are unique to the board. Ms. Herold added that the Board of Pharmacy has its own inspectors, staffed with licensed pharmacists, which also differ from other boards.

The committee was provided with the criteria that staff consider when assessing a fine which are included in California Code of Regulations, title 16, section 1775.2.

As part of the discussion, the committee clarified that the profession must understand all types of enforcement action. Additionally, the committee noted the need for ongoing transparency in all policies and procedures guiding the use of citations and fines.

Recent Update

During this meeting board staff will again provide a presentation on general enforcement information, board investigations as well as specific information about citations and fines issued by the board during 2017. **Note:** copies of the presentation will be provided at the meeting.

c. Discussion and Consideration of Disclosure of Enforcement Actions, Including Citation and Fines

Background

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 his or her enforcement matter.

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.

At the January 2018 board meeting, the board members voted to send this issue back to the committee for further discussion and reconsideration.

Committee Discussion

Board staff provided information about how other DCA boards are handling transparency in the

area of citations, fines and disciplinary actions for all licensees. Board staff stated that a review of a few boards disclosed that some boards post citations as an attachment to license searches. The degree of disciplinary transparency varies amongst the individual boards. Decision points are based differently, depending on the needs of the specific board.

The committee was informed that currently, the board posts items related to discipline but citations and fines are not disclosed.

After discussion the committee directed board staff to survey all healing arts boards to examine how each healing arts board handles transparency in all areas of discipline. The results will be brought back to the next committee meeting.

The committee also asked that the agenda item for the next committee meeting be changed to reflect that the committee would be discussing general transparency in reporting citation and fines for all licensees, not just for board members.

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

Attachment 2

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, known as Uniform Standard 4. The committee must determine whether the existing criteria should be updated. A report is due to the Legislature by January 1, 2019.

The first SACC meeting was scheduled for Monday, April 23, 2018 from 10 a.m. to 3 p.m. in the DCA HQ2 Hearing Room.

Committee Discussion

Ms. Herold informed the committee that she is a member of the SACC panel. Ms. Herold stated that the SACC meeting should, in part, discuss a modification to the frequency of fluid testing.

The committee did not take action on this item.

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

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

Attachment 3

Background

Information on the Pew Charitable Trusts State Oversight of Drug Compounding Report was provided. 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. The committee was informed that 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.

The Pew Charitable Trusts "State Oversight of Drug Compounding" 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.

Committee Discussion

Ms. Herold confirmed that California is one of the 10 states that are compliant with USP.

As part of its discussion, the committee discussed the state's provision that allows pharmacies to compound for prescriber office use but such practice is prohibited under federal law.

Committee Actions:

The committee directed that staff shall share the Pew Charitable Trusts "State Oversight of Drug Compounding" Report with the Medical Board and Veterinary Medical Board, in order to support oversight.

Committee Recommendation (Motion): Advocate for changes at the federal level to allow for compounding for office use, consistent with the board's regulations.

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

f. Matters Related to United States Pharmacopeia Chapter (USP) 797, USP 800, and Other USP Chapters Relating to Compounding

1. Anticipated Release of Updates and Impact on the Board's Regulation of Pharmacy

Background

The proposed revisions for USP Chapter 795 were released in March 2018 and an open microphone session was held on April 20, 2018. On May 1, 2018, Chapter 795 will be formally published in *Pharmacopeial Forum* for review and public comment. The public comment period on USP 795 will close on July 31, 2018.

USP Chapter 797 will be formally published in the *Pharmacopeial Forum* for review and public comment on September 4, 2018. An open microphone session on Chapter 797 is scheduled for September 5, 2018. The public comment period for Chapter 797 will close on November 30, 2018.

Committee Discussion and Action
As part of a larger discussion, the committee was advised of the proposed changes to USP Chapters 795 and 797.

The committee briefly reviewed the proposed changes to Chapter 795 and noted that further modifications would be made to the chapter. The committee asked staff to draft a summary of the proposed changes to be discussed at the next committee meeting.

Recent Update
Board staff participated in the open microphone session on April 20, 2018, and note that it appears that Chapter 795 may establish practice guidance, but may not be strictly enforced.

It is anticipated that the final versions of chapters 795 and 797 will be available June 1, 2019. Board staff will continue to monitor developments and will keep the committee apprised of such efforts. As the chapters become finalized staff will provide the committee with summary documents highlighting the changes and any staff recommendations for consideration.

2. Discussion and Consideration of Statutory Proposal to Require USP Compliance in Pharmacy Law

Background
For several years this committee and the board have discussed the regulation of sterile and nonsterile compounding and most recently hazardous compounding. The results of these discussions were comprehensive regulations promulgated to ensure compounded drug preparations are 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.

Committee Discussion
The committee discussed the following:

- Whether the board could adopt USP 797.
- Whether USP 795, 797 and 800 could all be included.
- Whether, following adoption, regulations would be used to identify higher California standards.

The committee heard comments from the public that not all chapters of USP are relevant to compounding of drug preparations and that it may be unclear which sections of USP would require compliance.

Committee Recommendation (Motion): Draft statutory proposal to incorporate USP into the board's requirements for compounding of drug preparations.

Recent Update
Following the meeting, board staff and counsel drafted the following proposed statutory language.

Add Section BPC 4122.5 as follows:

> The compounding of drug preparations for furnishing, distribution, or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

g. Enforcement Statistics

Attachment 4

The board received 2055 complaints and has closed 2242 investigations. The board has issued 166 Letters of Admonishment, 1590 Citations and referred 253 cases to the Office of the Attorney General. The board has secured seven interim suspension orders, been granted eight Penal Code 23 suspensions, and issued one Cease and Desist. Further, the board has revoked 85 licenses, accepted the disciplinary surrender of 55 licenses, and imposed other levels of discipline against 138 licensees and/or applicants.

