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Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Christine Poleski (608) 266-2112
January 28, 2021

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 actions of the Board.

AGENDA

11:00 A.M.
(OR IMMEDIATELY FOLLOWING THE PHARMACY RULES COMMITTEE)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes
1) December 3, 2020 **(5-9)**
2) January 13, 2021**(10-11)**

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition

E. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Annual Policy Review **(12)**
3) Election of Officers, Appointment of Liaisons and Alternates, Delegation of Authorities **(13-23)**
4) Board Members – Term Expiration Dates
   a. O'Hagan, Tiffany – 7/1/2024
   b. Peterangelo, Anthony – 7/1/2023
   c. Trapskin, Philip – 7/1/2021
   d. Walsh, Michael – 7/1/2024
   e. Weiss, Shana – 7/1/2023
   f. Weitekamp, John – 7/1/2022
   g. Winters, Cathy – 7/1/2021

F. Legislative and Policy Matters – Discussion and Consideration (24)
1) Assembly Bill 4: Relating to Pharmacy Technicians and Pharmacy Students Administering Vaccines **(25-29)**
2) Senate Bill 3: Relating to Pharmacy Benefit Manager, Prescription Drug Benefits, and Granting Rulemaking Authority **(30-54)**

G. Administrative Rule Matters – Discussion and Consideration (55)

1) Development of 2021 Biennial Report Under s. 227.29, Wis. Stats. **(56-57)**
2) Pending or Possible Rulemaking Projects
    a. Phar 2 (Emergency and Permanent Rule) **(58-61)**

H. Public Agenda Request: Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration – Discussion and Consideration (62-199)

I. Variances – Discussion and Consideration (200)

1) Review, Discussion and Consideration of All Current Variances
2) Review, Discussion and Consideration of Any Proposed Variances
    a. Variance on Consulting and Delivery
    b. Pharmacy Society of Wisconsin Request for Variance to Supervision Requirements for Pharmacy Students **(201)**
    c. Variance Requests Received After Preparation of the Agenda

J. Education and Examination Matters – Discussion and Consideration

1) Multistate Pharmacy Jurisprudence Examination (MPJE) Update

K. Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration

1) Travel Report: NABP Interactive Member Forum – January 27, 2021 – Cathy Winters
2) National Association of Boards of Pharmacy (NABP)/American Association of Colleges of Pharmacy (AACP) District IV – 2022 Annual Meeting Planning

L. COVID-19 – Discussion and Consideration

M. Pilot Program Matters – Discussion and Consideration

1) Final Checks in Community Pharmacies

N. Discussion and Consideration on Items Added After Preparation of Agenda

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Pilot Program Matters
13) Variances
14) Liaison Reports
15) Board Liaison Training and Appointment of Mentors
16) Informational Items
17) Division of Legal Services and Compliance (DLSC) Matters

18) Presentations of Petitions for Summary Suspension
19) Petitions for Designation of Hearing Examiner
20) Presentation of Stipulations, Final Decisions and Orders
21) Presentation of Proposed Final Decisions and Orders
22) Presentation of Interim Orders
23) Pilot Program Matters
24) Petitions for Re-Hearing
25) Petitions for Assessments
26) Petitions to Vacate Orders
27) Requests for Disciplinary Proceeding Presentations
28) Motions
29) Petitions
30) Appearances from Requests Received or Renewed
31) Speaking Engagements, Travel, or Public Relation Requests, and Reports

O. 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.).

P. Deliberation on Division of Legal Services and Compliance Matters

1) Case Closings

a. 18 PHM 162 – G.P.W., P.P. **(202-208)**
b. 19 PHM 046 – R.R.V.P. **(209-211)**
c. 19 PHM 081 – I.N.L. **(212-220)**
d. 19 PHM 083 – F.S.S.P. **(221-225)**
e. 19 PHM 135 – M.L. **(226-231)**
f. 19 PHM 160 – A.S.L.M.C. **(232-237)**
g. 19 PHM 175 – W. **(238-241)**
h. 19 PHM 304 – H.I. **(242-246)**
i. 20 PHM 046 – C.H.O.H., C.P. **(247-251)**

2) Administrative Warnings

a. 20 PHM 046 – J.L.H. **(252-253)**
b. 20 PHM 132 – E.J.T. **(254-255)**

3) Proposed Stipulations, Final Decisions, and Orders

a. 17 PHM 152 – Wells Pharmacy Network, LLC **(256-261)**
b. 18 PHM 170 – Cynthia R. Hennen, R.Ph. **(262-268)**
c. 19 PHM 017 – Guardian Pharmacy of Wisconsin **(269-274)**
d. 20 PHM 065 – Andrew Seidlitz, R.Ph. **(275-287)**

