Wisconsin Department of Safety and Professional Services
Division of Policy Development
1400 E. Washington Ave
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

Scott Walker, Governor
Laura Gutiérrez, Secretary

PHARMACY EXAMINING BOARD
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
April 11, 2018

Notice: The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the action and deliberation of the Board.

AGENDA

11:00 A.M. or Immediately Following the Rules Committee Meeting

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-4)**

B. **Approval of Minutes of March 13, 2018 (5)**

C. **Administrative Updates – Discussion and Consideration**
1) Staff Updates
2) Board Member – Term Expiration Date
   a. Grace Degner – 7/1/2018
   b. Franklin LaDien – 7/1/2020 (reappointed, not yet confirmed)
   c. Terry Maves – 7/1/2018
   d. Thaddeus Schumacher – 7/1/2019
   e. Kristi Sullivan – 7/1/2020 (reappointed, not yet confirmed)
   f. Philip Trapskin – 7/1/2021 (reappointed, not yet confirmed)
   g. Cathy Winters – 7/1/2021 (reappointed, not yet confirmed)
3) Delegated Authority Update
4) DLSC Request for Delegation **(6)**
5) DLSC Request for Motion Regarding Continuing Education (CE) Material **(7)**

D. **Pilot Program Matters – Discussion and Consideration**
1) Aurora West Allis and Monroe Clinic Pilot Program Request – Discussion and Consideration **(8-12)**

E. **PDMP Update – Discussion and Consideration (13-36)**

F. **Legislation/Administrative Rule Matters – Discussion and Consideration**
1) Petition for Repeal of Phar 5.03 **(38-40)**
2) Scope for Phar 6.07 Relating to Storage **(41-42)**
3) Scope for Phar 8 Relating to Requirements for Controlled Substances **(43-44)**
4) Phar 17 Relating to Interns **(45-62)**
5) Update on Legislation and Pending and Possible Rulemaking Projects

G. **Speaking Engagements, Travel, or Public Relations Requests**

1) Designation of Cathy Winters to Attend the 2018 National Association of Boards and Pharmacy (NABP) on May 5 – 8, 2018 in Denver, CO

H. **Informational Items – Discussion and Consideration**

1) State Oversight of Drug Compounding -A Report from The Pew Charitable Trusts and NABP **(63-127)**

I. Items Received After Preparation of the Agenda

1) Introductions, Announcements and Recognition
2) Election of Board Officers
3) Appointment of Board Liaisons
4) Administrative Updates
5) Education and Examination Matters
6) Credentialing Matters
7) Practice Matters
8) Legislation/Administrative Rule Matters
9) Informational Items
10) Disciplinary Matters
11) Presentations of Petitions for Summary Suspension
12) Petitions for Designation of Hearing Examiner
13) Presentation of Proposed Stipulations, Final Decisions and Orders
14) Presentation of Proposed Final Decision and Orders
15) Presentation of Interim Orders
16) Petitions for Re-Hearing
17) Petitions for Assessments
18) Petitions to Vacate Orders
19) Requests for Disciplinary Proceeding Presentations
20) Motions
21) Petitions
22) Appearances from Requests Received or Renewed
23) Speaking Engagement(s), Travel, or Public Relations Request(s)
24) Division of Legal Services and Compliance (DLSC) Matters
25) Prescription Drug Monitoring Program Information
26) Consulting with Legal Counsel
27) Liaison Report(s)
    a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Philip Trapskin
    b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
    c. Credentialing Liaison(s): Cathy Winters, Terry Maves-Alternate
    d. Digest Liaison: Philip Trapskin
    e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
    f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
    g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters-Alternate
    h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
    i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin
    j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
    k. Screening Panel: Franklin LaDien, Cathy Winters, Kristi Sullivan
    l. Pilot Program Report Liaison(s): Philip Trapskin, Cathy Winters

J. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

K. **Deliberation on Division of Legal Services and Compliance (DLSC) Matters**

1) **Administrative Warnings**
   a. 17 PHM 028 (H.A.Z.) **(128-129)**
2) **Stipulations, Final Decisions and Orders**
   a. 16 PHM 127, Cassidy L. Rockey, R.Ph. **(130-135)**
   b. 17 PHM 015, Bentley Pharmacies, Inc. **(136-143)**
   c. 17 PHM 077, Specialty Veterinary Pharmacy **(144-149)**
   d. 17 PHM 131, Robert M. Stresing, R.Ph. **(150-155)**
3) **Case Closings**
   a. 17 PHM 023 **(156-159)**
   b. 17 PHM 028 **(160-162)**
   c. 17 PHM 064 **(163-172)**
   d. 17 PHM 071 **(173-182)**
   e. 17 PHM 072 **(183-187)**
   f. 17 PHM 086 **(188-193)**
   g. 17 PHM 122 **(194-197)**
4) **Discuss Inspection of NorthStar Radioisotopes (Pharmacy Manufacturer) (198-237)**

L. Consulting with Legal Counsel

M. Deliberation of Items Received After Preparation of Agenda

1) Education and Examination Matters
2) Credentialing Matters
3) Disciplinary Matters
4) Monitoring Matters
5) Professional Assistance Procedure (PAP) Matters
6) Petitions for Summary Suspension
7) Petitions for Designation of Hearing Examiner
8) Stipulations, Final Decisions and Orders
9) Administrative Warnings
10) Review of Administrative Warnings
11) Proposed Final Decisions and Orders
12) Orders Fixing Costs/Matters Related to Costs
13) Case Closings
14) Interim Orders
15) Petitions for Assessments and Evaluations
16) Petitions to Vacate Orders
17) Remedial Education Cases
18) Motions
19) Petitions for Re-Hearing
20) Appearances from Requests Received or Renewed

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

N. **Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate**

O. Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration

P. Board Strategic Planning and its Mission, Vision, and Values – Discussion and Consideration

ADJOURNMENT

Next Scheduled Meeting: May 24, 2018

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
MEETING MINUTES
March 13, 2018

PRESENT: Grace Degner, Franklin LaDien, Terry Maves, Thaddeus Schumacher, Kristi Sullivan,

EXCUSED: Philip Trapskin, Cathy Winters

STAFF: Dan Williams, Executive Director; Laura Smith, Bureau Assistant; Sharon Henes, Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 8:30 a.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF JANUARY 9, 2018

MOTION: Kristi Sullivan moved, seconded by Franklin LaDien, to approve the minutes of January 9, 2018 as published. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Adoption of Phar 15 Relating to Compounding Pharmaceuticals

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to approve the Adoption Order for Clearinghouse Rule 16-085, relating to compounding pharmaceuticals. Motion carried unanimously.

ADJOURNMENT

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 8:37 a.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Gretchen Mrozinski, Attorney Supervisor	February 12, 2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
February 22, 2018	☐ Yes ☒ No	Request for delegation

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes (Fill out Board Appearance Request) ☐ No	

10) Describe the issue and action that should be addressed:

Attorney Mrozinski is requesting that the Board adopt the following motion.

1. To delegate to DLSC the following prescreening authority: to prescreen complaints prior to a meeting of the screening panel to open any case that demonstrates a clear violation of law; to close at prescreening any case that clearly demonstrates that no violation took place; to close at prescreening complaints that the Board has already reviewed and acted upon that are the result of multiple-state discipline based on original violations; and, to refrain from sending to the screening panel NABP-VPP cases until such time as the final pharmacy response to the complaint is available from NABP.

11) Authorization

Signature of person making this request — Date

Supervisor (if required) — Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

State of Wisconsin
Department of Safety and Professional Services

AGENDA REQUEST FORM

Name and Title of Person Submitting the Request:	Date When Request Submitted:
Cori Altmann, Paralegal on behalf of Attorney Gretchen Mrozinski Division of Legal Services and Compliance	March 23, 2018 **Items will be considered late if submitted after 4:30 p.m. and less than:** ▪ **8 work days before the meeting for Medical Board** ▪ **8 work days before meeting for all other boards**

Name of Board, Committee, Council:

Pharmacy Examining Board

Board Meeting Date:	Attachments:	How should the item be titled on the agenda page?
April 11, 2018	☒ Yes ☐ No	Request for motion regarding CE material

Place Item in:	Is an appearance before the Board being scheduled? If yes, by whom?	Name of Case Advisor(s), if required:
☐ Open Session ☒ Closed Session ☐ Both	☒ Yes by Gretchen Mrozinski ☐ No	n/a

Describe the issue and action the Board should address:

The board members need to review and consider the following motion requested by the DLSC:

_____moves, seconded by _____ to delegate to DLSC staff, the authority to prescreen complaints for the purpose of reviewing submitted continuing education (CE) materials and to determine if CE requirements are met. If CE requirements are met, then DLSC staff should remove such CE documentation from the screening materials prior to screening. If the submitted documentation does not clearly establish that CE requirements are met, such documentation shall be forwarded to the screening panel for review.

Authorization:

Cori Altmann — 3/23/18

Signature of person making this request — **Date**

Supervisor signature (if required) — **Date**

Executive Director signature (indicates approval to add late items to agenda) — **Date**

Directions for including supporting documents:

1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Board's Executive Director.**
3. **If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Dan Williams	Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

3) Name of Board, Committee, Council, Sections:

Wisconsin Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
April 11, 2018	☒ Yes ☐ No	**Aurora West Allis and Monroe Clinic pilot program request – Discussion and Consideration**

7) Place Item in:	8) Is an appearance before the Board being scheduled? If yes, who is appearing?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes by ☐ No	N/A

Wisconsin law mandates that a pharmacist perform the final product verification for all medication products prior to the medication being dispensed or administered to the patient.[1] Tech-check-tech pilot programs are variances granted by the Wisconsin Pharmacy Examining Board that allow for a trained pharmacy technician to perform the final product verification check, instead of a pharmacist.[2] Currently, tech-check-tech (TCT) pilot programs exist for the community setting and institutional setting. However, neither of these programs include tech-check-tech for sterile products.[3] Over the last 3 months, Aurora West Allis Medical Center has collected data analyzing technician checking accuracy for sterile products with the hopes of presenting the data to the PEB to gain pilot program approval. The benefits of adding a pilot program for TCT sterile products include expanding the technician's role and increasing the availability of a pharmacist to provide direct patient care services.

March 23rd, 2018

Aurora West Allis Medical Center
8901 W Lincoln Ave.
West Allis, WI 53227

Monroe Clinic Hospital- SSM
515 22nd Ave.
Monroe, WI 53566

Dear Pharmacy Examining Board,

Wisconsin law mandates that a pharmacist perform the final product verification for all medication products prior to the medication being dispensed or administered to the patient.[1] Tech-check-tech pilot programs are variances granted by the Wisconsin Pharmacy Examining Board (PEB) that allow for a trained pharmacy technician to perform the final product verification check, instead of a pharmacist.[2] Currently, tech-check-tech (TCT) pilot programs exist for the community setting and institutional setting. However, neither of these programs include tech-check-tech for sterile products.[3] Over the last 3 months, Aurora West Allis Medical Center has collected data analyzing technician checking accuracy for sterile products with the hopes of presenting the data to the PEB to gain pilot program approval. The benefits of adding a pilot program for TCT sterile products include expanding the technician's role and increasing the availability of a pharmacist to provide direct patient care services.

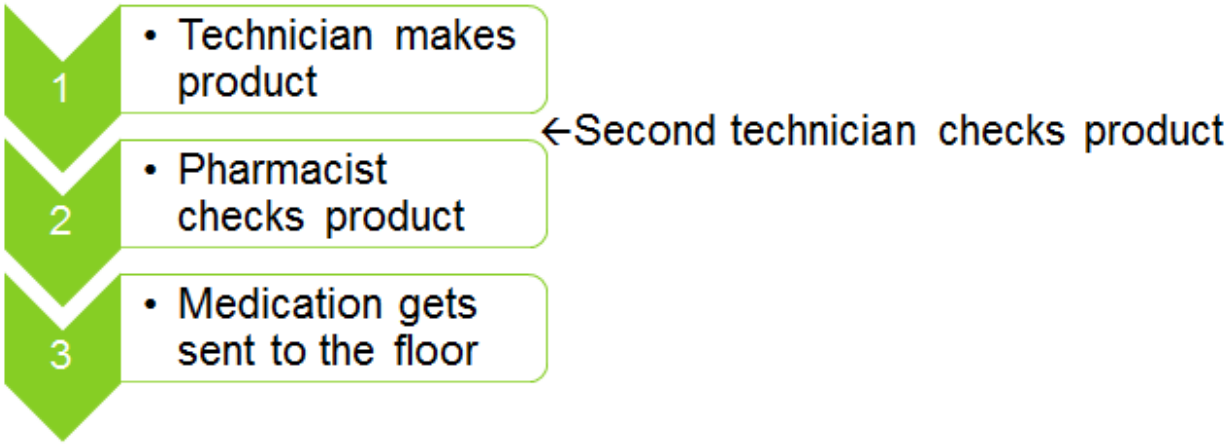
A new pilot program for sterile products would be very similar to the current PEB institutional tech-check-tech pilot program, with only a few differences. One additional requirement would be for the validated technicians to complete training on calculations for sterile products. One modification would be on the eligible medications. All sterile products would be eligible for the new pilot program.

Please see my attached PEB pilot program for sterile products document for further details on this new pilot program. The layout of the document is very similar to the current PEB institutional tech-check-tech pilot program document. Below, you will see a flow-sheet for what the workflow would be for a pharmacy implementing this new pilot program at their site (Figure 1). I would welcome the opportunity to discuss more details about this potential new pilot program at a future PEB meeting.

Sincerely,

Rachel Miller, PharmD

Figure1: Flowsheet of checking work-flow



Reference:

1. Pharmacy Examining Board: Chapter Phar 7.01.
2. Pharmacy Examining Board: Chapter 450.02 (3r).
3. Pharmacy Examining Board: Institutional Tech-Check-Tech Pilot Program Information.

Pharmacy Examining Board

Mail To: P.O. Box 8935
Madison, WI 53708-8935
FAX #: (608) 261-7083
Phone #: (608) 266-2112

1400 E. Washington Avenue
Madison, WI 53703
E-Mail: DSPSCredPharmacy@wisconsin.gov
Website: http://dsps.wi.gov

Sterile Products Tech-Check-Tech Pilot Program
Information

Authority:
Pursuant to Wisconsin Stat. § 450.02(3r)(a), this pilot program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state. **The Board may modify the parameters of the Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

Purpose: The purpose of institutional tech-check-tech (TCT) pilot program is to study the safety, quality, and efficiency of a pharmacy technician to make a final check of another pharmacy technician on the accuracy and correctness of the final dispensed medication. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of a pharmacist for involvement for other patient care activities.

Waives: Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Phar 15.09 (5), Wis. Admin. Code

Pilot Duration: TBD

Pharmacy Eligibility:
1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the TCT program. The final checks made by the validated technicians will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.

Program Requirements:
1. Validated Technicians
   a. Initial Validation: In order to become a validated technician, the following requirements must be met and maintained:
      i. Employment averaging at least 20 hours per week at the pilot pharmacy
      ii. A minimum of 2000 hours of experience as a pharmacy technician and at least 6 months of employment at the pilot pharmacy
      iii. Completion of a didactic and practical training curriculum that includes the following:
         1. Elements of a package label (i.e. drug name, dose, dosage form, control or lot number and expiration date)
         2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication (e.g., mg, mEq, ER, IR, tab, cap)
         3. Calculations review specific to sterile products.
         4. Common dispensing medication errors and concepts (i.e. wrong medication, wrong dose, wrong dosage form, expired medication, wrong beyond use date, wrong product labeling, look-alike sound-alike errors, high-alert medications).
         5. Organizational policies and procedures on reporting of medication errors
         6. Overview of the organizations medication use process (i.e. procurement, ordering, dispensing, administration, and monitoring).
         7. A practical training designed to assess the competency of the technician prior to starting the validation process.
      iv. Completion of the following validation process:
         1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 250 final checks over a minimum of 10 separate days and achieve an accuracy rate of 99.8% or greater.