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

h. Future Committee Meeting Dates

Enforcement Committee dates for 2018:

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

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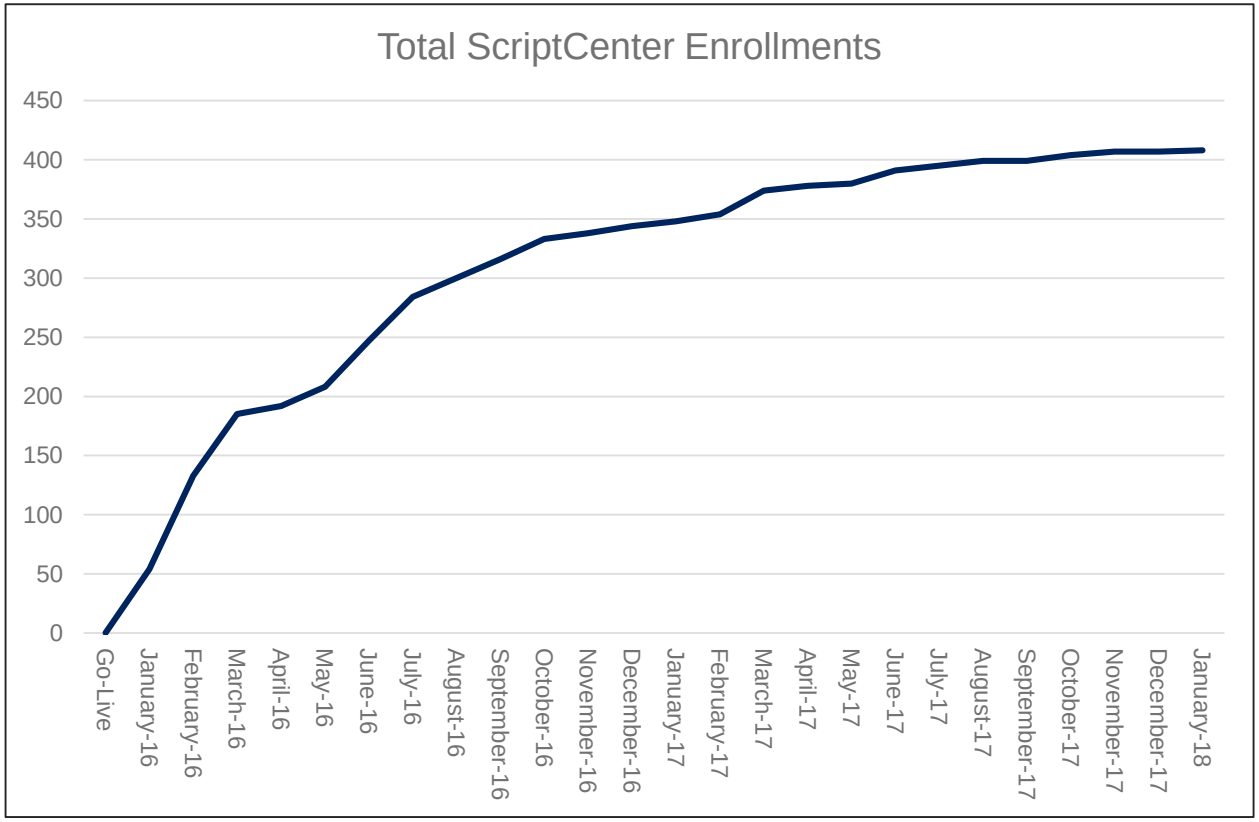
Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