4) Monitoring Matters

a. Kevin Litten, R.Ph. – Requesting Full Licensure **(288-303)**

Q. Deliberation on Proposed Final Decisions and Orders

1) Jennifer Reithmeyer, R.Ph., Respondent (DHA Case Number SPS-20-0027/DLSC Case Number 18 PHM 180) **(304-320)**

R. Deliberation of Items Added After Preparation of the Agenda
   1) Education and Examination Matters
   2) Credentialing Matters
   3) Application Reviews
   4) DLSC Matters
   5) Monitoring Matters
   6) Professional Assistance Procedure (PAP) Matters
   7) Petitions for Summary Suspensions
   8) Petitions for Designation of Hearing Examiner
   9) Proposed Stipulations, Final Decisions and Orders
   10) Proposed Interim Orders
   11) Administrative Warnings
   12) Review of Administrative Warnings
   13) Proposed Final Decisions and Orders
   14) Matters Relating to Costs/Orders Fixing Costs
   15) Case Closings
   16) Board Liaison Training
   17) Petitions for Assessments and Evaluations
   18) Petitions to Vacate Orders
   19) Remedial Education Cases
   20) Motions
   21) Petitions for Re-Hearing
   22) Appearances from Requests Received or Renewed

S. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

T. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

U. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: MARCH 4, 2021

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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 4822 Madison Yards Way, 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. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
DECEMBER 3, 2020

PRESENT: Tiffany O'Hagan, Anthony Peterangelo, Philip Trapskin, John Weitekamp, Cathy Winters, Michael Walsh

EXCUSED: Shana Weiss

STAFF: Christine Poleski, Executive Director; Jameson Whitney, Legal Counsel; Dale Kleven, Administrative Rules Coordinator; Daniel Betekhtin, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Advanced; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 9:10 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF OCTOBER 22, 2020

MOTION: Cathy Winters moved, seconded by John Weitekamp, to approve the Minutes of October 22, 2020 as published. Motion carried unanimously.

PRELIMINARY PUBLIC HEARING: SCOPE STATEMENT, SS 136-20 (PHAR 15), RELATING TO RE-USE OF PERSONAL PROTECTIVE EQUIPMENT

Review and Respond to Public Comments and Clearinghouse Report

MOTION: Cathy Winters moved, seconded by Tiffany O'Hagan, to approve Scope Statement (SS) 136-20 (Phar 15), relating to re-use of personal protective equipment, for implementation. Motion carried unanimously.

PRELIMINARY PUBLIC HEARING: SCOPE STATEMENT, SS 137-20 (PHAR 1, 6, 7, 8, 12 AND 13), RELATING TO ELECTRONIC TRACK AND TRACE PEDIGREE SYSTEM, DRUG SUPPLY CHAIN SECURITY, MANUFACTURERS, AND DISTRIBUTORS

Review and Respond to Public Comments and Clearinghouse Report

MOTION: Cathy Winters moved, seconded by Michael Walsh, to affirm the Board has reviewed the public comments received concerning SS 137-20 (Phar 1, 6, 7, 8, 12 and 13), relating to electronic track and trace pedigree

system, drug supply chain security, manufacturers, and distributors. Additionally, after considering the public comments received the Board approves SS 137-20 for implementation after consideration of all public comments and feedback. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Phar 5, 6, 7, 11, and 12, Relating to Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References and Technical Correction

MOTION: Cathy Winters moved, seconded by Michael Walsh, to authorize the Chairperson to approve the preliminary rule draft of Phar 5, 6, 7, 11, and 12, relating to name and address change, floor design, procedures for disciplinary proceedings, superseded references and technical correction, for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Phar 2, Relating to Endorsement Requirements for Pharmacists

Proposals for Emergency Rule

MOTION: Michael Walsh moved, seconded by John Weitekamp, to approve the Scope Statement for Phar 2, relating to endorsement requirements for pharmacists, for implementation. Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Michael Walsh, to authorize the Chairperson to approve the emergency rule for Phar 2, relating to endorsement requirements for pharmacists, for emergency rule submission to the governor and publication in an official newspaper. Motion carried unanimously.

Phar 15, Relating to Re-Use of Personal Protective Equipment

Proposals for Emergency Rule

MOTION: Anthony Peterangelo moved, seconded by Cathy Winters, to authorize the Chairperson to approve the emergency rule for Phar 15, relating to re-use of personal protective equipment, for emergency rule submission to the governor and publication in an official newspaper. Motion carried unanimously.

Administrative Rules Reporting Requirement Under 227.29, Stats

Proposals for 2021 Report

MOTION: John Weitekamp moved, seconded by Michael Walsh, to designate Cathy Winters to serve as liaison to DSPS staff for drafting a report pursuant to Wis. Stat. s. 227.29 for submission in 2021, relating to administrative rules, and to authorize the Chairperson, or highest-ranking officer, or

longest serving member of the board, in order of succession, to approve the report for submission to the Joint Committee for Review of Administrative Rules. Motion carried unanimously.