2. At least one occurrence each of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose shall be artificially introduced by a pharmacist who will ensure they are removed prior to delivery to a patient care area.
3. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

b. Re-validation:

i. An assessment of validated technician accuracy shall be completed quarterly of the previous 12 months of ITCT final checks. A technician shall be revalidated if a validated technician fails to maintain a final check accuracy rate of 99.8% or has not performed TCT final checks within the last 6 months.

2. Eligible Medications
   a. Medications are to be sterile products, which may include compounded, packaged or manufactured medications.
   b. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
   c. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.
3. Quality Assurance

   a. A minimum of 5% of all TCT final checks shall be audited by a licensed pharmacist each day that TCT is performed.

   b. The accuracy of each validated technician shall be tracked individually.
4. Policies and Procedures

   a. Each pharmacy shall maintain policies, procedures, and training materials for the TCT program that will be made available to the Board upon request.
5. Records

   a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:

      i. All initial validation and revalidation records of each validated technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
      ii. Names the supervising TCT pharmacist including start date and end date of supervision responsibilities.
      iii. Daily quality assurance logs of the 5% pharmacist TCT audit including the name of technician, total number of final checks performed, number of final checks audited by the pharmacist, percentage of final checks audited by pharmacist, number of final check errors identified, and type of error (i.e., wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose)
6. Reporting Requirements
   a. The supervising pharmacist of the tech-check-tech program shall annually submit to the Board, on a form approved by the Board, all of the following:
      i. Total number of TCT final checks
      ii. Total number TCT final checks audited by a pharmacist
      iii. Total number of errors identified in the TCT final check pharmacist audit that were of the type of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose
      iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

Application: The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Andrea Magermans	03/30/2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:
Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
04/11/18	☒ Yes ☐ No	PDMP Update – Discussion and Consideration

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☒ Yes, by PDMP Staff ☐ No	

10) Describe the issue and action that should be addressed:

1. PDMP Update
2. Discussion of criteria for CSB/PDMP Referrals, based on the following motions from 3/9/18 CSB meeting:

<u>Discussion of Disclosures of PDMP Data to Relevant Boards Under CSB 4.15(5)</u>
MOTION: Leonardo Huck moved, seconded by Yvonne Bellay, to create a Work Group of Peter Kallio, Timothy Westlake, Doug Englebert, and Philip Trapskin to develop criteria for analyzing prescribing and dispensing practices that should be brought to the Board's attention. Motion carried unanimously.

MOTION: Peter Kallio moved, seconded by Yvonne Bellay, to request that the Department place an appearance by PDMP staff for the following Boards at their next meeting: Board of Nursing, Medical Examining Board, Dentistry Examining Board, Optometry Examining Board, Podiatry Affiliated Credentialing Board and Pharmacy Examining Board. Motion carried unanimously.

CSB 4.15 is attached, for reference.

11) Authorization

Signature of person making this request **Date**

Andrea Magermans 3/30/18

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
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2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

CSB 4.15 Disclosure of suspicious or critically dangerous conduct or practices.

(1) The board may review dispensing data, monitored prescription drug history reports, PDMP data, and data compiled pursuant to s. CSB 4.12 to determine whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist, pharmacy, practitioner, or patient.

(2) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacist or pharmacy:

(a) The pharmacist or pharmacy's monitored prescription drug dispensing practices deviate from accepted pharmacist or pharmacy practices.

(b) There are unusual patterns in the payment methodology used by patients to whom monitored prescription drugs are dispensed by the pharmacist or pharmacy.

(c) The history of actions taken against the pharmacist or pharmacy by other state agencies, agencies of another state, or law enforcement.

(d) The type and number of monitored prescription drugs dispensed by the pharmacist or at the pharmacy.

(e) The pharmacist or pharmacy has dispensed forged prescription orders for a monitored prescription drug.

(f) The distance patients travel to have monitored prescription drugs dispensed at the pharmacy.

(g) The number of patients dispensed monitored prescription drugs at the pharmacy or by the pharmacist who satisfy any of the criteria identified in sub. (4).

(3) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a practitioner:

(a) The practitioner's monitored prescription drug prescribing practices deviate from accepted prescribing practices.

(b) The practitioner prescribes potentially dangerous combinations of monitored prescription drugs to the same patient.

(c) The type and number of monitored prescription drugs prescribed by the practitioner.

(d) The history of actions taken against the practitioner by other state agencies, agencies of another state, or law enforcement.

(e) The distance patients travel to obtain monitored prescription drug prescriptions from the practitioner.

(f) The number of patients to whom the practitioner prescribed a monitored prescription who satisfy any of the criteria identified in sub. (4).

(4) The board may include any of the following factors when determining whether circumstances indicate suspicious or critically dangerous conduct or practices of a patient:

(a) The number of practitioners from whom the patient has obtained a prescription for a monitored prescription drug.

(b) The number of pharmacies from where the patient was dispensed a monitored prescription drug.

(c) The number of prescriptions for a monitored prescription drug obtained by the patient.

(d) The number of monitored prescription drug doses dispensed to the patient.

(e) Whether the monitored prescription drugs dispensed to the patient include dangerous levels of any drug.

(f) The number of times the patient is prescribed or dispensed a monitored prescription drug before the previously dispensed amount of the same or a similar monitored prescription drug would be expected to end.

(g) The payment methodology used by the patient to obtain controlled substances at a pharmacy.

(5) Upon determining that circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, practitioner, or patient, the Board may disclose monitored prescription drug history reports, audit trails, and PDMP data to any of the following:

(a) A relevant patient.

(b) A relevant pharmacist or practitioner.

(c) A relevant state board or agency.

(d) A relevant agency of another state.

(e) A relevant law enforcement agency.

(6) Upon determining that a criminal violation may have occurred, the board may refer a pharmacist, pharmacy, or practitioner to the appropriate law enforcement agency for investigation and possible prosecution. The board may disclose monitored prescription drug history reports, audit trails, and PDMP data to the law enforcement agency as part of the referral.

Controlled Substances Board

WISCONSIN | ePDMP

Report 3

January 1 – December 31, 2017

Contact Information

Wisconsin Controlled Substances Board
Chairperson: Doug Englebert

Members:

Englebert, Doug, Chairperson	DHS Designated Member
Bloom, Alan, Vice Chairperson	Pharmacologist
Bellay, Yvonne M., Secretary	DATCP Designated Member
Barman, Subhadeep	Psychiatrist
Huck, Leonardo	Dentistry Board Representative
Kallio, Peter J.	Board of Nursing Representative
Smith, Jason	Attorney General Designee
Trapskin, Philip	Pharmacy Board Representative
Westlake, Timothy W.	Medical Board Representative

Wisconsin Department of Safety and Professional Services

1400 E Washington Ave
Madison, WI 53703
608-266-2112
DSPS@wisconsin.gov
Website: https://dsps.wi.gov

Wisconsin Prescription Drug Monitoring Program

PDMP@wisconsin.gov
Website: https://pdmp.wi.gov/

Table of Contents

Introduction

The Wisconsin Prescription Drug Monitoring Program (PDMP) was deployed in June 2013. It is administered by the Wisconsin Department of Safety and Professional Services (DSPS) pursuant to the regulations and policies established by the Wisconsin Controlled Substances Board (CSB). Since being deployed, the PDMP primarily has been a tool to help healthcare professionals make more informed decisions about prescribing and dispensing controlled substance prescription drugs to patients. It also discloses data as authorized by law to governmental and law enforcement agencies.

On January 17, 2017, DSPS launched the enhanced PDMP (WI ePDMP) system. The enhanced design has allowed the WI ePDMP to become a multi-faceted tool in Wisconsin's efforts to address prescription drug abuse, misuse, and diversion through clinical decision support, prescribing practice assessment, communication among disciplines, and public health surveillance. In the second half of 2017, the WI ePDMP was invited by the National Alliance of Model State Drug Laws (NAMSDL) to present at the PDMP Briefing to the Congressional Caucus on Prescription Drug Abuse as an example of the "PDMP of the Future" containing all the components of a strong PDMP. DSPS was further recognized for the WI ePDMP by the Center for Digital Government and was awarded a Government Experience Award in the Government-to-Business Experience category. In November, DSPS was invited to testify before the U.S. Senate Committee on Health, Labor, Education, and Pensions about the WI ePDMP as part of Wisconsin's efforts to address the opioid crisis.

In October 2017, DSPS launched the WI ePDMP Public Statistics Dashboard, which provides interactive data visualizations about the controlled substance prescriptions dispensed in Wisconsin, the law enforcement reports submitted to the WI ePDMP, and the use of the WI ePDMP by healthcare professionals and others. Many of the data visualizations from the Public Statistics Dashboard have been incorporated into this report, and additional information about PDMP-related statistics, including county-level detail about many of the charts, can be found on the Public Statistics Dashboard. The Dashboard was the product of a 2014 Harold Rogers grant from the U.S. Department of Justice Bureau of Justice Assistance, and DSPS was awarded a 2017 Harold Rogers grant to continue to enhance the WI ePDMP based on user feedback.

At the end of December 2017, the PDMP stored a total of over 50 million prescription records submitted by over 2,000 pharmacies and dispensing practitioners. Between January 17, 2017, and December 31, 2017, over 42,000 registered prescribers, pharmacists, and their delegates performed over 6 million queries for patient prescription reports. The number of queries performed by healthcare users per day has risen significantly, with an average of over 19,000 queries performed each day between October 1 and December 31, 2017, up from an average of approximately 6,800 queries performed per day during the first quarter of 2017, prior to the requirement for prescribers to review PDMP records before writing controlled-substance prescription orders went into effect on April 1, 2017, pursuant to 2015 Wisconsin Act 266.

Pursuant to ss. 961.385 (5) – (6), Wis. Stats., the CSB is required to submit a report to DSPS about the PDMP. This report is intended to satisfy that requirement. Significant resources were dedicated in 2017 to the development of the WI ePDMP, which is still in active development, and the Public Statistics Dashboard, which presents PDMP data elements to the public in an easily-digestible format. The reporting capabilities of the WI ePDMP are still evolving and the reports continue to be refined.

User Satisfaction

DSPS did not conduct a user satisfaction survey during 2017. All available PDMP resources were dedicated to the ongoing development and enhancement of the Wisconsin Enhanced Prescription Drug Monitoring Program (WI ePDMP). DSPS intends to conduct a user survey at the end of Q1 2018, after users have become more familiar with the WI ePDMP and the enhancements released over the course of 2017. Results of the survey will likely be available in the Q2 2018 report. DSPS will gather additional information about user satisfaction and ideas for potential enhancements through user groups which will be forming in Q1 and Q2 of 2018. The user groups are part of a grant project for user-led enhancements with funding from the U.S. Department of Justice Bureau of Justice Assistance Harold Rogers PDMP grant program. Through informal feedback throughout 2017, users have reported being very satisfied with the enhanced functionality and ease of use of the WI ePDMP.

Impact on Referrals for Investigation

Between January 1 and December 31, 2017, the Controlled Substances Board (CSB) did not make any referrals for possible investigation and disciplinary action pursuant to s. 961.385 (2) (f), Wis. Stats. Efforts were focused on developing and enhancing the WI ePDMP, as well as educating prescribers and pharmacists about how to use the WI ePDMP to promote safe prescribing and dispensing practices. The CSB has requested a report of the number of patients whose prescribers and dispensers are writing or filling prescriptions greater than 90 MME, with or without benzodiazepines, and including information on prescriber use of the PDMP. The number of patients, prescribers, and dispensers in the preliminary report will help the CBS determine thresholds for possible referrals to professional boards, such as the Medical Examining Board, Pharmacy Examining Board, Board of Nursing, and Dentistry Examining Board. Developing thresholds will then assist with prioritizing the future reporting needs of the PDMP related to referrals for investigation for failure to submit dispensing data, non-compliance with practitioner requirements, or circumstances indicating suspicious or critically dangerous conduct or practices. On the data submission side, reports have already been made to the CSB about the number and types of errors in the dispensing data submitted. In anticipation of a formal dispenser compliance audit in 2018, dispenser outreach in 2017 focused on bringing dispensers into compliance and educating them about the most common errors and how to correct them to ensure that records are loaded.

Monitored Prescription Drug Use Trend

The amount of monitored prescription drugs, and opioids in particular, dispensed in 2017 shows an overall downward trend since 2015. In 2017, the total number of monitored drug prescriptions dispensed was 9,136,817, approximately 14% less than the total number of monitored drug prescriptions dispensed in 2015, 10,628,329. Figure 1 below shows the decrease from 2015 to 2017.

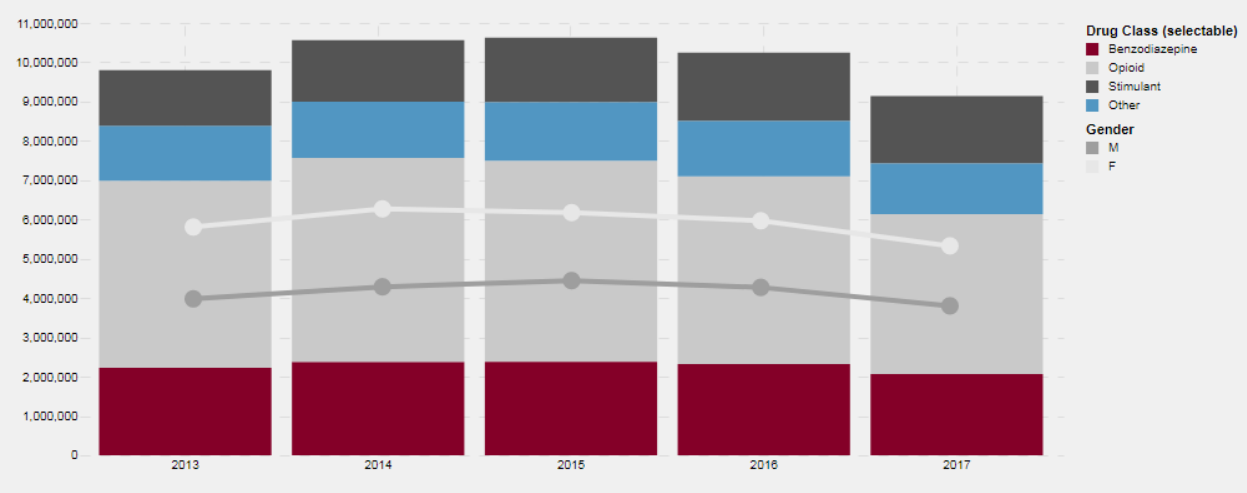

Figure 1. Monitored Prescription Drugs Dispensed in WI, 2013-2017, All Drug Classes

When looking at opioids specifically, there was a 20% decrease in the number of prescriptions dispensed, from 5,105,729 in 2015 to 4,066,083 in 2017. Figure 2 below shows the decrease in opioid prescriptions dispensed.