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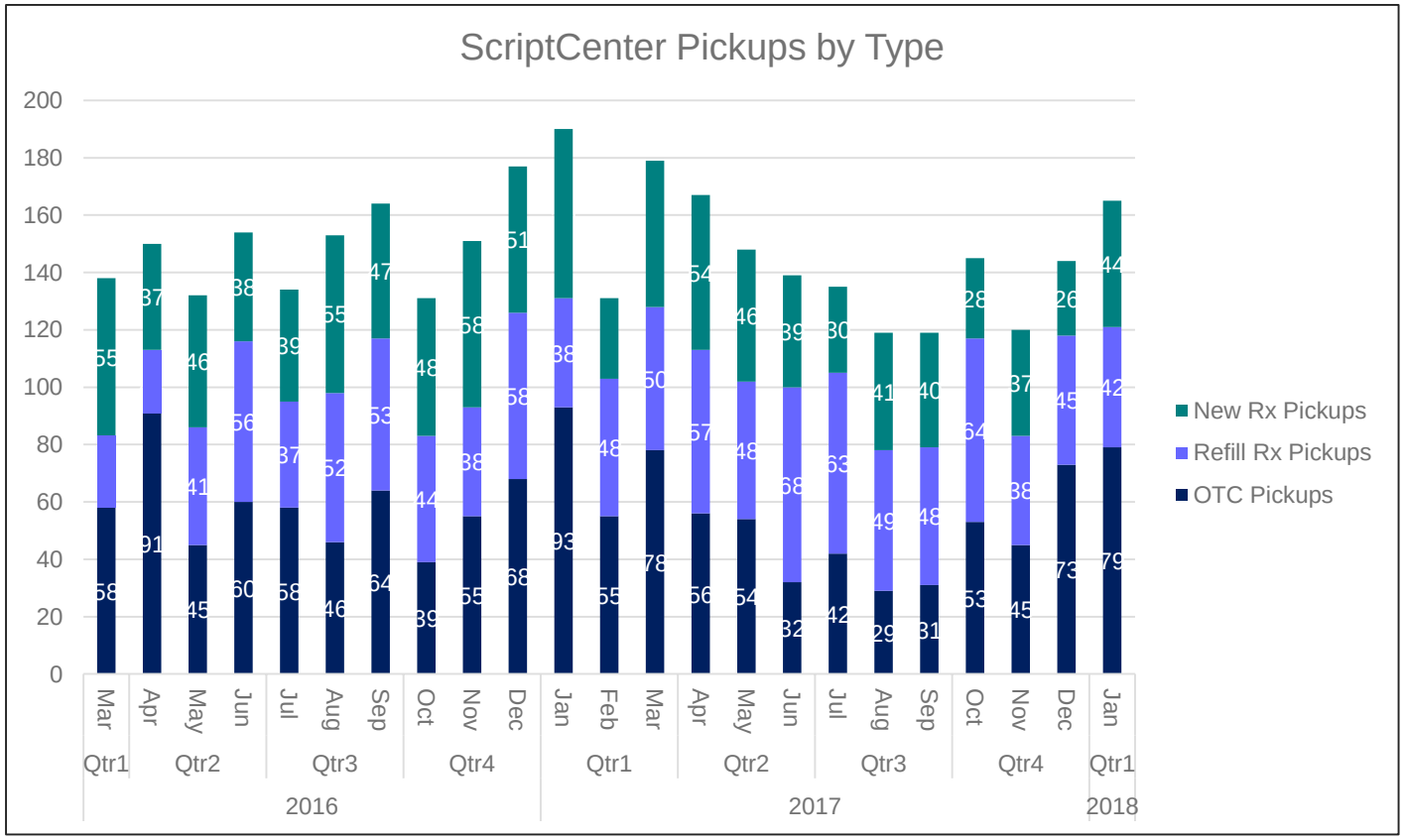
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*

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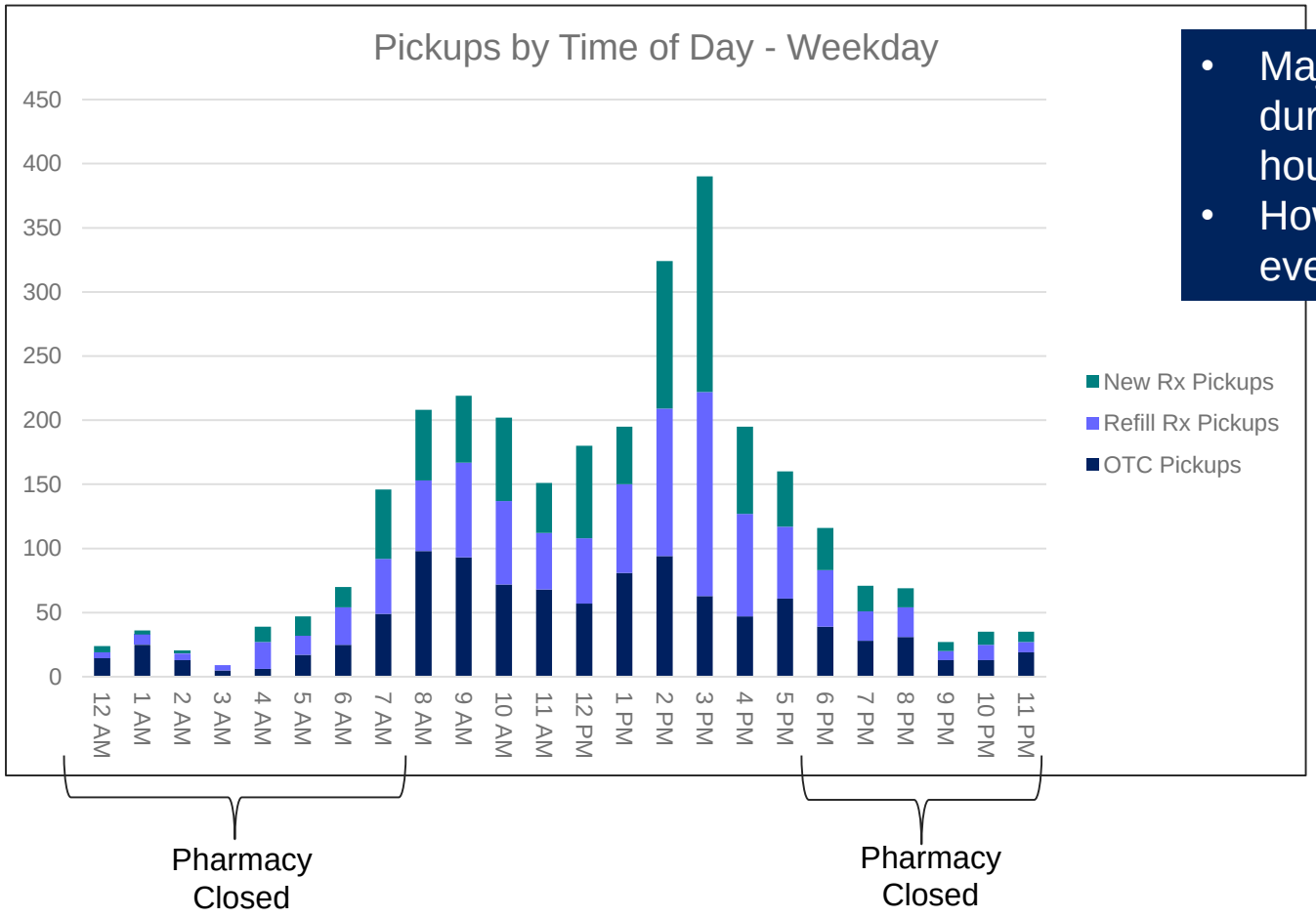
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*