VARIANCES

Review, Discussion and Consideration of All Current Variances

MOTION: John Weitekamp moved, seconded by Cathy Winters, to extend the existing variances regarding wholesale delivery to board-approved addresses, dispensing in locations that are not licensed pharmacies, and re-use of PPE for sterile compounding to 90 days from the current expiration date of January 1, 2021. The Board specifically finds that the requirements of § 450.02(3m) have been met. Motion carried unanimously.

Review, Discussion and Consideration of Any Proposed Variances

Pharmacy Society of Wisconsin Variance Request

MOTION: Cathy Winters moved, seconded by Michael Walsh, to delegate the authority to approve the final version of the draft variance regarding pharmacists' delegation of administration of vaccines to the Variance Liaison. The Board specifically finds that the requirements of § 450.02(3m) have been met. Motion carried unanimously.

SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS

MOTION: Michael Walsh moved, seconded by John Weitekamp, to designate Cathy Winters to attend the Virtual NABP Interactive Member Forum on January 27, 2021. Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Michael Walsh, to 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.). Philip Trapskin, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Tiffany O'Hagan-yes; Anthony Peterangelo-yes; Philip Trapskin-yes; Michael Walsh-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:53 p.m.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Case Closings

MOTION: Michael Walsh moved, seconded by John Weitekamp, to close the following DLSC Cases for the reasons outlined below:

1. 18 PHM 109 – D.R.K., S.R., & H.H. – No Violation
2. 19 PHM 024 – P.N.S.P. – Insufficient Evidence
3. 19 PHM 137 – I.P.C. – Prosecutorial Discretion (P2)
4. 19 PHM 159 – V.R.D. – Prosecutorial Discretion (P1)
5. 19 PHM 244 – A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., A.H.I.I., P.D.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.L.S.I., P.V.S.I., & P.V.S.I. – Prosecutorial Discretion (P2)
6. 19 PHM 284 & 20 PHM 009 – B.H.P. – No Violation
7. 20 PHM 014 – P.C. – Prosecutorial Discretion (P2)

Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adopt/reject the Findings of Fact, Conclusions of Laws and Orders in the matter of the following cases.

1. 18 PHM 109 – Thomas F. Shaw, R.Ph.
2. 19 PHM 020 – Marc C. Ertz, R.Ph.
3. 19 PHM 073 – Mark Kobin, R.Ph.
4. 19 PHM 169 – Paul A. Blazkovec, R.Ph.
5. 19 PHM 284 & 20 PHM 009 – Kari L. Seelig, R.Ph.
6. 20 PHM 115 – Kelly L. Fausek, R.Ph.

Motion carried unanimously.

Monitoring Matters

Brad Spross, R.Ph. – Requesting Reduction in Drug and Alcohol Screens

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to grant the request of Brad Spross, R.Ph., for a reduction in the frequency of drug and alcohol screens to twenty-four (24) per year, plus one annual hair test. Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 1:56 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

ADJOURNMENT

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:04 p.m.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
JANUARY 13, 2021

PRESENT: Tiffany O'Hagan, Anthony Peterangelo, Philip Trapskin, Michael Walsh, Shana Weiss, John Weitekamp, Cathy Winters

STAFF: Christine Poleski, Executive Director; Jameson Whitney, Legal Counsel; Kimberly Wood, Program Assistant Supervisor-Advanced; Megan Glaeser, Bureau Assistant; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 2:00 p.m. A quorum was confirmed with seven (7) members present.

ADOPTION OF AGENDA

MOTION: Cathy Winters moved, seconded by Michael Walsh, to adopt the Agenda as published. Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters moved, seconded by John Weitekamp, to 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.). Philip Trapskin, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Tiffany O'Hagan-yes, Anthony Peterangelo-yes; Philip Trapskin-yes; Michael Walsh-yes; Shana Weiss-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 2:09 p.m.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Proposed Stipulation and Interim Order

Deliberated.

RECONVENE TO OPEN SESSION

MOTION: Michael Walsh moved, seconded by John Weitekamp, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 2:33 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

20 PHM 179– Steven Brandenburg, R.Ph.

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Interim Order in the matter of disciplinary proceedings against Steven Brandenburg, R.Ph., DLSC Case Number 20 PHM 179. Motion carried unanimously.