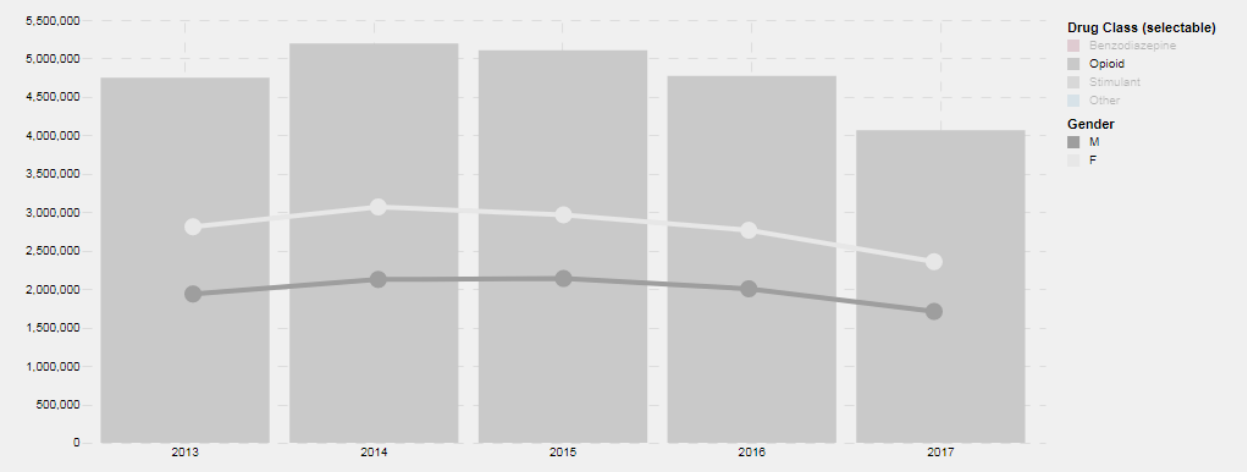

Figure 2. Monitored Prescription Drugs Dispensed in WI, 2013-2017, Opioids

Similarly, benzodiazepines show a decrease of approximately 13%, from 2,377,419 in 2015 to 2,069,958 in 2017. Figure 3 below shows the decrease in the number of benzodiazepine prescriptions dispensed.

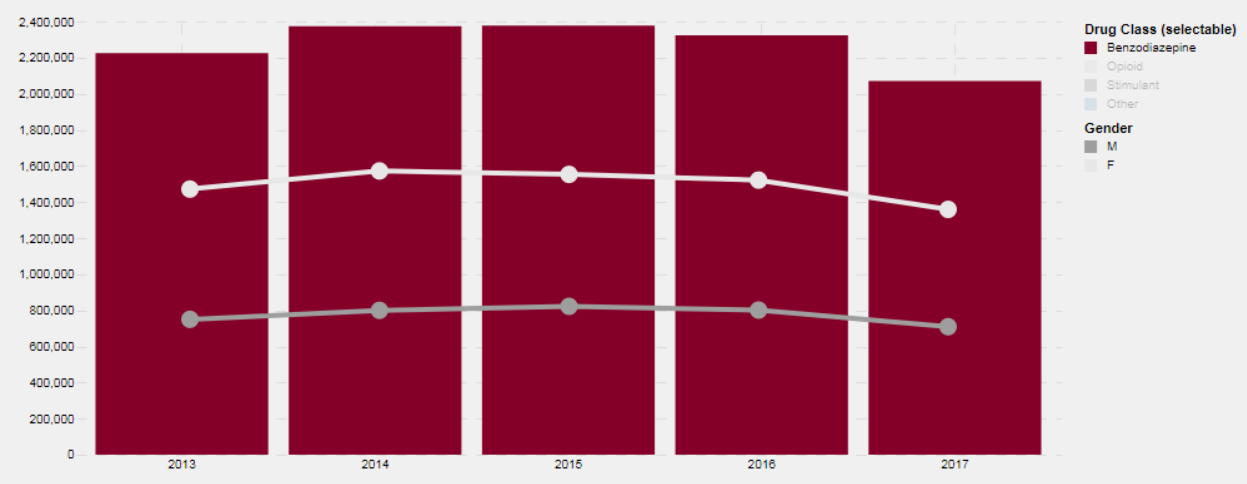

Figure 3. Monitored Prescription Drugs Dispensed in WI, 2013-2017, Benzodiazepines

Stimulants, however, show an increase of approximately 9% since 2014, even though there was a slight (approximately 1%) decrease from 2016 to 2017. In 2014, 1,570,130 stimulant prescriptions were dispensed; in 2016, 1,737,922 stimulant prescriptions were dispensed; and in 2017, 1,712,449 stimulant prescriptions were dispensed to patients in Wisconsin. Figure 4 below shows the increase in stimulant prescriptions dispensed from 2014 to 2017. Interestingly, the lines on the bars below show a reversal in the distribution of male and female patients receiving the prescriptions: for all controlled substance prescriptions, opioids, and benzodiazepines, female patients account for a greater portion of the dispensing records; however, for stimulants, male patients account for the largest portion of the prescriptions dispensed.

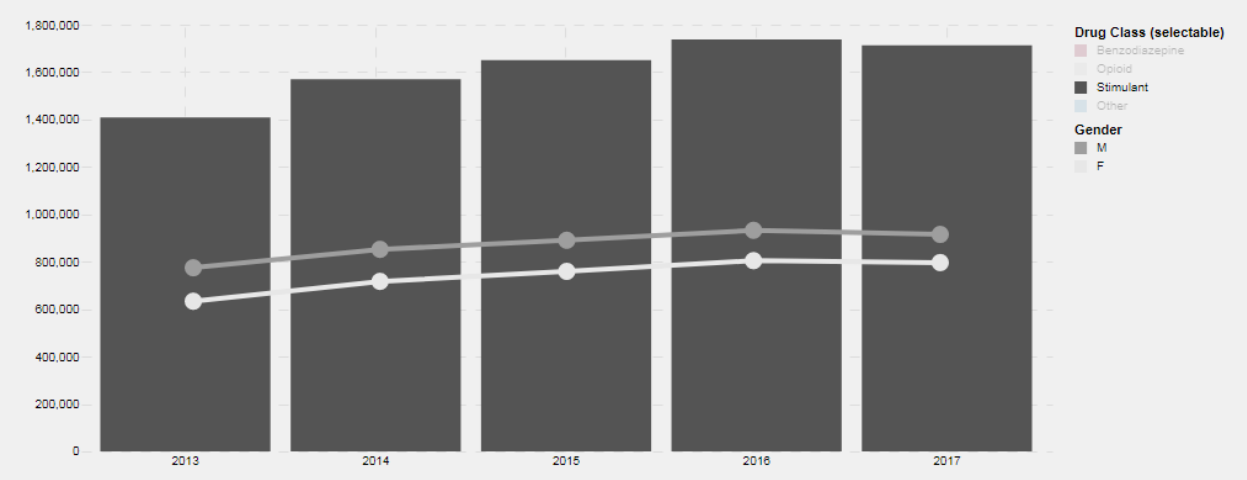

Figure 4. Monitored Prescription Drugs Dispensed in WI, 2013-2017, Stimulants

While there was a reduction in the overall volume of monitored prescription drugs dispensed, there has been little change in the 15 most dispensed monitored prescription drugs since 2015. Table 1 below shows the top 15 most dispensed monitored prescription drugs during 2017, ranked in order of the

volume of prescriptions dispensed. The top 15 monitored prescription drugs dispensed make up 88% of the dispensing records for any given quarter.

Drug Name	Prescriptions	Quantity
Hydrocodone-Acetaminophen	317,614	16,798,329
Amphetamine-Dextroamphetamine	198,695	9,514,720
Tramadol HCl	183,520	13,113,733
Oxycodone HCl	153,840	12,059,535
Alprazolam	152,050	8,682,036
Lorazepam	152,004	7,269,084
Clonazepam	127,513	7,481,833
Zolpidem Tartrate	125,198	4,166,920
Oxycodone w/ Acetaminophen	108,667	7,342,023
Methylphenidate HCl	98,054	4,617,602
Lisdexamfetamine Dimesylate	89,024	2,786,897
Pregabalin	61,474	4,540,811
Diazepam	54,256	2,268,581
Morphine Sulfate	51,384	3,016,613
Acetaminophen w/ Codeine	40,654	1,725,846

Table 1. Top 15 Monitored Drugs Dispensed in WI, Q4 2017, By Number of Prescriptions

The 5 most dispensed monitored drugs are listed in Table 2 below in the order of the total quantity of pills dispensed, rather than number of prescription orders filled.

Drug Name	Prescriptions	Quantity
Hydrocodone-Acetaminophen	317,614	16,798,329
Tramadol HCl	183,520	13,113,733
Oxycodone HCl	153,840	12,059,535
Amphetamine-Dextroamphetamine	198,695	9,514,720
Alprazolam	152,050	8,682,036

Table 2. Top 5 Monitored Drugs Dispensed in WI, Q4 2017, by Quantity Dispensed

The quantity of pills of each of the top 5 monitored drugs dispensed has decreased since 2015. The quantity of hydrocodone-acetaminophen pills dispensed decreased from 99,771,652 in 2015 to 74,326,164 in 2017, a difference of 25,445,488 pills or 26%. The quantity of Oxycodone Hcl pills saw a 21% decrease, from 67,827,911 pills in 2015 to 53,691,770 pills in 2017. The top benzodiazepine dispensed, Alprazolam, showed a 15% decrease in quantity of pills dispensed from 2015 to 2017, and the top stimulant dispensed, Amphetamine-Dextroamphetamine, showed an approximate 4% decrease in quantity of pills dispensed from 2015 to 2017. Figure 5 below shows the year-over-year decrease in the total quantity of pills dispensed of the top 5 monitored drugs. In all cases, the most significant decrease can be noted in 2017.

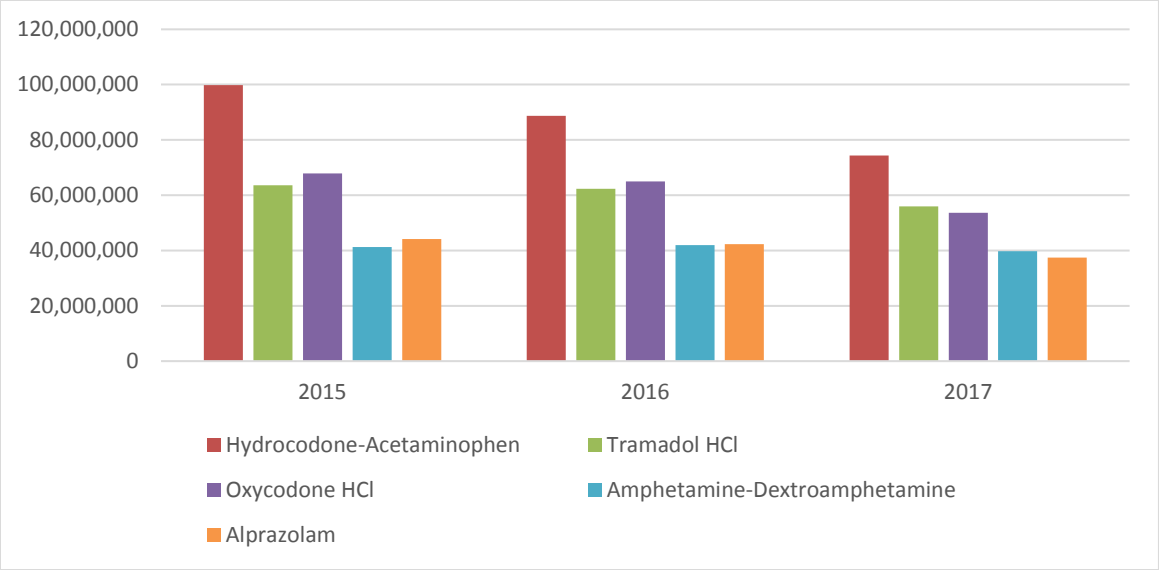

Figure 5. Top 5 Monitored Drugs Dispensed, 2015-2017, by Quantity

Law Enforcement Reports

Between October 1 and December 31, 2017, Wisconsin law enforcement agencies reported 705 events to the WI ePDMP. The reports were submitted by law enforcement agencies as required by s. 961.37 (3) (a), Wis. Stat. The law requires the agencies to submit a report in each of the following situations:

1. When a law enforcement officer receives a report of a stolen controlled substance prescription.
2. When a law enforcement officer reasonably suspects that a violation of the Controlled Substances Act involving a prescribed drug is occurring or has occurred.
3. When a law enforcement officer believes someone is undergoing or has immediately prior experienced an opioid-related drug overdose.
4. When a law enforcement officer believes someone died as a result of using a narcotic drug.

The reports submitted by law enforcement are attributed to patient reports in the PDMP and presented to the prescribers of the individuals involved in the incidents as alerts on the patient reports. In this way, the reports submitted by law enforcement provide valuable information to healthcare professionals, who are able to make prescribing, dispensing, and treatment decisions based on a more complete picture of their patients' controlled substance history. Figure 6 below shows the breakdown of the reports submitted to the PDMP by month for 2016 and 2017. There is no requirement for law enforcement agencies to submit their reports within a certain timeframe after the date of the event, so the numbers for events at the end of 2017 may still increase with submissions in early 2018. Outreach for law enforcement agencies is ongoing as part of an effort to increase awareness of the requirement to submit to the PDMP and the value of the information included in the reports.

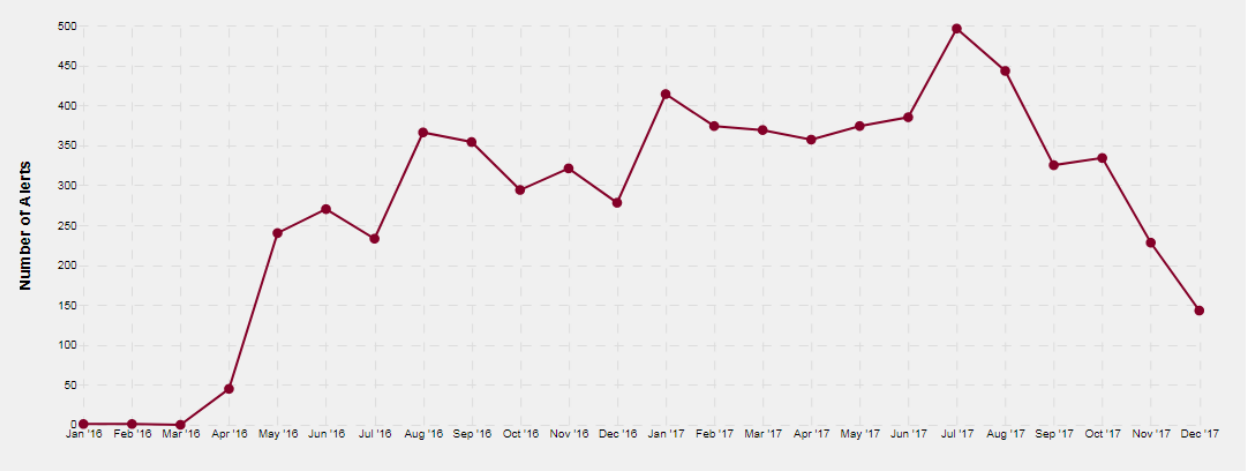

Figure 6. Law Enforcement Alerts Submitted to the WI ePDMP, 2016-2017

In 2017, 42% of the reports submitted by law enforcement agencies were reports of stolen controlled substance prescriptions, 29% were suspected violations of the Controlled Substances Act, 25% were suspected non-fatal opioid-related overdose events, and 4% were suspected narcotic-related deaths. This distribution can be seen in Figure 7 below.