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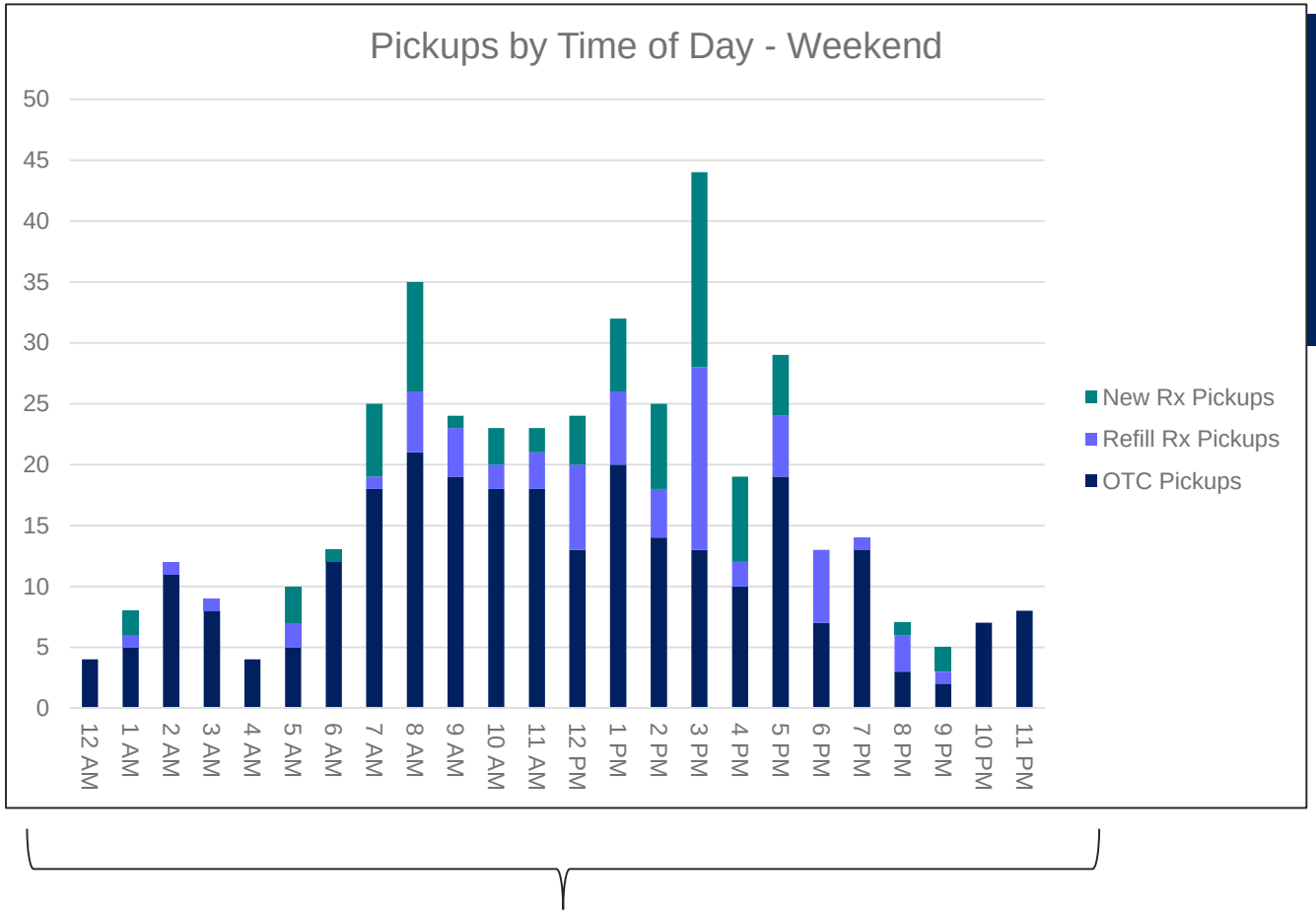
ScriptCenter Kiosk Activity 3/1/16 through 1/31/18 *(study period: 23 months)*



- 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)

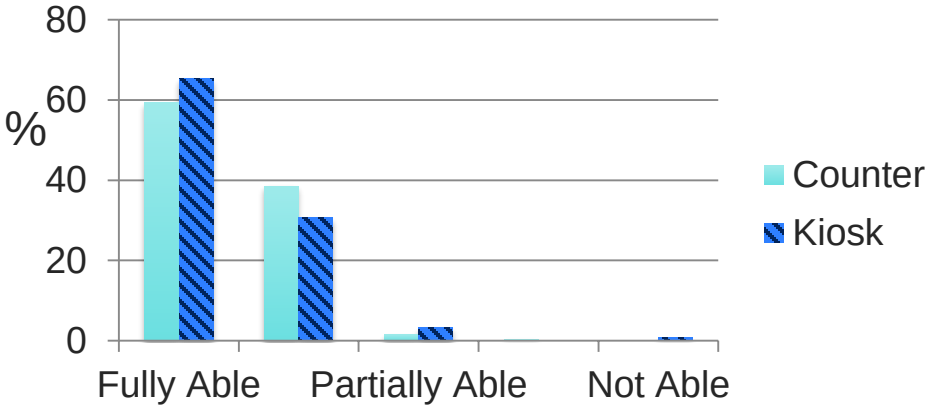
+ Regular Counter = Employees and Dependents only to “match” group using Kiosk