ADJOURNMENT

MOTION: Cathy Winters moved, seconded by Michael Walsh, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:40 p.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:
Kimberly Wood, Program Assistant Supervisor-Adv.	12/29/2020
	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:

All Boards

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
	☐ Yes ☒ No	Annual Policy Review

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 ☒ No	N/A

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

Please be advised of the following Annual Policy Review items:

1. Attendance/Quorum: Thank you for your service and for your commitment to meeting attendance. If you cannot attend a meeting or if you have scheduling conflicts impacting your attendance, please let us know ASAP. Timely notification is appreciated as quorum is required for our Boards, Sections and Councils to meet pursuant to Open Meetings Law.
2. Walking Quorum: Please refrain from discussing Board/Section/Council business with other members outside of legally noticed meetings so to avoid walking quorum issues pursuant to Open Meetings Law.
3. Agenda Deadlines: Please communicate agenda topics to your Executive Director before the agenda submission deadline which is 8 business days prior to a meeting.
4. Travel Voucher and Per Diem Submissions: Please submit all Per Diem and Reimbursement claims to DSPS within 30 days of the close of each month in which expenses are incurred.
5. Lodging Accommodations/Hotel Cancellation Policy: Lodging accommodations are available to eligible members. Standard eligibility: member must leave home before 6:00 a.m. to attend a meeting by the indicated start time.
   - If a member cannot attend a meeting it is their responsibility to cancel their reservation within the applicable cancellation timeframe. If a meeting is changed to occur remotely or is cancelled or rescheduled DSPS staff will cancel or modify reservations as appropriate.
6. Inclement Weather Policy: In the event of inclement weather the agency may change a meeting from an in-person venue to one that is executed remotely.

11) Authorization

Kimberly Wood *12/29/2020*

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 & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Kimberly Wood, Program Assistant Supervisor-Adv.	1/5/2021
	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?
1/**28**/2021	☒ Yes ☐ No	Administrative Matters 1) Election of Officers 2) Appointment of Liaisons and Alternates 3) Delegation of Authorities

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 ☒ No	N/A

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

1) The Board should conduct Election Officers: Chairperson, Vice Chairperson & Secretary
2) The newly elected Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate
3) The Board should review and then consider its existing delegated authorities and any proposals for modification of delegations.
    a. Credentialing Delegations (Questions: Sarah Norberg)
    b. Monitoring Delegations (Questions: Amy Mayo)
    c. Pre-Screening Delegations (Questions: Gretchen Mrozinski)

11) Authorization

Kimberly Wood *1/4/2021*

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.

PHARMACY EXAMINING BOARD

2020 Elections and Liaison Appointments

2020 ELECTION RESULTS	
Chairperson	Philip Trapskin
Vice Chairperson	Cathy Winters
Secretary	John Weitekamp

2020 LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Anthony Peterangelo, Tiffany O'Hagan, John Weitekamp
Office of Education and Examinations Liaison(s)	Cathy Winters *Alternate:* John Weitekamp
Monitoring Liaison(s)	Cathy Winters *Alternate*: Philip Trapskin
Professional Assistance Procedure (PAP) Liaison(s)	Philip Trapskin *Alternate*: Anthony Peterangelo
Travel Liaison	Chairperson *Alternate:* Vice Chairperson
Legislative Liaison(s)	Cathy Winters, Philip Trapskin, Tiffany O'Hagan, John Weitekamp
Pilot Program Liaison(s)	Philip Trapskin, Cathy Winters
Digest Liaison(s)	Cathy Winters *Alternate:* Philip Trapskin
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	Anthony Peterangelo

	Alternate: John Weitekamp
2020 SCREENING PANEL APPOINTMENTS	
January – December 2020	John Weitekamp, Tiffany O'Hagan, Michael Walsh *Alternate:* Cathy Winters
2020 COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Cathy Winters, Philip Trapskin, John Weitekamp

Delegation Motions

Document Signature Delegations

MOTION: Cathy Winters moved, seconded by John Weitekamp, to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Michael Walsh, in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Michael Walsh moved, seconded by Cathy Winters, that in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

Delegation to Chief Legal Counsel Due to of Loss of Quorum

MOTION: Cathy Winters moved, seconded by Michael Walsh, to delegate authority to the Chairperson (or, in the absence of the Chairperson, the highest-

ranking officer or longest serving board member in that succession), to delegate the review of disciplinary cases to the Department's Chief Legal Counsel due to lack of/loss of quorum. Motion carried unanimously.

Monitoring Delegations

MOTION: John Weitekamp moved, seconded by Cathy Winters, to adopt the "Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor" as presented in the January 30, 2020 agenda materials. Motion carried unanimously.

Credentialing Authority Delegations

Delegation of Authority to Credentialing Liaison (Generic)

MOTION: Cathy Winters moved, seconded by Michael Walsh, to delegate authority to the Credentialing Liaison(s) to serve as a liaison between DSPS and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them. Motion carried unanimously.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate credentialing authority to DSPS to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION: Anthony Peterangelo moved, seconded by Michael Walsh, that the Department's Attorney Supervisors, DLSC Administrator, or their designee are authorized to serve as the Board's designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential. Motion carried unanimously.