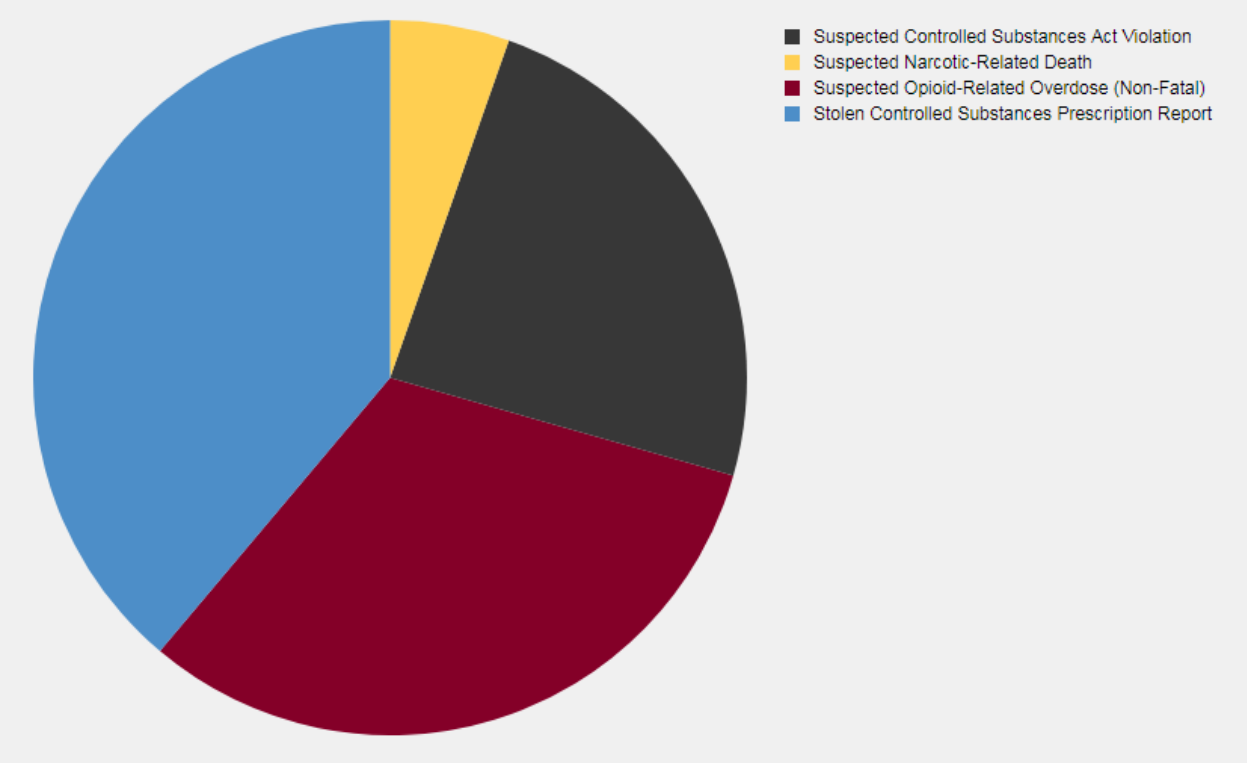

Figure 7. Breakdown of Law Enforcement Alerts Submitted to the WI ePDMP, by Alert Type, 2017

Disclosure of PDMP Data

Between October 1 and December 31, 2017, healthcare users made 1,803,597 patient queries. The total number of patient queries by healthcare users remained high, after the initial increase during the month of April 2017, when the requirement for prescribers to review the WI ePDMP prior to issuing a controlled substance prescription went into effect, as seen in Figure 8 below, taken from the WI ePDMP Public Statistics Dashboard.

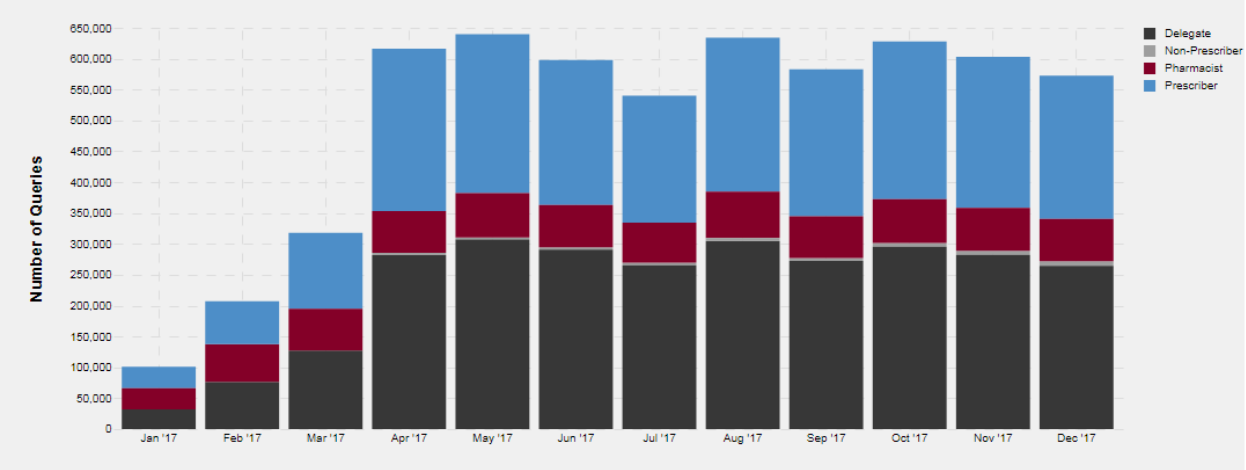

Figure 8. WI ePDMP Patient Queries by Healthcare Professionals, 2017

The daily average of queries by healthcare users reflects a similar increase during the month of April 2017, as seen in Figure 9 below. An average of over 19,000 queries were performed each day between October 1 and December 31, 2017, up from an average of approximately 6,800 queries performed per day during the first quarter of 2017.

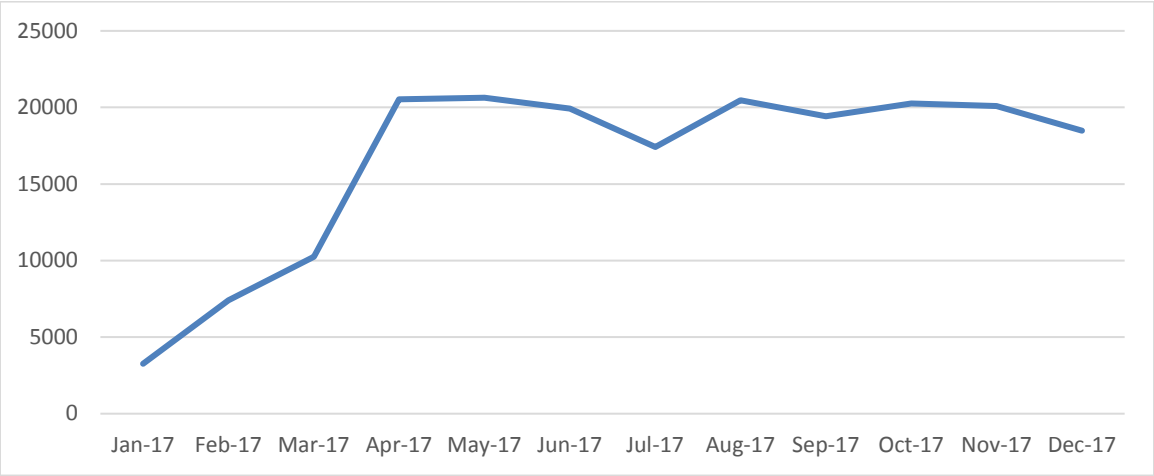

Figure 9. Average Number of Healthcare Patient Queries Per Day, 2017

The two pie charts below in Figures 10 and 11 show the breakdown of patient queries by prescribers, pharmacists, non-prescribers, and prescriber/pharmacist delegates for the first quarter of 2017 compared to the fourth quarter of 2017. The portion of queries performed by prescriber and prescriber/pharmacist delegates increased after the first quarter of 2017, and legislation allowing non-prescriber healthcare professionals, such as substance abuse counselors and individuals authorized to treat substance abuse, to register and use the PDMP went into effect on April 1, 2017.

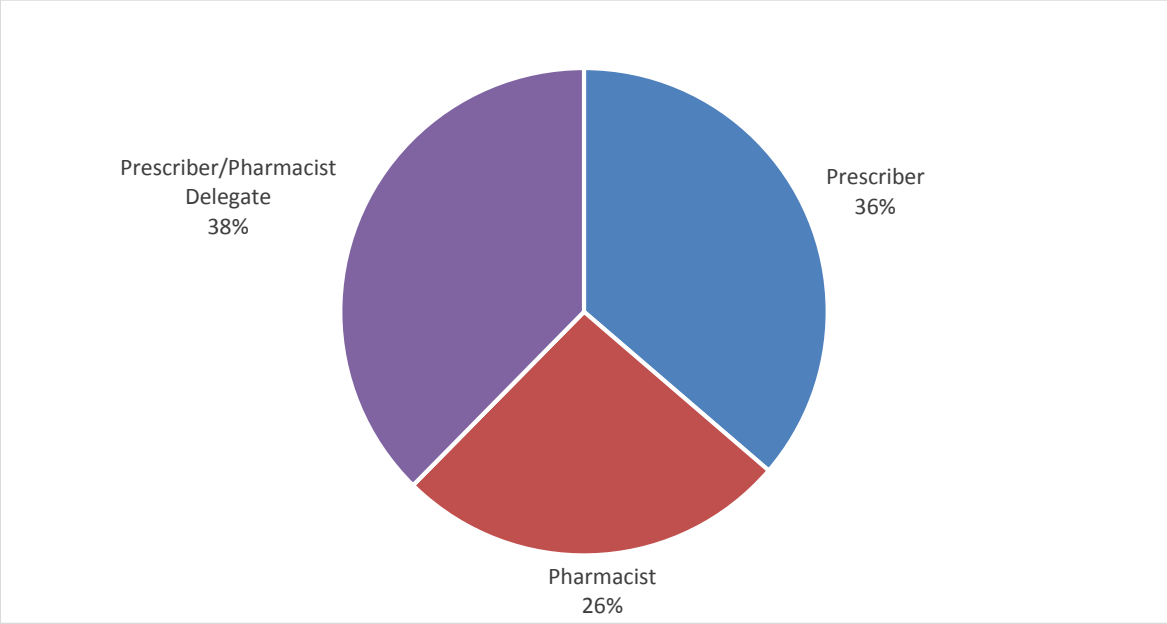

Figure 10. Patient Queries by Healthcare Users, by User Group, Q1 2017

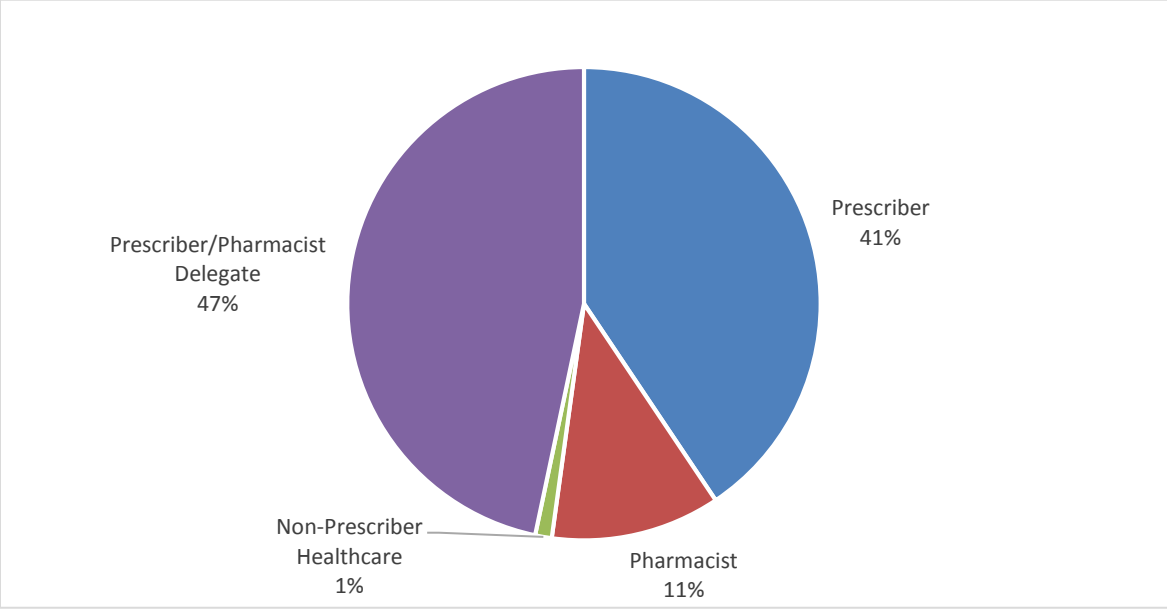

Figure 11. Patient Queries by Healthcare Users, by User Group, Q4 2017

In addition to the enhanced user interface of the WI ePDMP, a direct link to WI ePDMP patient reports from within electronic medical records (EMR) has increased the accessibility of WI ePDMP patient reports for providers within participating health systems. Users in health systems with the direct linkage are not required to navigate to a different website, log in, and enter the patient's name and date of birth; the username and patient information are securely transferred to the PDMP behind the scenes. Users report that it can take as few as three seconds to obtain a WI ePDMP patient report in this way from the patient's EMR. As of December 31, 2017, ten health systems had the integrated access to the PDMP from within their EMR platforms. The number of patient queries coming from the direct integration has increased steadily since April, 2017, as Figure 12 below shows. In December 2017, 33% of patient queries were through the direct integration.

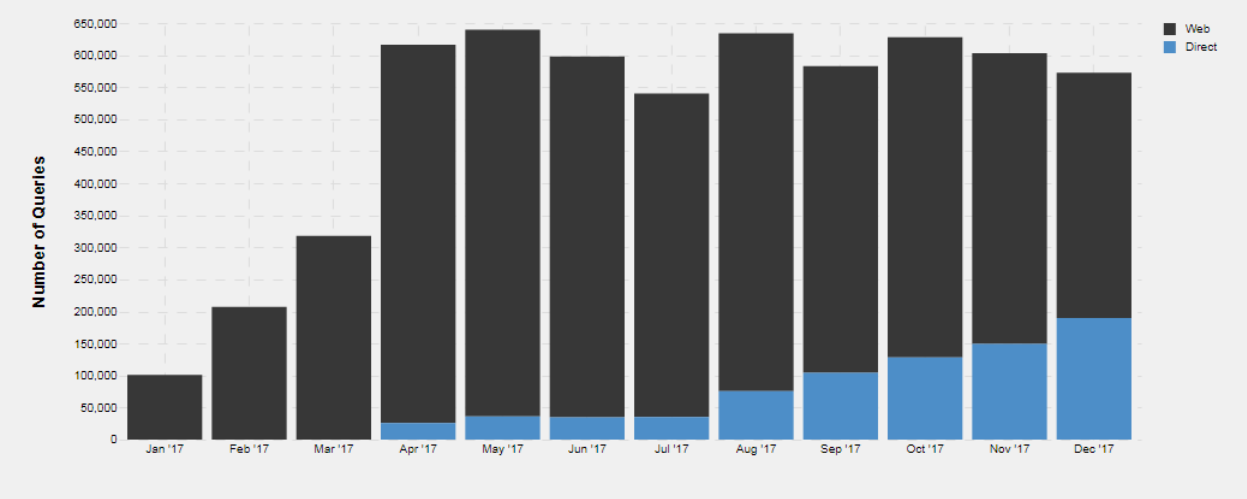

Figure 12. WI ePDMP Patient Queries, by Source, 2017

Authorized individuals from non-healthcare groups made 232 requests for PDMP data in Q4 of 2017. Figure 13 below shows that there has not been a significant increase in law enforcement requests for PDMP reports since the requirement of a court order for law enforcement access to PDMP records was removed in April 2017 pursuant to 2015 Wisconsin Act 266.

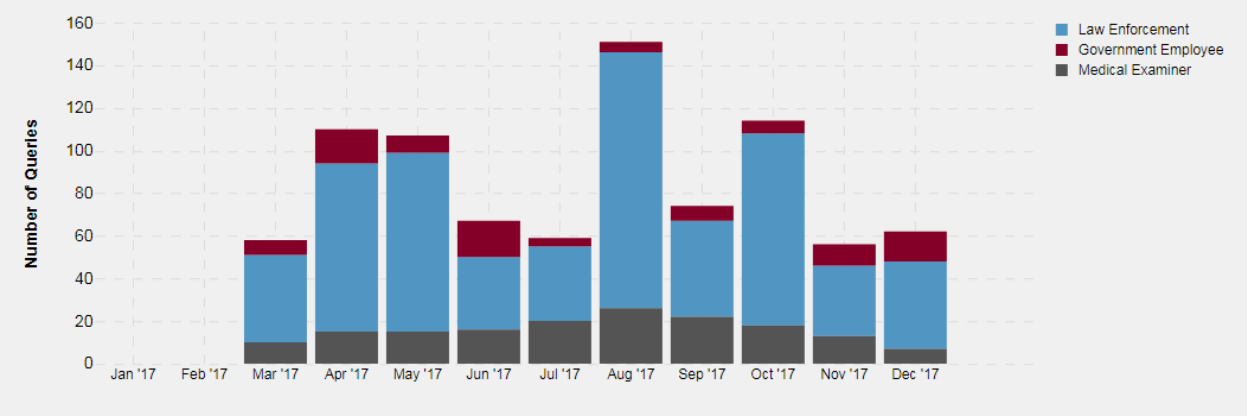

Figure 13. Non-Healthcare WI ePDMP Queries, 2017

Non-healthcare requests for PDMP reports prior to March 2017 were tracked using a different mechanism prior and therefore do not appear on the chart in Figure 13. Prior to the change in access for law enforcement in April 2017, there was an average of 58 authorized non-healthcare requests for PDMP reports per month.