- Monthly mean period

** Significant difference

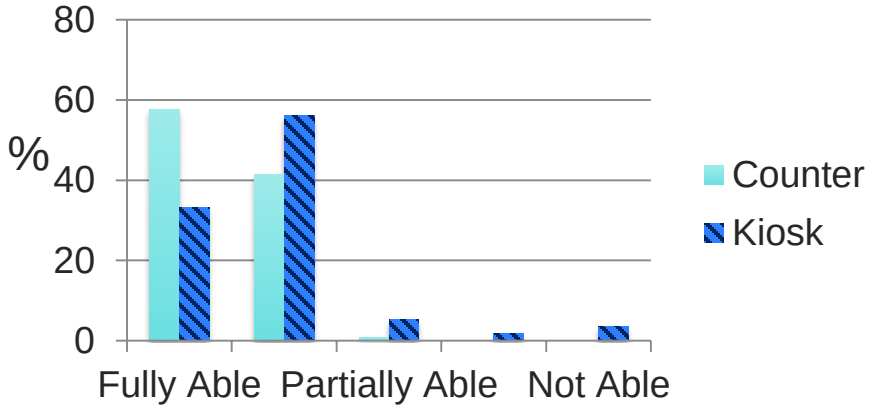
Pharmacist Assessments of Ability to:

Build Therapeutic Relationship



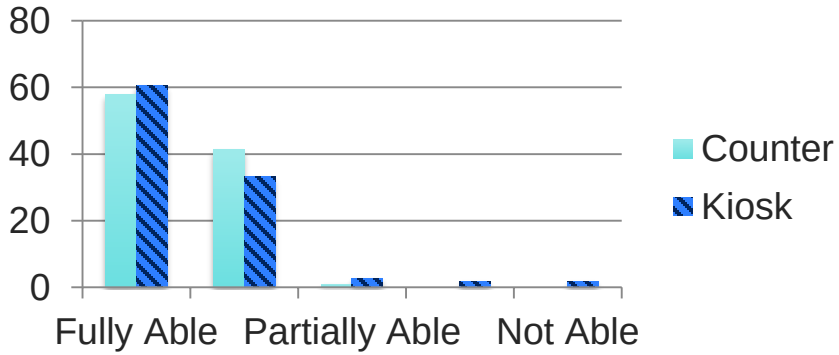
Pharmacist indicated not applicable (N/A):
Counter n=12, Kiosk n=72

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?

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.