Delegation of Prescreening Authority to DLSC Staff

MOTION: John Weitekamp moved, seconded by Cathy Winters, 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. Motion carried unanimously.

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to DLSC staff the following prescreening authority: to prescreen complaints prior to a meeting of the screening panel to open any case that if the allegations, if taken as true, demonstrate a violation of law; to request additional information if needed; to close at prescreening any case that demonstrates that no violation took place; and 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. Motion carried unanimously.

Pre-Screen Delegation

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to delegate pre-screening decision making authority to the DSPS screening attorney for opening cases as outlined below:

1. OWIs of 3 or more that occurred in the last 5 years.
2. Reciprocal discipline cases.
3. Impairment and/or diversion at work that includes a positive drug/alcohol test or admission by respondent.
4. Conviction of a misdemeanor or felony that the attorney believes is substantially related and is not otherwise excluded from consideration via Wis. Stat. ch. 111
5. No response from the respondent after intake requested a response (case would be opened for the failure to respond issue as well as the merits).

Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate pre-screening decision making authority to the DSPS screening attorney for closing cases as outlined below:

1. One OWI that is non-work related and if AODA assessment completed, assessment does not indicate dependency.
2. Complaints that even if allegations are true, do not amount to a violation of law or rules.

Motion carried unanimously.

Voluntary Surrenders

MOTION: Michael Walsh moved, seconded by Cathy Winters, to delegate authority to the assigned case advisor to accept or refuse a request for voluntary

surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter. Motion carried unanimously.

Education, Continuing Education and/or Examination Delegation(s)

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate authority to the Education, Continuing Education and/or Examination Liaison(s) to address all issues related to education, continuing education, and examinations. Motion carried unanimously.

Pilot Program Delegation

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate authority to the Pilot Program Liaison to address all issues related to pilot program matters. Motion carried unanimously.

Authorization for DSPS to Provide Board Member Contact Information to National Regulatory Related Bodies

MOTION: Cathy Winters moved, seconded by Michael Walsh, to authorize DSPS staff to provide national regulatory related bodies with all Board member contact information that DSPS retains on file. Motion carried unanimously.

Optional Renewal Notice Insert Delegation

MOTION: Cathy Winters moved, seconded by John Weitekamp to designate the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to provide a brief statement or link relating to board-related business within the license renewal notice at the Board's or Board designee's request. Motion carried unanimously.

Rules Committee Delegation

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to grant the Rules Committee the ability to address all rulemaking as related to drafting and making recommendations to the full Board. Motion carried unanimously.

Legislative Liaison Delegation

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate authority to the Legislative Liaisons to speak on behalf of the Board regarding legislative matters. Motion carried unanimously.

Travel Delegation

MOTION: Cathy Winters moved, seconded by Michael Walsh, to delegate authority to the Travel Liaison to approve any board member travel. Motion carried unanimously.

PROPOSED 2021 CREDENTIALING DELEGATION MOTIONS

Delegation of Authority to Credentialing Liaison

MOTION: to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION: to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review.

Delegation of Authority for Predetermination Reviews

MOTION: to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f).

Delegation of Authority for Conviction Reviews

MOTION: to delegate authority to the Department Attorneys to review and approve applications with convictions which are not substantially related to the practice of pharmacy.

Or, alternatively,

MOTION: to delegate authority to Department Paralegals to review and approve applications with [optional: up to X] municipal/ordinance violations which are not substantially related to the practice of pharmacy.

MOTION: to delegate authority to Department Attorneys to review and approve applications with [optional: up to X] municipal/ordinance violations and misdemeanors [optional: each more than X years old and] which are not substantially related to the practice of pharmacy.

Delegation to DSPS When Applicant's History Has Been Previously Reviewed

MOTION: to delegate authority to Department staff to approve applications where criminal background checks have been approved for a previous pharmacy credential and there is no new conviction record.

Delegation of Authority for Reciprocity/Endorsement Reviews

MOTION: to delegate authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the applicant met requirements comparable to those that existed in this state at the time the person became licensed in the other state.

Delegated Authority for Application Denial Reviews

MOTION: to delegate authority to the Department's Attorney Supervisors to serve as the Board's designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential.

Roles and Authorities Delegated for Monitoring

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors ("Monitor") to enforce Board/Section orders as explained below.

~~Current~~ Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board/Section:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor ("Monitor") will draft an order and sign on behalf of the Liaison.

2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/disciplinary/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.

5. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing/disciplinary/remedial education.

6. Grant a maximum of one extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.

7. Grant a maximum of one extension, if warranted and requested in writing by Respondent, to complete a Board/Section-ordered evaluation or exam.

~~7.~~8. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order without deviation. The Monitor will draft an order and obtain ~~the signature or~~ written authorization from the Liaison to sign on their behalf.