Data-Driven Alerts

The WI ePDMP application uses sophisticated data analytics to assess a patient's controlled substance prescription history. Data-driven alerts are integral to the important task of analyzing a patient's prescription history and bringing the most relevant information in the prescription history to the immediate attention of the user. Analytics are performed on the prescription history to identify and alert WI ePDMP users to potential indications of abuse, diversion, or overdose risk, such as high morphine milligram equivalent doses, overlapping benzodiazepine and opioid prescriptions, and multiple prescribers or dispensers.

Doctor Shopping and Pharmacy Hopping

The WI ePDMP application uses data analytics to alert providers about patients who have obtained controlled substance prescription orders from at least 5 prescribers or received controlled substance prescription dispensings from at least 5 pharmacies or other dispensers within the previous 90 days. Note that multiple prescribers or dispensers may be associated with the same clinic, practice, or location because the PDMP does not delineate health systems. Between October 1 and December 31, 2017, the number of patients meeting the criteria for the Multiple Prescribers or Pharmacies Alert declined, with 16,674 alerts in October, 14,798 alerts in November, and 12,135 alerts in December. The average number of monthly Multiple Prescribers or Pharmacies Alerts for Q4 2017, 14,535, is down 29% compared to Q1 2017. The number of monthly alerts for all of 2017 is represented below in Figure 14, taken from the WI ePDMP Public Statistics Dashboard.

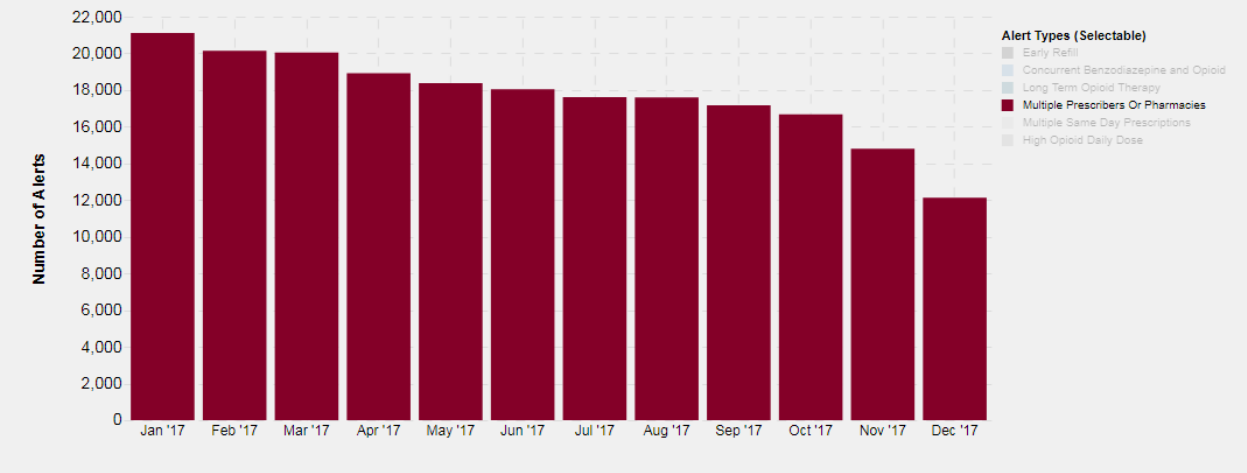

Figure 14. Multiple Prescriber or Dispenser Alerts, by Month, 2017

These alerts were not available in the WI PDMP prior to January 17, 2017. However, the criteria to meet the alerts were applied to data from previous years to give an indication of how many patients would have met the alert criteria for any given month. Figure 15 below shows the quarterly average number of patients in the WI ePDMP meeting the criteria for the Multiple Prescribers or Pharmacies Alert from January 2015 through December 2017. The Q4 2017 average of 14,535 monthly alerts is down 47% from the Q1 2015 average of 27,248 alerts per month.

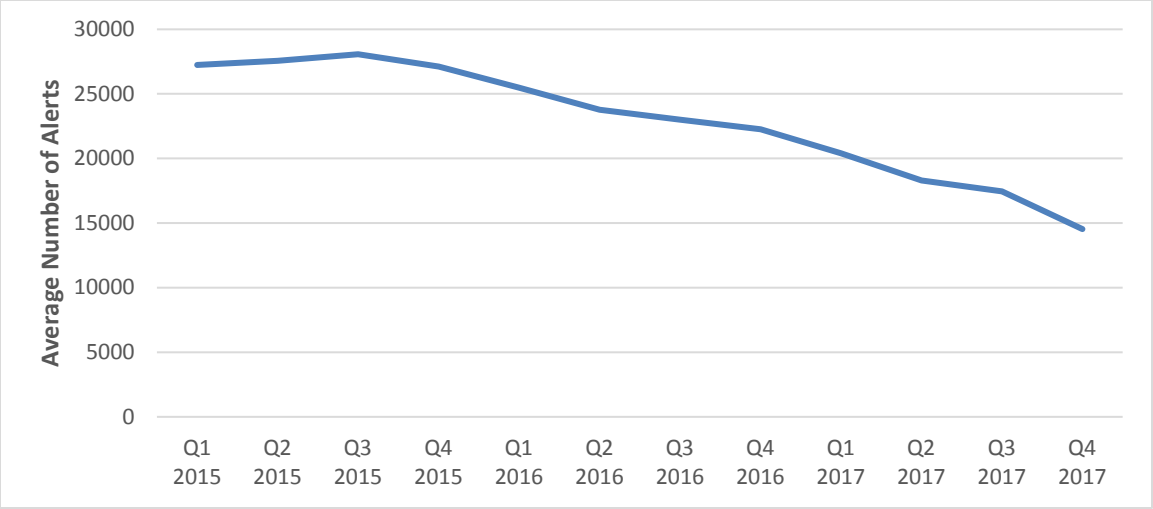

Figure 15. Average Number of Multiple Prescriber or Dispenser Alerts, by Quarter, 2015-2017

Morphine Milligram Equivalent (MME)

The WI ePDMP application uses data analytics to alert providers about patients who have Morphine Milligram Equivalents (MME) above 90. Between October 1 and December 31, 2017, the number of patients meeting the criteria for the High Opioid Daily Dose Alert remained relatively steady over the three months, with 24,790 alerts in October, 24,071 alerts in November, and 24,410 alerts in December. The average number of monthly high MME alerts for Q4 2017, 24,424, is down 22% compared to Q1 2017. The number of monthly high MME alerts for all of 2017 is represented below in Figure 16.

Figure 16. High Opioid Daily Dose Alerts, by Month, 2017

These alerts were not available in the WI PDMP prior to January 17, 2017. However, the criteria to meet the alerts were applied to data from previous years to give an indication of how many patients would have met the alert criteria for any given month. Figure 17 below shows the quarterly average number of patients in the WI ePDMP meeting the criteria for the High Opioid Daily Dose Alert from January 2015 through December 2017. The Q4 2017 average of 24,424 monthly alerts is down 37% from the Q1 2015 average of 38,833 alerts per month.

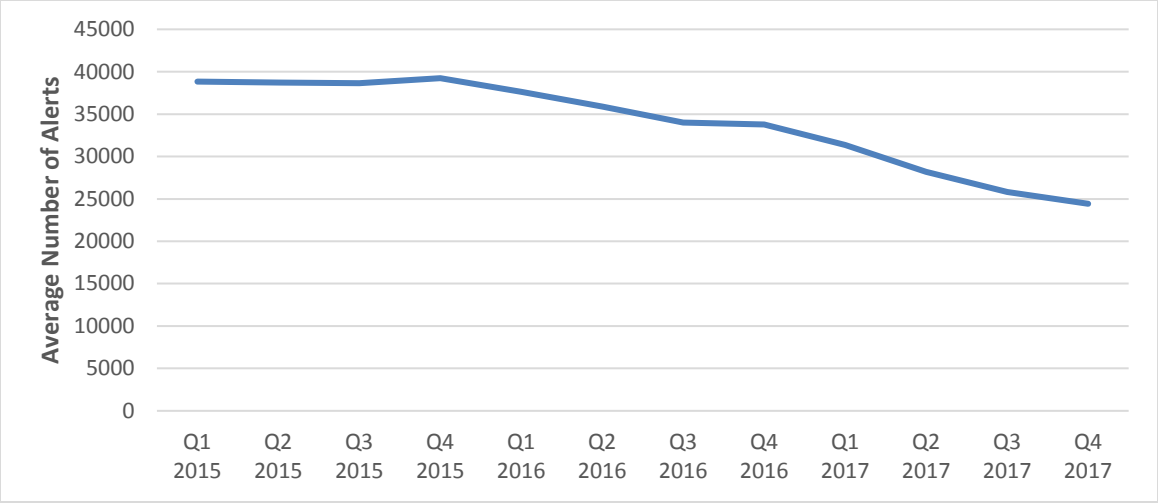

Figure 17. Average Number of High Opioid Daily Dose Alerts, by Quarter, 2015-2017

Opioid-Benzodiazepine Overlap

The WI ePDMP application uses data analytics to alert providers about patients who have overlapping benzodiazepine and opioid prescriptions. Between October 1 and December 31, 2017, the number of patients meeting the criteria for the Concurrent Benzodiazepine and Opioid Prescription Alert remained relatively steady over the three months, with 26,366 alerts in October, 25,509 alerts in November, and 25,416 alerts in December. The average number of monthly alerts for Q4 2017, 25,764, is down 17% compared to Q1 2017. The number of monthly alerts for all of 2017 is represented below as a chart taken from the WI ePDMP Public Statistics Dashboard.

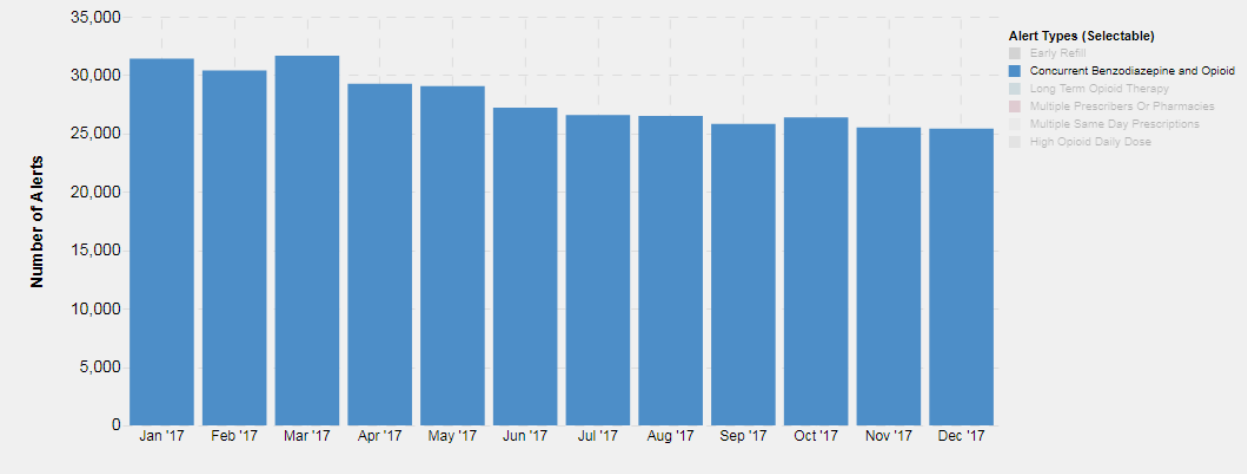

Figure 18. Concurrent Benzodiazepine and Opioid Prescription Alerts, by Month, 2017

These alerts were not available in the WI PDMP prior to January 17, 2017. However, the criteria to meet the alerts were applied to data from previous years to give an indication of how many patients would have met the alert criteria for any given month. The chart below shows the quarterly average number of patients in the WI ePDMP meeting the criteria for the Concurrent Benzodiazepine and Opioid

Prescriptions Alert from January 2015 through December 2017. The Q4 2017 average of 25,764 monthly alerts is down 30% from the Q1 2015 average of 37,026 alerts per month.

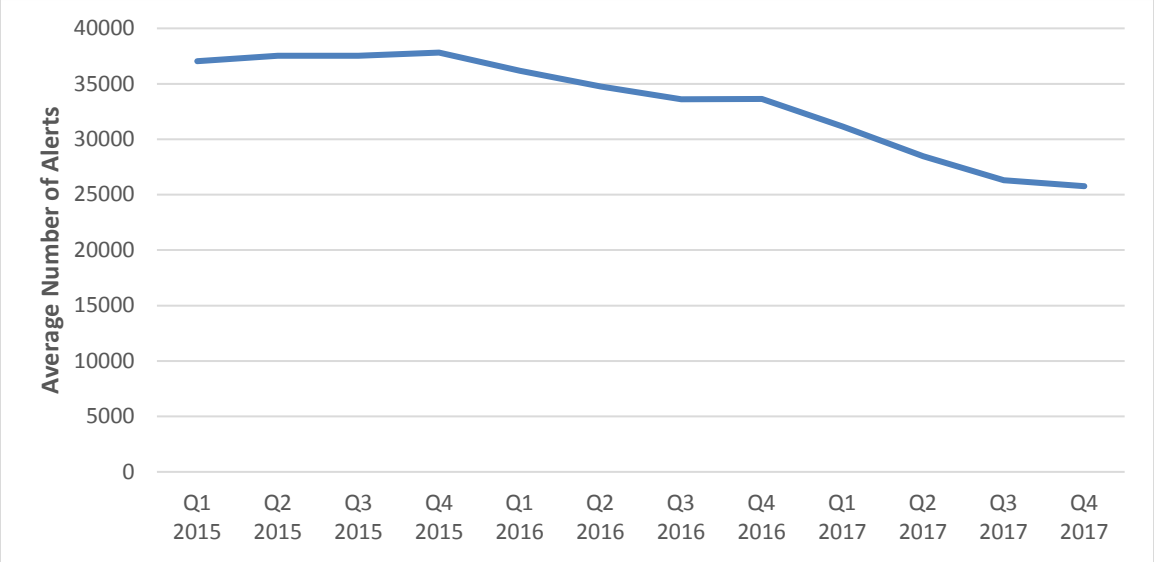

Figure 19. Average Number of Concurrent Benzodiazepine and Opioid Prescription Alerts, by Quarter, 2015-2017

Summary

2017 was an important year for the growth and enhancement of the Wisconsin Prescription Drug Monitoring Program as a clinical decision support tool, a prescribing practice assessment tool and a public health tool in Wisconsin's efforts to address the opioid crisis.