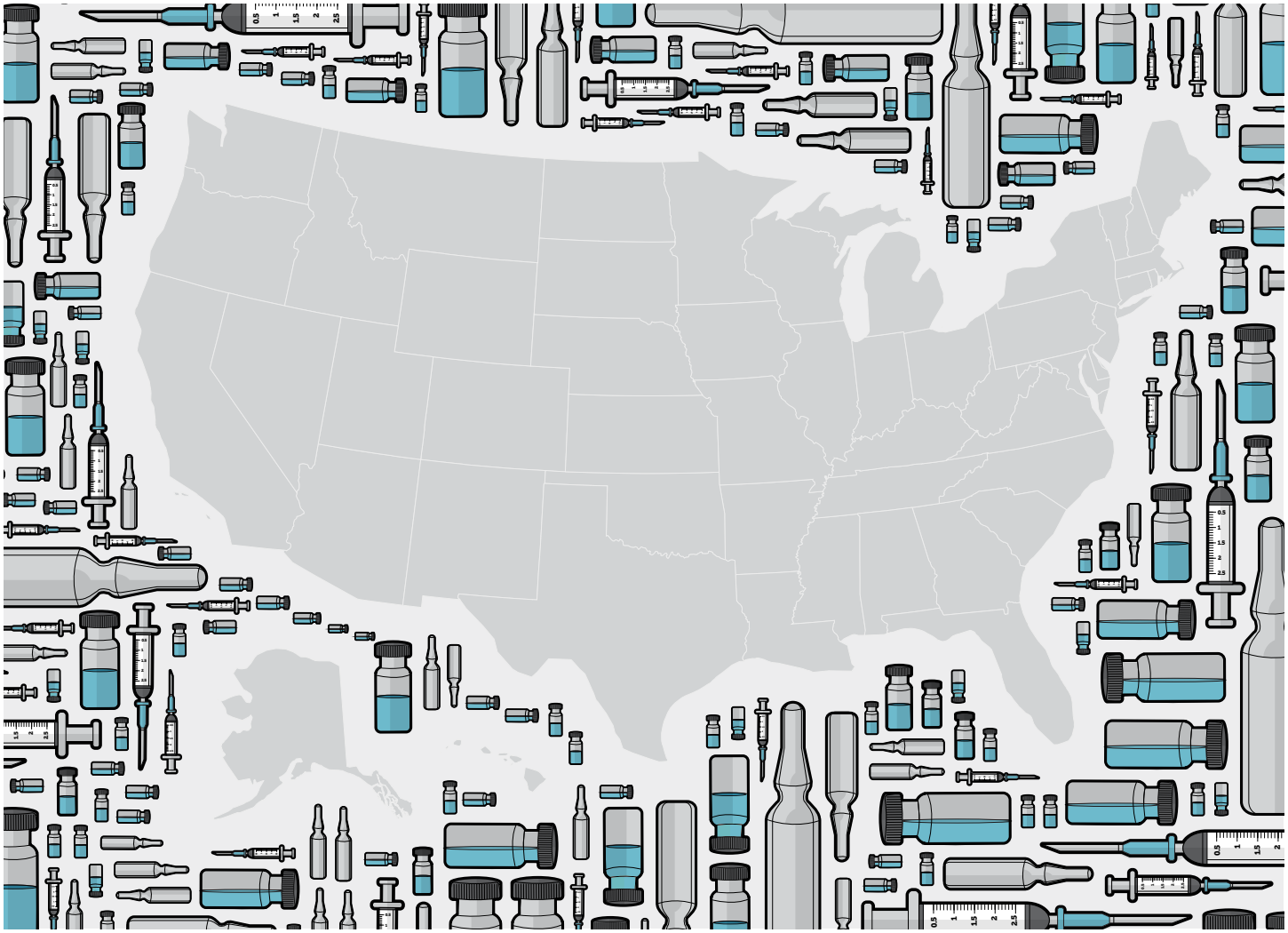
Data Collection

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.

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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.

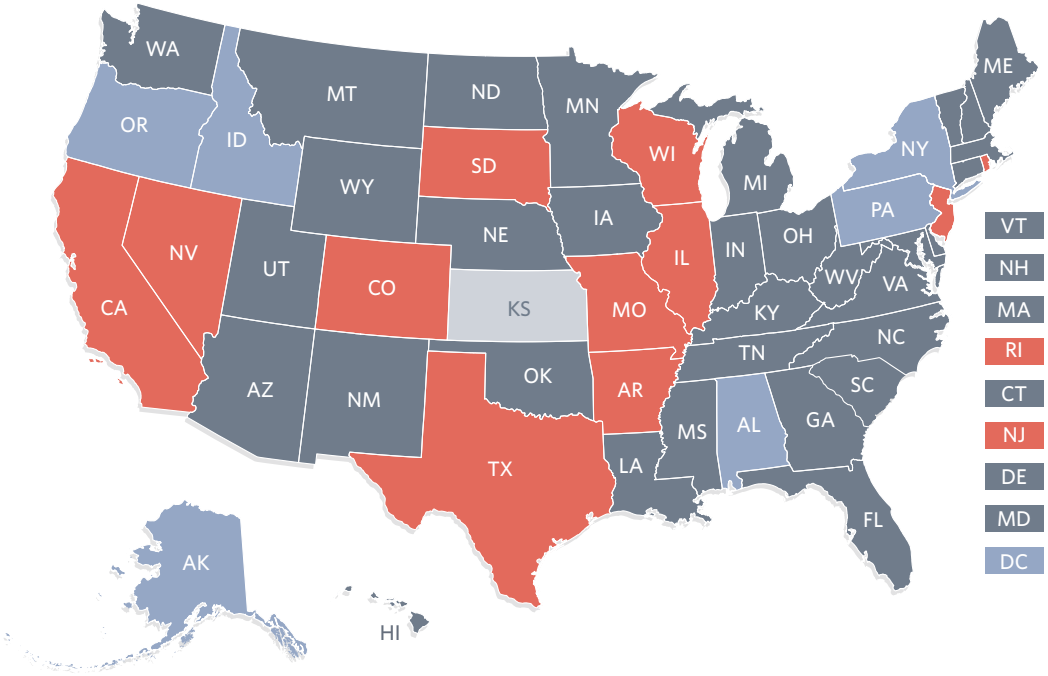
Our study found that 32 state boards of pharmacy require traditional pharmacies that compound sterile drugs for humans to be in full compliance with Chapter <797>. An additional 11 states have strong standards for sterile compounding practice, which 10 states characterize as "equivalent to or stricter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

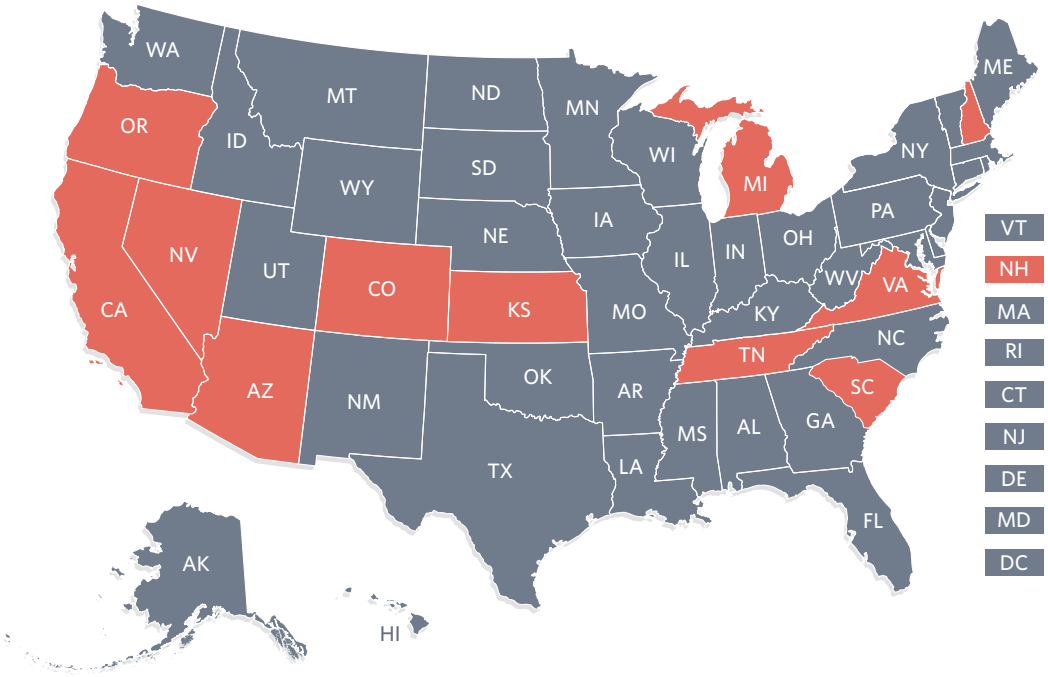
FDA finalized its prescription requirement guidance for industry in December 2016, an important step toward fully implementing the DQSA. The document clarifies the law's requirement that traditional compounders dispense or distribute compounded products only upon receipt of a valid prescription. Because 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

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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	
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

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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	
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.