~~8.~~9. Grant or deny a request to appear before the Board/Section in closed session.

~~9.~~10. ~~Board Monitoring~~ The Liaison may determine whether Respondent's petition is eligible for consideration by the full Board/Section.

~~10.~~11. *(Except Pharmacy and Medical)* Accept Respondent's written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review.

~~11.~~12. ~~*(Except Pharmacy)*~~ Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison. Orders that do not start at 49 screens will still follow the same standard schedule.

a. Initial ~~Year 1~~: 49 screens (including 1 hair test, if required by original order)
b. 1st Reduction ~~Year 2~~: 36 screens (plus 1 hair test, if required by original order)
c. 2nd Reduction ~~Year 3~~: 28 screens plus 1 hair test
~~d. Year 4: 28 screens plus 1 hair test~~

~~e. Year 5: 14 screens plus 1 hair test~~
d. 3rd Reduction: 14 screens plus 1 hair test

~~12.~~13. *(Dentistry only)* Ability to approve or deny all requests from a respondent.

~~13.~~14. ~~*(Except Nursing) – Board Monitoring*~~ The Liaison may approve or deny Respondent's request to be excused from drug and alcohol testing for work, travel, etc.

~~Current~~ Authorities Delegated to the Department Monitor

The Monitor may take the following actions on behalf of the Board/Section, draft an order and sign:

1. Grant full reinstatement of licensure if education ~~CE~~ is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2. Suspend the license if Respondent has not completed Board/Section-ordered education ~~CE~~ and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof of completion and/or payment have been received.

3. Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.

Authorities Delegated to Board Legal Counsel

Board Legal Counsel may take the following actions on behalf of the Board/Section:

1. Sign Monitoring orders that result from Board/Section meetings on behalf of the Board/Section Chair.

Pharmacy Section Pre-screening Delegation

2020:

MOTION: Michael Walsh moved, seconded by Anthony Peterangelo, to delegate to DLSC staff the following prescreening authority: to prescreen complaints prior to a meeting of the screening panel to open any case that if the allegations, if taken as true, demonstrate a violation of law; to request additional information if needed; to close at prescreening any case that demonstrates that no violation took place; and 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. Motion carried unanimously.

Pre-Screen Delegation

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to delegate pre-screening decision making authority to the DLSC screening attorney for opening cases as outlined below:

1. OWIs of 3 or more that occurred in the last 5 years.
2. Reciprocal discipline cases.
3. Impairment and/or diversion at work that includes a positive drug/alcohol test or admission by respondent.
4. Conviction of a misdemeanor or felony that the attorney believes is substantially related and is not otherwise excluded from consideration via Wis. Stat. ch. 111
5. No response from the respondent after intake requested a response (case would be opened for the failure to respond issue as well as the merits).

Motion carried unanimously.

MOTION: Cathy Winters moved, seconded by Anthony Peterangelo, to delegate pre-screening decision making authority to the DLSC screening attorney for closing cases as outlined below:

1. One OWI that is non-work related and if AODA assessment completed, assessment does not indicate dependency.
2. Complaints that even if allegations are true, do not amount to a violation of law or rules.

Motion carried unanimously.

DLSC is requesting that the first motion be eliminated, that the second and third motions be made, and that the following be added to the third motion:

> 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.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Kassandra Walbrun, Administrative Rules Coordinator	2) Date when request submitted: 1/22/2021 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: 1/28/2021	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Legislative and Policy Matters – Discussion and Consideration 1. Wisconsin Assembly Bill AB 4 2. Wisconsin Senate Bill SB 3
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes ☒ No	9) Name of Case Advisor(s), if required:

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

1. AB 4 - Relating to: pharmacy technicians and pharmacy students administering vaccines. (Covid related)

2. SB 3 - Relating to: pharmacy benefit managers, prescription drug benefits, and granting rule-making authority.

11) Authorization

Kassandra Walbrun	*1/22/2021*
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
2021 - 2022 LEGISLATURE

LRB-1574/1
KP:cjs

2021 ASSEMBLY BILL 4

January 19, 2021 - Introduced by Representatives SANFELIPPO, CABRAL-GUEVARA, DITTRICH, DUCHOW, MOSES, MURPHY and ROZAR, cosponsored by Senator KOOYENGA. Referred to Committee on Health.

AN ACT ***to renumber and amend*** 450.035 (2g); ***to amend*** 450.03 (1) (f), 450.03 (1) (g), 450.03 (1) (i), 450.035 (2i) (a), 450.035 (2i) (b), 450.035 (2m), 450.035 (2t) (intro.), 450.035 (2t) (a), 450.035 (3) and 450.035 (4); and ***to create*** 450.035 (2h) of the statutes; **relating to:** pharmacy technicians and pharmacy students administering vaccines.