The number of monthly patient queries by healthcare professionals increased from approximately 100,000 queries in January 2017 to nearly 600,000 per month from April through December. The users that queried the PDMP benefitted from an enhanced user interface, including analytics driven alerts, to help support safe controlled-substance prescribing decisions. The effects are clear:

- 14% decrease in the total number of monitored drug prescriptions dispensed in 2017 compared to 2015
    - 20% decrease in the number of opioid prescriptions dispensed in 2017 compared to 2015
    - 13% decrease in the number of benzodiazepine prescriptions dispensed in 2017 compared to 2015
- 47% decrease in the average monthly doctor shopping alerts in Q4 of 2017 compared to Q1 of 2015
- 37% decrease in the average monthly high MME alerts in Q4 of 2017 compared to Q1 of 2015
- 30% decrease in the average monthly opioid-benzodiazepine alerts in Q4 2017 compared to Q1 of 2015

Additional data about these trends, including county-level detail for many of the charts, can be found on the WI ePDMP Public Statistics Dashboard (https://pdmp.wi.gov/statistics) under the corresponding tabs of Controlled Substance Dispensing, PDMP Utilization, and Law Enforcement Alerts.

The increased number of healthcare professionals reviewing records in the PDMP and the efforts made to present the most relevant information in the PDMP to those using it have had a positive effect on prescribing trends in Wisconsin. Future reports will show whether continued education for healthcare professionals and additional enhancements to the WI ePDMP to improve the usability of the system and its integration into healthcare workflows will continue to have an impact.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes **Administrative Rules Coordinator**	**26 March 2019** Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
11 April 2018	☐ Yes ☐ No	**Legislation and Rule Matters – Discussion and Consideration** 1. **Petition for Repeal of Phar 5.03** 2. **Scope for Phar 6.07 Relating to Storage** 3. **Scope for Phar 8 Relating to Requirements for Controlled Substances** 4. **Phar 17 Relating to Interns** 5. **Update on Legislation and Pending and Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

10) Describe the issue and action that should be addressed:

11) Authorization

Sharon Henes

Signature of person making this request **Date**

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

Revised 8/13

PHARMACY EXAMINING BOARD

1400 E Washington Ave
PO Box 8366
Madison WI 53708-8366

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-251-3032

11 April 2018

Senator Stephen Nass, Senate Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 10 South, State Capitol
Madison, WI 53702

Representative Joan Ballweg, Assembly Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 210 North, State Capitol
Madison, WI 53702

RE: Petition for Authorization to Repeal Rule Phar 5.03

Dear Senator Nass and Representative Ballweg:

I am petitioning for authorization to repeal rule Phar 5.03. A copy of the proposed rule is attached.

Phar 5.03 requires a pharmacist to display his or her license in a manner conspicuous to the public view at the pharmacy where he or she engages in the practice of pharmacy. 2017 Act 18 repealed s. 450.09 (5) which stated every original license issued by the board and the renewal license currently in force, if any, shall be displayed in the place of practice.

Therefore, the Pharmacy Examining Board is requesting authorization to repeal the rule by utilizing the expedited process under s. 227.26 (4), Stats.

Thank you.

Sincerely,

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES

The Pharmacy Examining Board is petitioning the
Joint Committee for Review of Administrative Rules to
repeal a rule the Pharmacy Examining Board has determined to be
an unauthorized rule using the process under s. 227.26 (4), Stats.

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 5.03 relating to a requirement that a pharmacist display his or her license at the pharmacy.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.09 (5), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (2), (3) (d) and (3), Stats.

Explanation of agency authority:

The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. [s. 15.08 (5) (b), Stats.]

The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05. [s. 450.02 (2), Stats.]

The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961. The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [ss. 450.02 (3) (d) and (e), Stats.]

Related statute or rule: n/a

Plain language analysis:

Phar 5.03 requires a pharmacist to display his or her license in a manner conspicuous to the public view at the pharmacy where he or she engages in the practice of pharmacy.

2017 Act 18 repealed s. 450.09 (5), Stats. which required every original license issued by the board and the renewal license currently in force, if any, to be displayed in the place of practice.

Therefore, the board has determined that Phar 5.03 is an unauthorized rule and seeks its repeal under s. 227.26 (4).

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

TEXT OF RULE

SECTION 1. Phar 5.03 is repealed.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 6.07

Relating to: Storage

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to provide clarity to the storage requirements for a pharmacy.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Currently the professional service area is required to have a refrigerator, sufficient shelf, drawer or cabinet space for labels and containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment. As health care evolves, there are different types of pharmacies, specifically consulting pharmacies, which may not require all the items listed in the current rule. The proposed rule will update the rule to reflect the requirements for current practices of pharmacy.

In addition, the rule will clarify the manner in which controlled substances must be stored.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

15.08 (5) (b) The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.

450.02 (3) (a) The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

450.02 (3) (d) The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

100 hours

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies and pharmacists.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The only portion of the proposed rule which also relates to federal regulations is the storage of controlled substances.

Title 21 CFR 1301
§1301.75 Physical security controls for practitioners.
(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
(c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by §1317.80(d).
(d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
(e) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

_____
Authorized Signature

_____
Date Submitted

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Requirements for controlled substances

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to complete a comprehensive review of Phar 8, Requirements for Controlled Substances and make revisions to ensure the chapters are statutorily compliant with state and federal law and are current with professional standards and practices.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Board intends to modernize Phar 8 to bring it in line with current pharmacy standards and practices. The Board will evaluate reducing the regulatory impact on pharmacies without negatively impacting public safety.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

15.08 (5) (b) The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.

450.02 (2) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

450.02 (3) (a) The Board may promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

450.02 (3) (b) The Board may promulgate rules establishing security standards for pharmacies.

450.02 (3) (d) The Board may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961.

450.02 (3) (e) The Board may promulgate rules establishing minimum standards for the practice of pharmacy.

961.31 The pharmacy examining board may promulgate rules relating to the manufacture, distribution and dispensing of controlled substances within this state.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

150 hours

6. List with description of all entities that may be affected by the proposed rule:

Pharmacies and pharmacists

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Sharon Henes, Administrative Rules Coordinator, (608) 261-2377

_____
Authorized Signature

_____
Date Submitted

Chapter Phar 17

PHARMACY INTERNSHIP

Phar 17.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), and 450.03 (1) (g) and (2) (b), Stats.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; **correction made under s. 13.92 (4) (b) 7., Stats., Register June 2015 No. 714.**

Phar 17.02 Definitions. In this chapter:

(1) "Academic internship" means a practical experience program consisting of the practice of pharmacy sponsored by a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) "Direct supervision" means immediate on premises availability to continually coordinate, direct and inspect at first hand the practice of another.

(3) "Foreign graduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has not graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(4) "Intern" means a person engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g), Stats.

(5) "Internship in the practice of pharmacy" means the completion of a minimum of 1500 hours in aggregate in the practice of pharmacy under subs. (1), (3), (6), (7) or (8).

(6) "Postgraduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(7) "Practical experience internship" means practical experience acquired in another state which is comparable to an internship as described in subs. (1), (3), (6) and (8).

(8) "Student non−academic internship" means the practice of pharmacy by a person which is not acquired in an academic internship.

(9) "Supervising pharmacist" means a pharmacist who supervises and is responsible for the actions of an intern in the practice of pharmacy.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.03 Academic internship. A person participating in an academic internship is not required to register as an intern with the board. There is no restriction in the number of hours earned in an academic internship.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.04 Foreign graduate internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a foreign graduate internship the person must file an application with the board for original licensure under s. Phar 2.02, and submit evidence satisfactory to the board of having obtained certification by the foreign pharmacy graduate examination committee.

(2) A foreign graduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request. Prior to performing duties as an intern or to receiving credit for hours in an internship in the practice of pharmacy under this section the supervising pharmacist shall be disclosed in the initial application and any change of a supervising pharmacist shall be disclosed to the board prior to further performing duties constituting the practice of pharmacy as an intern.

(4) Upon completing a maximum of 2000 hours of the practice of pharmacy in a foreign graduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; CR 06−050: am. (1), (2) and (4), r. (3) and (5) Register October 2006 No. 610, eff. 11−1−06.

Phar 17.05 Postgraduate internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a postgraduate internship, the person must file an application with the board for original licensure under s. Phar 2.02 and submit to the board evidence of having been graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A postgraduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

(3) Upon completing a maximum of 2000 hours of the practice of pharmacy in a postgraduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02; CR 06−050: am. (2) Register October 2006 No. 610, eff. 11−1−06.

Phar 17.06 Practical experience internship. There is no restriction in the number of hours earned in a practical experience internship. In determining comparable practical experience the board shall consider the duties performed constituting the practice of pharmacy as described in s. 450.01 (16), Stats.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Phar 17.07 Student non−academic internship. (1) Prior to performing duties as an intern or to receiving credit for hours participating in a student non−academic internship the person must successfully complete his or her second year in and be enrolled at a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A student non−academic internship is limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location

worked by an intern under his or her direct supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

History: CR 01−134: cr. Register July 2002 No. 559, eff. 8−1−02.

Sec. 9. (c) Any person registered as a pharmacy technician who is also enrolled in a first professional degree program in pharmacy in a school or college of pharmacy or a department of pharmacy of a university approved by the Department or has graduated from such a program within the last 18 months, shall be considered a "student pharmacist" and entitled to use the title "student pharmacist". A student pharmacist must meet all of the requirements for licensure as a registered pharmacy technician set forth in this Section excluding the requirement of certification prior to the second license renewal and pay the required registered pharmacy technician license fees. A student pharmacist may, under the supervision of a pharmacist, assist in the practice of pharmacy and perform any and all functions delegated to him or her by the pharmacist.

(d) Any person seeking licensure as a pharmacist who has graduated from a pharmacy program outside the United States must register as a pharmacy technician and shall be considered a "student pharmacist" and be entitled to use the title "student pharmacist" while completing the 1,200 clinical hours of training approved by the Board of Pharmacy described and for no more than 18 months after completion of these hours. These individuals are not required to become registered certified pharmacy technicians while completing their Board approved clinical training, but must become licensed as a pharmacist or become licensed as a registered certified pharmacy technician before the second pharmacy technician license renewal following completion of the Board approved clinical training.

(e) The Department shall not renew the registered pharmacy technician license of any person who has been licensed as a registered pharmacy technician with the designation "student pharmacist" who: (1) has dropped out of or been expelled from an ACPE accredited college of pharmacy; (2) has failed to complete his or her 1,200 hours of Board approved clinical training within 24 months; or (3) has failed the pharmacist licensure examination 3 times. The Department shall require these individuals to meet the requirements of and become licensed as a registered certified pharmacy technician.

Section 1330.310 Graduates of Programs Outside the United States

Applicants who are graduates of a first professional degree program in pharmacy located outside the United States or its territories that is not approved pursuant to the provisions of Section 1330.300 shall submit proof of:

e) Either:

1) Completion of a course of clinical instruction totaling 1,200 clinical hours approved by the Board as required by Section 7 of the Act. The course of clinical instruction shall be conducted under the supervision of a pharmacist registered in the State of Illinois. The applicant shall obtain prior approval of the Board before enrolling in the course of clinical instruction. In approving a course of clinical instruction, the Board shall consider, but not be limited to, whether the course:

A) Enhances development of effective communication skills by enabling consultation among the applicant, the prescriber and the patient;

B) Promotes development of medical data retrieval skills through exposure to patient medical charts, patient medication profiles and other similar sources of patient information;

C) Promotes development of the applicant's ability to research and analyze drug information literature; and

D) Promotes development of the applicant's ability to interpret laboratory test and physical examination results; or

2) Have been licensed in a U.S. jurisdiction or territory for at least 1 year with no disciplinary actions or encumbrances on their license or pending license.

IOWA

657—4.1 (155A) Definitions.
"Board" means the Iowa board of pharmacy.
"Pharmacist-intern" or "intern" means a person enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board, who is registered with the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. "Pharmacist-intern" includes a graduate of an approved college of pharmacy, or a foreign graduate who has established educational equivalency pursuant to the requirements of rule 657—4.7(155A), who is registered with the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist in Iowa. "Pharmacist-intern" may include an individual participating in a residency or fellowship program in Iowa, whether or not the individual is licensed as a pharmacist in another state.
"Pharmacist preceptor" or "preceptor" means a pharmacist licensed to practice pharmacy whose license is current and in good standing. Preceptors shall meet the conditions and requirements of

rule 657—4.9(155A). No pharmacist shall serve as a preceptor while the pharmacist's license to practice pharmacy is the subject of disciplinary sanction by a pharmacist licensing authority.

4.2 (155A) Goal and objectives of internship.
4.2(1) *Goal.* The goal of internship is for the pharmacist-intern, over a period of time, to attain and build upon the knowledge, skills, responsibilities, and ability to safely, efficiently, and effectively practice pharmacy under the laws and rules of the state of Iowa.
4.2(2) *Objectives.* The objectives of internship are as follows:

a. Managing drug therapy to optimize patient outcomes. The pharmacist-intern shall evaluate the patient and patient information to determine the presence of a disease or medical condition, to determine the need for treatment or referral, and to identify patient-specific factors that affect health, pharmacotherapy, or disease management; ensure the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems; and monitor the patient and patient information and manage the drug regimen to promote health and ensure safe and effective pharmacotherapy.

b. Ensuring the safe and accurate preparation and dispensing of medications. The pharmacist-intern shall perform calculations required to compound, dispense, and administer medication; select and dispense medications; and prepare and compound extemporaneous preparations and sterile products.

c. Providing drug information and promoting public health. The pharmacist-intern shall access, evaluate, and apply information to promote optimal health care; educate patients and health care professionals regarding prescription medications, nonprescription medications, and medical devices; and educate patients and the public regarding wellness, disease states, and medical conditions.

d. Adhering to professional and ethical standards. The pharmacist-intern shall comply with professional, legal, moral, and ethical standards relating to the practice of pharmacy and the operation of the pharmacy.

e. Understanding the management of pharmacy operations. The pharmacist-intern shall develop a general understanding of the business procedures of a pharmacy and develop knowledge concerning the employment and supervision of pharmacy employees.

657—4.3 (155A) 1500-hour requirements. Internship credit may be obtained only after internship registration with the board and commencement of the first professional year in a college of pharmacy. Internship shall consist of a minimum of 1500 hours, all of which may be a college-based clinical program approved or accepted by the board. Programs shall be structured to provide experience in community, institutional, and clinical pharmacy practices. A pharmacist-intern may acquire additional hours under the supervision of one or more preceptors in a traditional licensed general or hospital pharmacy, at a rate of no more than 48 hours per week, where the goal and objectives of internship in rule 657—4.2(155A) apply. Credit toward any additional hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served concurrent with academic training and outside a college-based clinical program. "Concurrent time" means internship experience acquired while the person is a full-time student carrying, in a given school term, at least 75 percent of the average number of credit hours per term needed to graduate and receive an entry-level degree in pharmacy. Recognized academic holiday periods, such as spring break and winter break, shall not be considered "concurrent time." The competencies in subrule 4.2(2) and the concurrent time limitations of this rule shall not apply to college-based clinical programs.

657—4.4 (155A) Iowa colleges of pharmacy clinical internship programs. The board shall periodically review the clinical component of internship programs of the colleges of pharmacy located in Iowa. The board reserves the right to set conditions relating to the approval of such programs.

657—4.5 (155A) Out-of-state internship programs. Candidates enrolled in out-of-state colleges of pharmacy who complete the internship requirements of that state shall be deemed to have satisfied Iowa's internship requirements. Candidates shall submit documentation from the out-of-state internship program certifying completion of that state's requirements. Candidates enrolled in colleges of pharmacy located in states with no formal internship training program shall submit documentation from that state's board of pharmacy or college of pharmacy certifying that the candidate has completed all prelicensure training requirements.

657—4.6 (155A) Registration, reporting, and authorized functions. Every person shall register with the board before beginning the person's internship experience, whether or not for the purpose of fulfilling the requirements of rule 657—4.3(155A). Registration is required of all students enrolled in Iowa colleges of pharmacy upon commencement of the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall annually certify to the board the names of students who are enrolled in the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall, within two weeks of any change, certify to the board the names of students who have withdrawn from the college of pharmacy.