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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.

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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.

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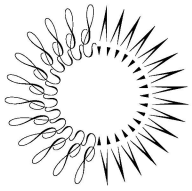


THE PEW CHARITABLE TRUSTS

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	749		2055
Closed	676	783	783		2242
4301 letters	6	5	8		19
Pending (at the end of quarter)	2283	2028	2023		2023
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	992	952	987		987
Drug Diversion/Fraud	370	307	321		321
RX Abuse	185	132	94		94
Compounding	130	86	78		78
Outsourcing	43	29	16		16
Probation/PRP	63	49	69		69
Mediation/Enforcement **	190	143	139		139
Criminal Conviction	320	330	319		319
Application Investigations					
Received	228	96	100		424
Closed					
Approved	92	125	73		290
Denied	17	20	16		53
Total ***	126	177	112		415
Pending (at the end of quarter)	192	153	90		90
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	30	73	63		166
Citations Issued	425	610	555		1590
Total Fines Collected ****	$535,944	$501,038	$636,545		$1,673,527

* 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 3/31/2018 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	68		253
Accusations Filed	78	43	84		205
Statement of Issues Filed	10	7	11		28
Petitions to Revoke Filed	2	0	4		6
Pending					
Pre-accusation	204	200	191		191
Post Accusation	245	237	246		246
Total*	471	516	484		484
Closed					
Revocation					
Pharmacist	7	2	7		16
Intern Pharmacist	1	0	1		2
Pharmacy Technician	22	17	20		59
Designated Representative	0	0	0		0
Wholesaler	0	1	1		2
Sterile Compounding	1	0	0		1
Pharmacy	2	1	2		5
Revocation,stayed; suspension/probation					
Pharmacist	2	3	2		7
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	17		39
Intern Pharmacist	1	0	1		2
Pharmacy Technician	0	1	2		3
Designated Representative	1	2	0		3
Wholesaler	0	1	1		2
Sterile Compounding	3	0	0		3
Pharmacy	9	12	6		27
Surrender/Voluntary Surrender					
Pharmacist	2	3	8		13
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	2		6
Pharmacy	6	3	9		18

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	4		12
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	3		8
Licenses Granted					
Pharmacist	1	1	0		2
Intern Pharmacist	1	3	2		6
Pharmacy Technician	1	2	3		6
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	1		5
Designated Representative	0	0	1		1
Wholesaler	0	0	0		0
Sterile Compounding	1	0	1		2
Pharmacy	0	0	0		0
Cost Recovery Requested**	$357,388	$439,458	$440,473		$1,237,318.59
Cost Recovery Collected**	$238,133	$189,505	$146,584		$574,222.07

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	0	3	4		7
Automatic Suspension / Based on Conviction	2	0	2		4
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	219		218
Intern Pharmacist	5	8	10		9
Pharmacy Technician	32	29	31		29
Designated Representative	1	3	2		2
Pharmacy	68	75	74		73
Sterile Compounding	15	16	15		16
Wholesaler	3	4	5		5
Probation Office Conferences	27	36	28		91
Probation Site Inspections	145	165	156		466
Successful Completion	6	7	9		22
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 March 31, 2018.

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and probations with substance abuse disorders.