Analysis by the Legislative Reference Bureau

This bill authorizes pharmacy technicians to administer vaccines. Under current law, a pharmacy technician is a person who provides services as directed, supervised, and inspected by a pharmacist. To administer vaccines under the bill, a pharmacy technician must complete two hours of training and must be supervised by a pharmacist.

Also, under the bill, any health care provider who is authorized to administer vaccines may supervise pharmacy students who have completed two years of pharmacy school while they administer a vaccine. Current law requires pharmacy students who have completed two years of pharmacy school to be supervised by a pharmacist while administering a vaccine.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.03 (1) (f) of the statutes is amended to read:

450.03 **(1)** (f) A person who has successfully completed his or her second year in, and is enrolled at, an accredited school of pharmacy and whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and administering vaccines under the direct supervision of a health care provider authorized to administer vaccines.

SECTION 2. 450.03 (1) (g) of the statutes is amended to read:

450.03 **(1)** (g) A person who has applied for a license under s. 450.05 whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and administering vaccines under the direct supervision of a health care provider authorized to administer vaccines during the period before which the board takes final action on the person's application.

SECTION 3. 450.03 (1) (i) of the statutes is amended to read:

450.03 **(1)** (i) Any person who is providing services, including administering vaccines, as directed, supervised, and inspected by a pharmacist who has the power to direct, decide, and oversee the implementation of the services rendered, subject to any rules promulgated by the board and subject to s. 450.035 (2m).

SECTION 4. 450.035 (2g) of the statutes is renumbered 450.035 (2g) (a) and amended to read:

450.035 **(2g)** (a) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine unless he or she acts under the direct supervision of a ~~pharmacist~~ health care provider authorized to administer vaccines and he or she ~~and the supervising pharmacist have~~ has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in vaccination storage, protocols, administration

technique, emergency procedures, and record keeping ~~and~~. If the supervising health care provider under this paragraph is a pharmacist, a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine unless the supervising pharmacist has successfully completed a course of study and training specified in sub. (2) and has satisfied the requirements specified in sub. (2t).

(b) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine under this subsection to a person who is under the age of 6.

SECTION 5. 450.035 (2h) of the statutes is created to read:

450.035 **(2h)** (a) A person engaged in the practice of pharmacy under s. 450.03 (1) (i) may not administer a vaccine unless all of the following are satisfied:

1. The person has successfully completed at least 2 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in hands–on injection technique and the recognition and treatment of emergency reactions to vaccines.

2. The person acts under the direct supervision of a pharmacist and the supervising pharmacist has successfully completed a course of study and training specified in sub. (2) and has satisfied the requirements specified in sub. (2t).

3. The person holds a current certification in basic life support or cardiopulmonary resuscitation.

4. The person holds a certified pharmacy technician certification from either the Pharmacy Technician Certification Board, or its successor organization, or the National Healthcareer Association, or its successor organization.

(b) A person engaged in the practice of pharmacy under s. 450.03 (1) (i) may not administer a vaccine under this subsection to a person who is under the age of 6.

SECTION 6. 450.035 (2i) (a) of the statutes is amended to read:

450.035 **(2i)** (a) Subject to subs. (2) ~~and,~~ (2g), and (2h), a pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or,~~ (g), or (i) may administer without a prescription order any vaccine listed in the current immunization schedules recommended by the federal advisory committee on immunization practices and published by the federal centers for disease control and prevention.

SECTION 7. 450.035 (2i) (b) of the statutes is amended to read:

450.035 **(2i)** (b) Subject to subs. (2) ~~and,~~ (2g), and (2h), a pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or,~~ (g), or (i) may initiate and administer any vaccine not listed in the current immunization schedules recommended by the federal advisory committee on immunization practices and published by the federal centers for disease control and prevention if the vaccine is administered pursuant to a prescription order, vaccination protocol, or standing order**.**

SECTION 8. 450.035 (2m) of the statutes is amended to read:

450.035 **(2m)** Except as provided in sub. (1t) ~~or,~~ (2g), or (2h), a pharmacist may not delegate to any person any administration of a prescribed drug product or device or vaccine under sub. (1r) or (2).

SECTION 9. 450.035 (2t) (intro.) of the statutes is amended to read:

450.035 **(2t)** (intro.) A pharmacist may not administer a vaccine under sub. (2) or supervise a person administering a vaccine under sub. (2g) or (2h) unless the pharmacist satisfies each of the following:

SECTION 10. 450.035 (2t) (a) of the statutes is amended to read:

450.035 **(2t)** (a) The pharmacist has in effect liability insurance that covers the pharmacist and a person who administers a vaccine under sub. (2g) or (2h) against loss, expense and liability resulting from errors, omissions or neglect in the administration of vaccines in an amount that is not less than $1,000,000 for each occurrence and $2,000,000 for all occurrences in any one policy year.