4.6(1) *Application for registration—required information.* Application for registration as a pharmacist-intern shall be on forms provided by the board, and all requested information shall be provided on or with such application. The application shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number or individual tax identification number (ITIN); and name and location of college of pharmacy and anticipated month and year of graduation. The college of pharmacy shall certify the applicant's

eligibility to practice as a pharmacist-intern.

4.6(2) *Supervision and authorized functions.* A licensed pharmacist shall be on duty in the pharmacy and shall be responsible for the actions of a pharmacist-intern during all periods of internship training. At the discretion of the supervising pharmacist, the following judgmental functions, usually restricted to a pharmacist, may be delegated to pharmacist-interns registered by the board:

a. Verification of the accuracy, validity, and appropriateness of the filled prescription or medication order;

b. Review and assessment of patient records for purposes identified in rule 657—8.21(155A);

c. Patient counseling;

d. Administration of vaccines pursuant to rule 657—8.33(155A).

4.6(3) *Term of registration.* Registration shall remain in effect as long as the board is satisfied that the intern is pursuing a degree in pharmacy in good faith and with reasonable diligence. A pharmacist-intern may request that the intern's registration be extended beyond the automatic termination of the registration pursuant to the procedures and requirements of 657—Chapter 34. Except as provided by the definition of pharmacist-intern in rule 657—4.1(155A), registration shall automatically terminate upon the earliest of any of the following:

a. Licensure to practice pharmacy in any state;

b. Lapse in the pursuit of a degree in pharmacy; or

c. One year following graduation from the college of pharmacy.

4.6(4) *Identification, reports, and notifications.* Credit for internship time will not be granted unless registration and other required records or affidavits are completed.

a. The pharmacist-intern shall be so designated in all relationships with the public and health professionals. While on duty in the pharmacy, the intern shall wear visible to the public a name badge including the designation "pharmacist-intern" or "pharmacy student."

b. Registered interns shall notify the board office within ten days of a change of name or address.

c. Notarized affidavits of experience in non-college-sponsored programs shall be filed with the board office after the successful completion of the internship. These affidavits shall certify only the number of hours and dates of training obtained outside a college-based clinical program as provided in rule 657—4.3(155A). An individual registered as a pharmacist-intern while participating in an Iowa residency or fellowship program shall not be required to file affidavits of experience.

4.6(5) *No credit prior to registration.* Credit will not be given for internship experience obtained prior to the individual's registration as a pharmacist-intern. Credit for Iowa college-based clinical programs will not be granted unless registration is issued before the student begins the program.

4.6(6) *Nontraditional internship.* Internship training at any site which is not licensed as a general or hospital pharmacy is considered nontraditional internship.

a. *Application.* Prior to beginning a period of nontraditional internship, the intern shall submit a written application, on forms provided by the board, for approval of the objectives of the nontraditional internship. The application shall identify objectives consistent with the unique learning experiences of the intern and consistent with the goal and objectives of internship in rule 657—4.2(155A).

b. *Preceptor.* A preceptor supervising a pharmacist-intern in a nontraditional

internship shall be a currently licensed pharmacist in the state where the internship is served, and the requirements of rule 657—4.9(155A) shall apply to all preceptors.

c. Certification, not credit. Hours obtained in nontraditional internship shall not be credited toward the total 1500 hours required pursuant to rule 657—4.3(155A) prior to licensure to practice pharmacy in Iowa. The board may, however, certify hours obtained in one or more approved nontraditional internships in recognition of the pharmacist-intern's training outside the scope of traditional pharmacy practice. Certification shall not be granted for experience obtained in a nontraditional internship unless the board, prior to the intern's beginning the period of internship, approved the objectives of the internship.

657—4.7 (155A) Foreign pharmacy graduates. Foreign pharmacy graduates who are candidates for licensure in Iowa will be required to obtain a minimum of 1500 hours of internship in a licensed pharmacy or other board-approved location.

4.7(1) *Registration.* Candidates shall register with the board as provided in rule 657—4.6(155A). Internship credit will not be granted until the candidate has been issued an intern registration. Applications for registration shall be accompanied by certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) as provided in 657—subrule 2.10(1).

4.7(2) *Certification of hours.* Following completion of any period of internship, internship hours shall be certified to the board by submission of notarized affidavits of experience as provided in paragraph 4.6(4)*"c."*

4.7(3) *Credit for foreign pharmacy practice.* The board may grant credit to a foreign pharmacy graduate, based on the candidate's experience in the practice of pharmacy, for all or any portion of the required 1500 hours of internship training. The candidate shall provide detailed information regarding the candidate's experience in the practice of pharmacy. The board shall determine, on a case-by-case basis, whether and to what extent the candidate's experience meets the goals and objectives established in rule 657—4.2(155A).

657—4.8 (155A) Fees. The fee for registration as a pharmacist-intern is $30, plus applicable surcharge pursuant to 657—30.8(155A), which shall be payable with the application.

657—4.9 (155A) Preceptor requirements.

4.9(1) *Licensed pharmacist.* A preceptor shall be a licensed pharmacist in good standing in the state where the internship is to be served pursuant to the definition of pharmacist preceptor in rule 657—4.1(155A).

4.9(2) *Affidavits.* A preceptor shall be responsible for completing the affidavit certifying the number of hours and the dates of each internship training period under the supervision of the preceptor for any period of internship completed outside a college-based clinical program.

4.9(3) *Number of interns.* A preceptor may supervise no more than two pharmacist-interns concurrently.

4.9(4) *Responsibility.* A preceptor shall be responsible for all functions performed by a pharmacist-intern.

657—4.10 (155A) Denial of pharmacist-intern registration. The board may deny an application for registration as a pharmacist-intern for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A or 205, or any rule of

the board.

657—4.10 (155A) Denial of pharmacist-intern registration. The board may deny an application for registration as a pharmacist-intern for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A or 205, or any rule of the board.

657—4.11 (155A) Discipline of pharmacist-interns.

4.11(1) *Grounds for discipline.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205, or any rule of the board.

4.11(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacist-intern registration.

b. Suspension of a pharmacist-intern registration until further order of the board or for a specified period.

c. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts.

d. Such other sanctions allowed by law as may be appropriate.

MICHIGAN

Definitions
(h) "Unconventional internship" means an educational program of professional and practical experience involving those pharmacy or related pharmaceutical experiences which, by practical, on-the-job training, provide knowledge useful to the practice of the profession of pharmacy without meeting all of the criteria of a conventional internship.

R 338.473 Intern licensure; eligibility; limitations.
Rule 3. (1) An applicant for a pharmacy intern license shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall establish that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).
(2) An intern shall engage in the practice of pharmacy only under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist.

R 338.473a Interns; eligibility; limited license; qualifications; supervision; notice of position change; duties; professional and practical experience; denial, suspension, or revocation of license.
Rule 3a. (1) An individual is eligible for intern licensure at the beginning of the first professional year of study in an accredited college or school of pharmacy.
(2) Upon application and payment of appropriate fees, a limited license shall be issued by the department to qualified applicants.
(3) The limited license shall be renewed annually and shall remain active while the applicant is actively pursuing a degree in an accredited college or school of pharmacy and until the applicant is licensed as a pharmacist, or for not more than 1 year from the date of graduation from the pharmacy program.
(4) An intern shall annually submit verification to the department that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).
(5) An intern shall complete not less than 1,600 hours of internship experience. An intern working in this state shall hold an intern license in order to earn the hours of internship experience required in this state. The minimum number of hours of internship experience may be satisfied by complying with any of the following provisions:

(a) Obtaining the minimum number of hours of experience under the personal charge of a qualified, approved preceptor.

(b) Completing a structured practical experience program within the college or school of pharmacy curriculum.

(c) Through a combination of subdivisions (a) and (b) of this subrule.

(6) When eligible, a student shall apply for licensure as an intern.
(7) Hours of internship experience shall be computed from the date of board certification as a licensed intern. In computing the hours of internship experience, all of the following provisions shall apply:

(a) Experience shall be granted only upon verification by an approved pharmacy preceptor or other person previously approved by the board.
(b) The board may grant internship experience gained in unconventional internship programs. Up to 400 hours of internship experience may be granted for such unconventional education experiences.
(c) A maximum of 40 hours of internship experience shall be granted per calendar week served by the intern.
(d) A maximum of 16 hours of non-college-sponsored internship experience shall be granted per calendar week while the intern is a full-time student in a college or school of pharmacy, except during authorized vacation periods.
(e) The board may grant credit for internship experience obtained through practice as an intern in another jurisdiction if the experience was comparable to the minimum standards in these rules.
(f) The board may accept experience as a licensed pharmacist in another state or Canada as the equivalent of internship experience.

(8) The intern shall be responsible for verifying board approval of his or her pharmacy preceptor, required under R 338.473(2).

(9) Within 30 days, an intern shall notify the board if he or she is no longer actively enrolled in a pharmacy degree program at an accredited college or school of pharmacy.

(10) Interns shall complete and submit such forms or examinations, or both, as deemed necessary by the board.

(11) Interns shall receive professional and practical experience in at least all of the following areas:

(a) Pharmacy administration and management.
(b) Drug distribution, use, and control.
(c) Legal requirements. (d) Providing health information services and advising patients.
(e) Pharmacists' ethical and professional responsibilities.
(f) Drug and product information.

(12) Interns shall keep abreast of current developments in the internship program and the pharmacy profession.

(13) The board may deny, suspend, or revoke the license of an intern or may deny hours of internship for failure to comply with pharmacy law or rules relating to pharmacy practice or internship.

R 338.473c Preceptors; approval; qualifications; duties; denial, suspension, or revocation of preceptor approval.

Rule 3c. (1) Before training an intern, a licensed pharmacist in this state shall apply to the board for approval as a preceptor. A pharmacist shall have at least 1 year of practice before being approved as a preceptor.

(2) There shall be not more than 2 interns per pharmacist on duty at the same time. However, the approved preceptor is responsible for the overall internship program at the pharmacy.

(3) A preceptor is responsible for arranging the intern's training in areas of practice as defined in R 338.473a(9).

(4) A preceptor shall annually submit internship training affidavits on forms provided by the board.

(5) The preceptor shall determine the degree of professional skill possessed by the intern and shall develop a training program whereby the intern will be able to improve upon and develop his or her ability in the practice of pharmacy.
(6) The preceptor shall allow sufficient time to instruct the intern in the practice of pharmacy and to frequently review and discuss his or her progress.
(7) Upon completion of the intern training, the preceptor under whom the training was obtained shall give the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the board may require further training before allowing the intern to take the examination for licensure as required by R 338.474.
(8) The board may deny, suspend, or revoke the preceptor's approval for failure to properly supervise the intern during the internship training program or for violation of the laws and rules relating to the practice of pharmacy or the internship program.
(9) The board may deny, suspend, or revoke the preceptor's approval of a pharmacist who has been convicted of any violation of a federal, state, or local law, ordinance, or rules relating to pharmacy practice within 5 years of the application for approval as a preceptor.

R 338.473d Graduates of a non-accredited college or school of pharmacy; requirements; internship.
Rule 3d. (1) An applicant who is a graduate of a non-accredited college or school of pharmacy may be granted an intern license to comply with the requirements of R 338.473a(5) upon making application, payment of appropriate fees, and providing evidence of successful completion of the foreign pharmacy graduate examination committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056.
(2) The limited license shall be renewed annually. The limited license shall remain active while the applicant is actively completing the requirements of R 338.473a(5), and until the applicant is licensed as a pharmacist.

MINNESOTA

6800.5100 DEFINITIONS.

"Experiential education program" means the pharmacy practice experience component of the professional pharmacy curriculum of an accredited college or school of pharmacy.

"Concurrent time internship " means internship experience gained during the second, third, and fourth professional academic years only, while a person is a full-time student carrying, in any given school term, 12 or more credits.

"Hour" means the standard 60-minute division of time.

"Pharmacist-intern" and "intern" mean:

A. a natural person satisfactorily progressing toward the degree in pharmacy required for licensure;

B. a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

C. a qualified applicant awaiting examination for licensure; or

D. a participant in a residency or fellowship program, not licensed to practice pharmacy in the state of Minnesota, who is a licensed pharmacist in another state or who is a graduate of the University of Minnesota College of Pharmacy or another pharmacy college approved by the board.

"Preceptor" means a natural person licensed as a pharmacist by the Board of Pharmacy, or a licensed pharmacist working in a federal health care facility, who participates in instructional programs approved by the board and is providing instruction and direction to pharmacist-interns related to their practical experience.

6800.5300 REGISTRATION AND REPORTING.

6800.5300 REGISTRATION AND REPORTING.

Registration. Every person shall register with the board before beginning a pharmacy internship in Minnesota. Every person participating in a pharmacy residency or fellowship shall either register as an intern or be licensed as a pharmacist. Applications for the registration of a pharmacist-intern shall be on a form or forms the Board of Pharmacy prescribes and shall be accompanied by a fee established in Minnesota Statutes, chapter 151. Registration remains in effect if notices of employment, progress report affidavits, or similar forms are submitted as required by the board, and if the board is satisfied that the registrant is in good faith and with reasonable diligence pursuing a degree in pharmacy, is a qualified applicant awaiting an examination for licensure, or is completing a pharmacy residency or fellowship. Registration as an intern for purposes of participating in a residency or fellowship program remains in effect until the individual obtains licensure as a pharmacist, for two years, or until the completion of the residency or fellowship program, whichever occurs first. Credit for internship hours will not be granted unless registration forms and materials, notices of employment, and progress report affidavits are submitted as required by the board.

Identification. The pharmacist-intern shall be so designated in professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall

on proper registration issue to the intern a pocket registration card for purposes of identification and verification of the intern's registration.

Change of address. All registered interns shall notify the board immediately upon change of employment or residence address.

Manual. Interns completing 400 hours or more of their internship requirement in Minnesota must complete an internship manual, provided by the board, before the board will recognize the completed hours as acceptable for use in meeting the board's internship requirement.

Termination. No person who terminates efforts toward the completion of the educational or other prerequisites of licensure, or of completion of a residency or fellowship, is entitled to the continued privileges of internship registration.

Improper use of title. No person not properly registered with the board as a pharmacist-intern shall take, use, or exhibit the title of pharmacist-intern, pharmacist-apprentice, pharmacist-extern, or any other term of similar or like import.

6800.5350 PRECEPTORS.

Certificates. Pharmacists intending to act as preceptors for pharmacist-interns must register as preceptors with the board by submitting an application and any supporting documentation required by the board. A preceptor registration shall expire every other year on the anniversary of its issuance. The board shall grant registrations or renewals to applicants who fulfill the requirements of subparts 2 and 3.

Training and practice. Applicants must show that:

A. they are participating in the Experiential Education Program of the University of Minnesota College of Pharmacy as an approved preceptor; or

B. they have completed at least 4,000 hours of practice as a licensed pharmacist, with at least 2,000 hours of that practice occurring within the state of Minnesota.

Other requirements. In addition to fulfilling the requirements of subpart 2, item A or B, applicants must show that:

A. they are currently in practice at least 20 hours per week as a pharmacist;

B. they have a history of exemplary practice with respect to compliance with state and federal laws;

C. they will provide time on a regular basis, at least three times each month, for the purpose of helping their interns meet the competencies of the internship requirement; and

D. for renewal of a registration only, that they have participated in an instructional program specifically for preceptors, provided by or approved by the board, within the previous 24 months.

6800.5400 TRAINING.

Intent. The intent of this rule is to establish minimum standards for the training of interns so that they are provided with a proper preceptor-intern relationship and a broad base of practical experience that supplements didactic academic training in a manner which prepares them for all aspects of the practice of pharmacy.

Nonreciprocity. Nothing in this rule shall imply that the standards described herein are acceptable to other states on a reciprocal basis.