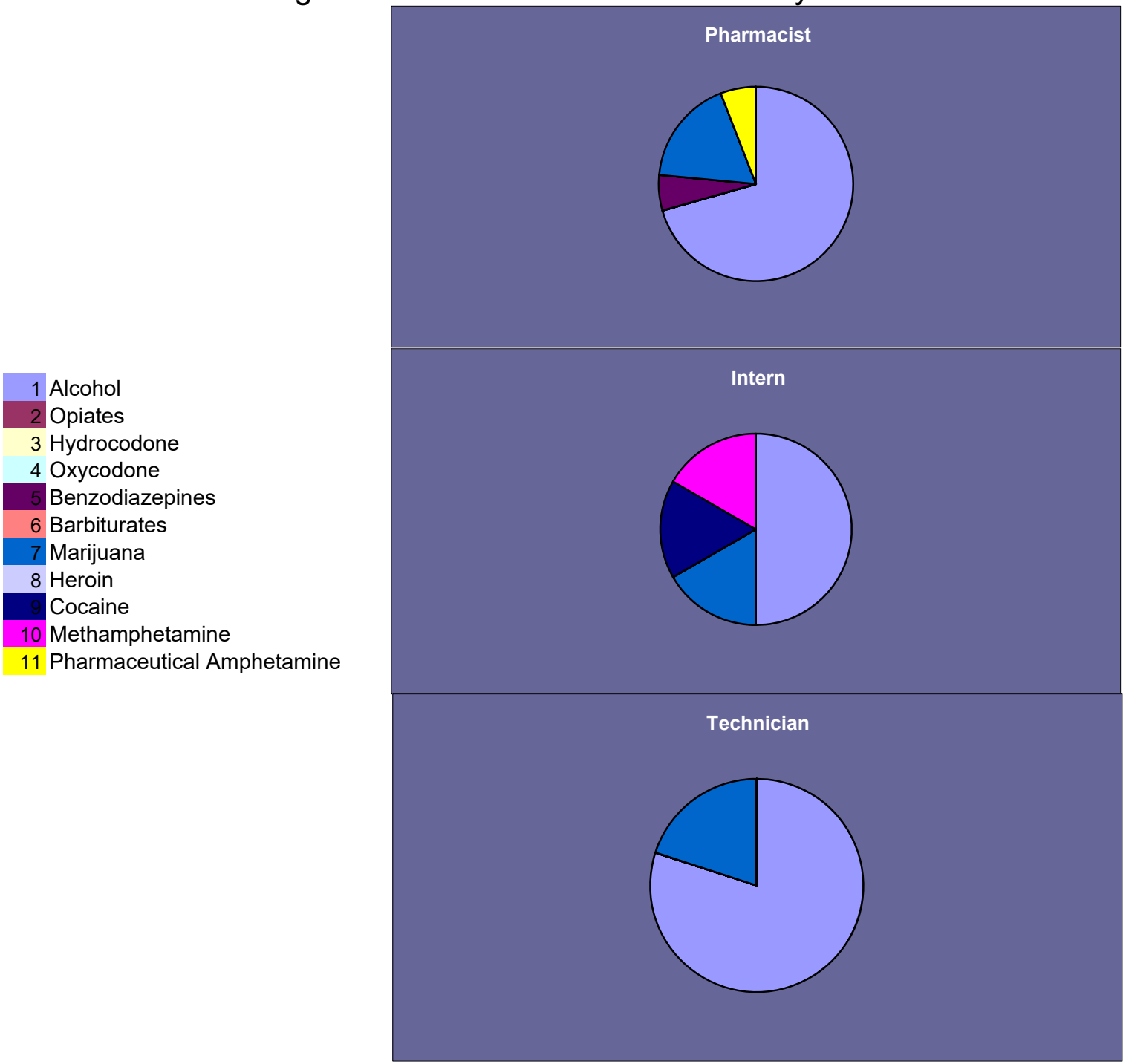
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 17/18
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	5	5	7		17
PRP Under Investigation	2		3		5
PRP In Lieu Of (investigation conducted)	1				1
Total Number of PRP Intakes	8	6	10		24
New Probationers					
Pharmacists	5	9	7		21
Intern Pharmacists			4		4
Pharmacy Technicians			4		4
Total New Probationers	5	9	15		29
PRP Participants and Recovery Agreements					
Total PRP Participants	49	47	50		N/A
Recovery Agreements Reviewed	40	49	51		140
Probationers and Inspections					
Total Probationers	77	81	83		N/A
Inspections Completed	145	165	156		466
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1	6	7		14
Drug Tests					
Drug Test Ordered (PRP and Probationers)	858	846	841		2545
Drug Tests Conducted (PRP and Probationers)	844	843	840		2527
Relapses					
Relapsed (PRP and Probationers)	1	11	1		13
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	9	9	12		30
Termination from PRP	2	4	1		7
Probationers Referred for Discipline	1	2	2		5
Closure					
Successful Completion (PRP and Probationers)	5	9	4		18
Termination (Probation)	1	1			2
Voluntary Surrender (Probation)	4	2	5		11
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	2	2	1		5
Non-compliance (PRP and Probationers)	15	20	7		42
Other (PRP)	3	2	1		6
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)	None	None	None	None	None

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and probations with substance abuse disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 17/18
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 17/18**
Alcohol	5	4	3		12
Ambien					
Opiates					
Hydrocodone					
Oxycodone			1		1
Morphine					
Benzodiazepines		1	2		3
Barbiturates					
Marijuana					
Heroin					
Cocaine		1			1
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol			1		1
Carisprodol			1		1
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 17/18**
Alcohol	1	1	1		3
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana			1		1
Heroin					
Cocaine	1				1
Methamphetamine	1				1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 17/18**
Alcohol			4		4
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana			1		1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2017 to June 2018



Printed on 4/19/2018

California State Board of Pharmacy
Citation and Fine Statistics
January 1, 2018 - March 31, 2018

556 Citations were Issued this Quarter

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine**	PIC no fine**	TCH with fine	TCH no fine
556	253	27	90	86	113	44	44	3

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed Person
9	7	2	0	1	2	2	8	2

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

**These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	26%	1716 - Variation from prescription	26%	11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	19%
1716 - Variation from prescription	20%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	20%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	18%
11164(a)/1761(a)(b) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	14%	11164(a)/1761(a) - Prescriptions for schedule II, III, IV, and controlled substance: form and content; record of practitioner dispensing schedule II controlled substance/No pharmacist shall compound o	13%	4113(c)/1714(b) - Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsibility	13%
1761(a)&(b)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/A pharmacist shall not compound or dispense a prescription for a con	10%	11164(a)/1761(a)(b) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	8%	1716 - Variation from prescription	12%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	6%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	8%	4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	8%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	6%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacist	6%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	7%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	6%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1714(c) - Operational Standards and Security; Pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	7%
1761(a)&(b) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/A pharmacist shall not compound or dispense a prescription for a controlled s	4%	1761(a)&(b)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/A pharmacist shall not compound or dispense a prescription for a con	5%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	6%
4113(c)/1714(b) - Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy/Operational Standards and Security; pharmacy responsibility	4%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	4%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	5%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	4%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	4%	11164(a)/1761(a)(b) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	5%