Training in other state. When an intern desires to obtain credit for training received in a state other than Minnesota, the intern shall abide by the internship rules in that state, and shall provide evidence from that state's Board of Pharmacy confirming completion of the number of internship hours for which credit is being requested. The board may deny requests for approval of credit for training received in a state other than Minnesota if the training does not meet the standards for internship described in this subpart.

Maximum number of interns. A licensed pharmacist shall not be the preceptor for more than two interns at one time.

Supervision: intern dispensing and compounding. An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Except in the case of internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may not supervise more than one intern who is performing tasks associated with dispensing or compounding. In the case of an internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may supervise two interns who are performing tasks associated with dispensing or compounding. The ultimate responsibility for the actions of an intern performing tasks associated with dispensing or compounding shall remain with the licensed pharmacist who is supervising the intern.

Supervision, generally. Immediate and direct supervision by a licensed pharmacist is not required when an intern completes a medication history, gathers information for the purpose of formulating a pharmaceutical care plan or making a drug therapy recommendation, conducts educational activities for patients or staff, provides patient counseling, participates in patient rounds, or performs similar tasks that do not involve dispensing and compounding. However, all drug therapy and related recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made. An intern's supervising pharmacist is responsible for the accuracy and completeness of statements made by the intern while providing counseling to patients or health-related education to patients or staff.

Competencies. Upon registration, interns and preceptors will be furnished a copy of the board's internship manual, which lists the minimum competencies that should be the focus of internship training. The competencies are furnished to suggest appropriate types and order of training experience and shall be used to ensure that the intern's practical experiences are commensurate with the intern's educational level, and broad in scope.

Evidence of completion. Applicants for licensure as pharmacists who are examined and licensed after September 17, 1973, shall submit evidence that they have successfully completed not less than 1,500 hours of internship under the instruction and supervision of a preceptor. Effective May 1, 2003, candidates for licensure shall submit evidence that they have successfully completed not less than 1,600 hours of internship under the direction and supervision of a preceptor. Credit for internship shall be granted only to registered interns who have completed the third year of the five-year or six-year pharmacy curriculum, provided, however, that:

A. no more than 400 hours of concurrent time internship will be granted to an intern; and

B. 800 hours of internship credit may be acquired through experiential education program experiences that do not have as their focus traditional compounding, dispensing,

and related patient counseling activities. The remaining 800 hours of the 1,600 hour total requirement must focus on traditional compounding, dispensing, and related patient counseling activities.

6800.5500 LICENSURE TRANSFER STANDARDS.

The board may accept internship credit from applicants for licensure transfer who have submitted evidence of completion of internship training in another state, provided that the training is, in the opinion of the board, substantially equivalent to the standards herein provided, and is in compliance with the internship standards of the National Association of Boards of Pharmacy.

6800.5600 ADVISORY COMMITTEE.

The board shall appoint an advisory committee on internship to advise the board on the administration of parts 6800.5100 to 6800.5600. The committee shall include practicing pharmacists, pharmacist-educators, pharmacist-interns, and representatives of the board.

Model Rules for Pharmacy Interns

Section 1. Licensure.

Every individual shall be licensed by the Board of Pharmacy before beginning Pharmacy practice experiences in this State.[1] A license to practice Pharmacy as a Pharmacy Intern shall be granted only to those individuals who:

(a) are enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(b) are graduates of an approved professional degree program of a school or college of Pharmacy or are graduates who have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who are currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

(c) are qualified applicants awaiting examination for licensure or meeting Board requirements for re-licensure;

(d) are participating in a residency or fellowship program; or

(e) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule.

Section 2. Identification.

The Pharmacy Intern shall be so designated in his or her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a Pharmacist. The Board shall issue to the Pharmacy Intern a license for purposes of identification and verification of his or her role as a Pharmacy Intern, which license shall be surrendered to the Board upon discontinuance of Pharmacy practice experiences for any reason including licensure as a Pharmacist. No individual not properly licensed by the Board as a Pharmacy Intern shall take, use, or exhibit the title of Pharmacy Intern, or any other term of similar like or import.

Section 3. Supervision.

A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the supervision of a Pharmacist. A Pharmacist shall be in contact with, and actually giving instructions to, the Pharmacy Intern during all professional activities throughout the entire Pharmacy practice experience period. The Pharmacist is responsible for supervising all the Practice of Pharmacy activities performed by the Pharmacy Intern, including but not limited to the accurate Dispensing of the Drug.[2]

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[1] The ACPE *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007) requires schools and colleges of Pharmacy seeking and maintaining ACPE accreditation to incorporate introductory Pharmacy practice experiences within their professional curricula, and such experiences must account for not less than 5% of the total curricular length (not less than 300 contact hours). Under the supervision of a Preceptor and usually taken throughout the first three academic years of the professional program, these introductory Pharmacy practice experiences expose students to and allow students to participate in activities such as processing/Dispensing Medication Orders, conducting Patient interviews, or presenting Patient cases in an organized format.

It is also encouraged that Boards of Pharmacy allow Pharmacy students to be registered as Pharmacy Interns as early as initial enrollment in a Board-approved professional program as long as the Pharmacy student has begun to take professional degree courses.

[2] According to the ACPE Accreditation Standards and Guidelines, most Pharmacy practice experiences must be under the supervision of a qualified Pharmacist Preceptor licensed in the United States. Realizing that in some cases non-Pharmacist Preceptors can also provide valuable

Section 4. Change of Address.

All Pharmacy Interns shall notify the Board immediately upon change of employment and residential address.

Section 5. Evidence of Completion.

Applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies; and (2) not less than 1,740 hours of Pharmacy practice experience credit under the instruction and supervision of a Preceptor.[3]

learning opportunities, it is hoped that Boards of Pharmacy recognize these experiences and that schools and colleges of pharmacy ensure, in most cases through faculty, that the desired competencies are being met.

Supervision includes an actual review of the Prescription Drug Order and the dispensed Drug or Product to ensure public protection.

[3] These requirements coincide with the ACPE Accreditation Standards and Guidelines. Boards of pharmacy are strongly encouraged to utilize these Accreditation Standards and Guidelines as a basis for the establishment and revision of Board standards for Pharmacy practice experiences. Introductory Pharmacy practice experiences, which are not less than 300 contact hours, are in addition to the advanced practice experiences taken during the final professional year, which account for not less than 25 % of the curricular length or 1,440 contact hours. The total Pharmacy practice experience hour requirement, therefore, is not less than 1,740 hours. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

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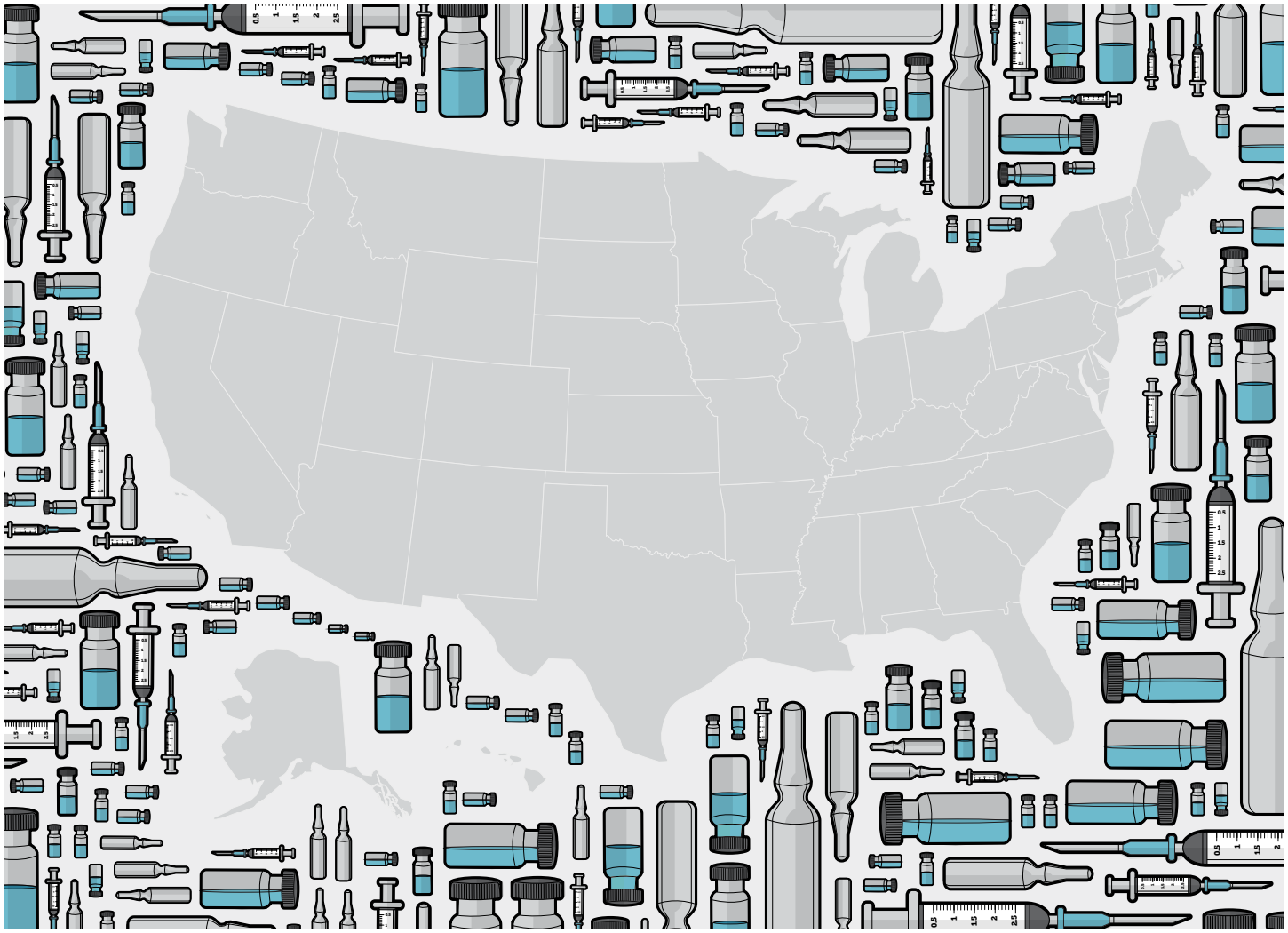

THE PEW CHARITABLE TRUSTS

State Oversight of Drug Compounding

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

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The Pew Charitable Trusts

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Elizabeth Jungman, *director, public health programs*

National Association of Boards of Pharmacy

Eileen Lewalski, *senior manager, professional affairs*
Scotti Russell, *manager, government affairs*

External reviewers

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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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Contact: Sara Brinda, senior associate, communications
Email: sbrinda@pewtrusts.org
Project website: pewtrusts.org/drugsafety

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.

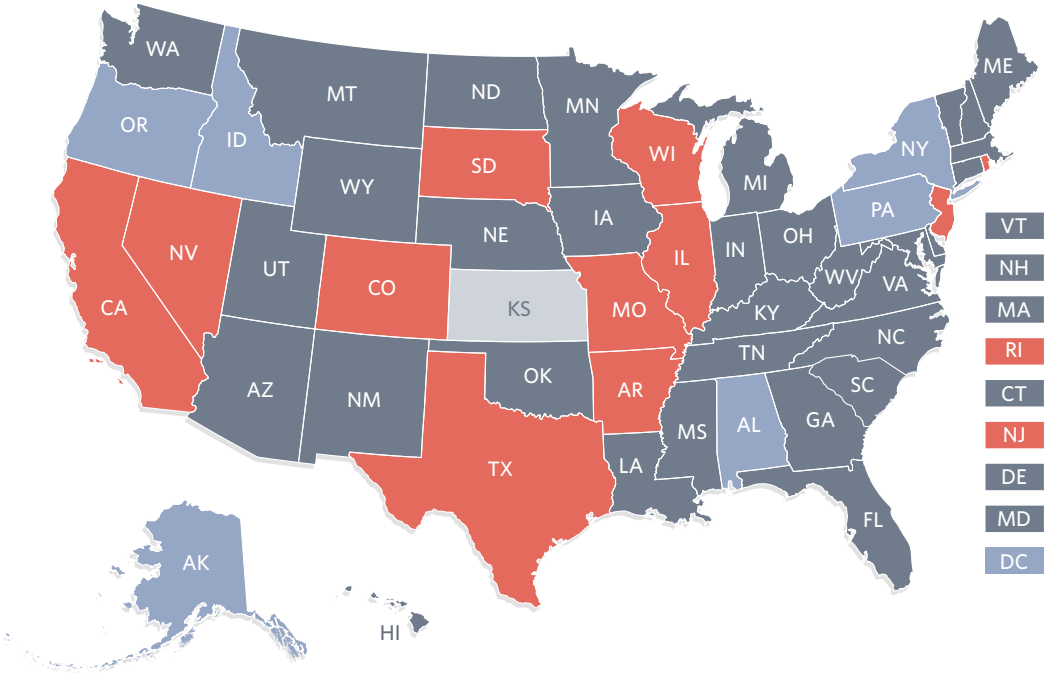
Our study found that 32 state boards of pharmacy require traditional pharmacies that compound sterile drugs for humans to be in full compliance with Chapter <797>. An additional 11 states have strong standards for sterile compounding practice, which 10 states characterize as "equivalent to or stricter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

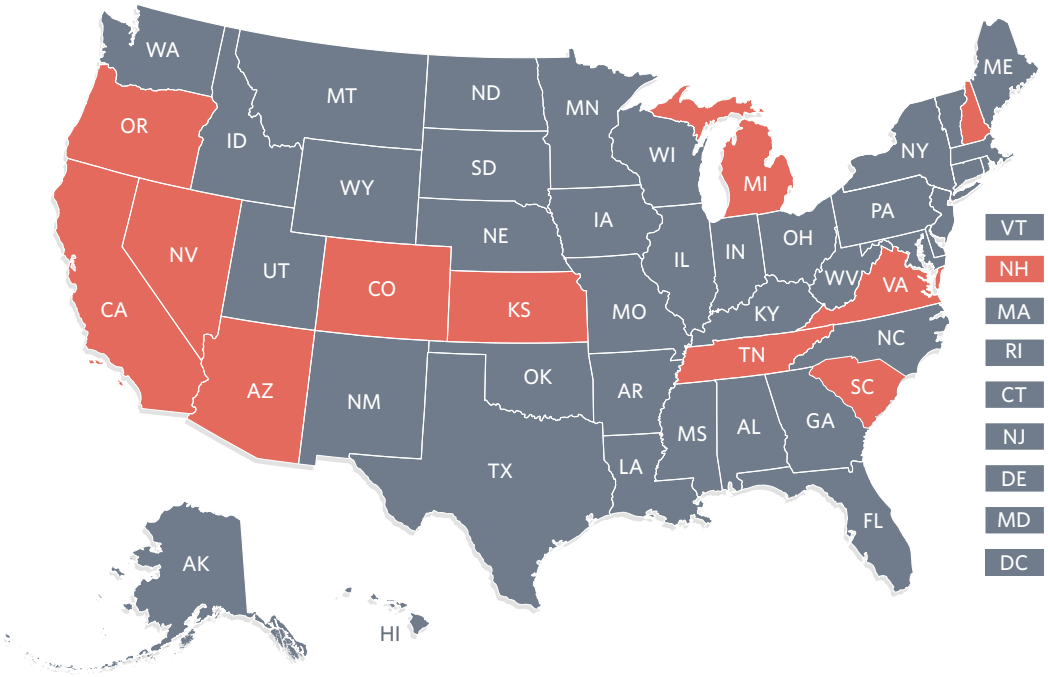
FDA finalized its prescription requirement guidance for industry in December 2016, an important step toward fully implementing the DQSA. The document clarifies the law's requirement that traditional compounders dispense or distribute compounded products only upon receipt of a valid prescription. Because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

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	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

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

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

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

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

15 Ibid.

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

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

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

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

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

21 Ibid.

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

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

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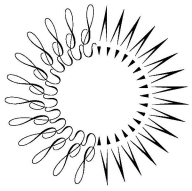

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