SECTION 11. 450.035 (3) of the statutes is amended to read:

450.035 **(3)** A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or,~~ (g), or (i) who successfully completes a course of study and training specified in sub. (1r), (1t), (2), ~~or~~ (2g), or (2h), or holds a certification under sub. (2h), shall maintain proof of completion or holding the certification and, upon request, provide copies of such proof to the department or the board.

SECTION 12. 450.035 (4) of the statutes is amended to read:

450.035 **(4)** A pharmacist or person engaged in the practice of pharmacy under s. 450.03 (1) (f) ~~or,~~ (g), or (i) who administers a vaccine to a person under this section shall update, or cause a pharmacy to update, the Wisconsin Immunization Registry established by the department of health services within 7 days of administering the vaccine.

(END)

State of Wisconsin
2021 - 2022 LEGISLATURE

LRB-1116/1
TJD:cdc

2021 SENATE BILL 3

January 15, 2021 - Introduced by Senators FELZKOWSKI, ROTH, ERPENBACH, BERNIER, COWLES, DARLING, FEYEN, MARKLEIN, RINGHAND, SMITH, WANGGAARD, WIRCH, BALLWEG, JACQUE, LARSON, NASS and L. TAYLOR, cosponsored by Representatives SCHRAA, DITTRICH, DUCHOW, HORLACHER, KRUG, RAMTHUN, NOVAK, J. RODRIGUEZ, SPIROS, TAUCHEN, TITTL, ARMSTRONG, BROOKS, CABRAL-GUEVARA, CALLAHAN, EDMING, GUNDRUM, JAMES, KITCHENS, KUGLITSCH, LOUDENBECK, MAGNAFICI, MOSES, MURSAU, PETERSEN, PLUMER, ROZAR, SKOWRONSKI, SNYDER, SORTWELL, SWEARINGEN, THIESFELDT, TRANEL, VORPAGEL and ZIMMERMAN. Referred to Committee on Health.

AN ACT ***to repeal*** 40.51 (15m) and 632.86; ***to renumber*** 632.865 (1) (a); ***to renumber and amend*** 632.865 (1) (c) and 633.01 (4); ***to amend*** 40.51 (8), 40.51 (8m), 66.0137 (4), 120.13 (2) (g), 185.983 (1) (intro.), 450.135 (9), 601.31 (1) (w), 601.46 (3) (b), 609.83, 616.09 (1) (a) 2., chapter 633 (title), 633.01 (1) (intro.) and (c), 633.01 (3), 633.01 (5), 633.04 (intro.), 633.05, 633.06, 633.07, 633.09 (4) (b) 2. and 3., 633.11, 633.12 (1) (intro.), (b) and (c), 633.13 (1) and (3), 633.14 (2) (intro.) and (c) 1. and 3. and (3), 633.15 (1) (a), (1m), and (2) (a) 1., 2. and 3. and (b) 1., 633.15 (2) (b) 2. and 633.16; and ***to create*** 450.13 (5m), 450.135 (8m), 632.861, 632.865 (1) (ae) and (ak), 632.865 (1) (c) 2., 632.865 (1) (dm), 632.865 (3) to (7), 633.01 (2r), 633.01 (4g), 633.01 (4r), 633.01 (6), 633.15 (2) (b) 1. d. and 633.15 (2) (f) of the statutes; **relating to:** pharmacy benefit managers, prescription drug benefits, and granting rule-making authority.

Analysis by the Legislative Reference Bureau

This bill generally requires pharmacy benefit managers to be licensed with the commissioner of insurance or to have an employee benefit plan administrator license

under current law. The bill also establishes certain requirements on pharmacy benefit managers and certain health plans regarding their interactions with pharmacies and pharmacists. Under the bill, a pharmacy benefit manager is an entity that contracts to administer or manage prescription drug benefits on behalf of an insurer, a cooperative, or another entity that provides prescription drug benefits to Wisconsin residents.

Licensure of pharmacy benefit managers

The bill requires a pharmacy benefit manager to be licensed either as a pharmacy benefit manager or as an employee benefit plan administrator, which is an existing license under current law, in order to perform the activities of a pharmacy benefit manager. The bill specifies that an entity that is both an employee benefit plan administrator and a pharmacy benefit manager need only have a single license as an administrator. To obtain a license, the pharmacy benefit manager must pay the applicable fee; supply a bond; provide its federal employer identification number; and show to the commissioner that the pharmacy benefit manager intends to act in good faith in compliance with applicable laws, rules, and commissioner's orders through certain competent and trustworthy individuals, to designate an individual to directly administer the prescription drug benefits, and, if not organized in Wisconsin, to agree to be subject to the jurisdiction of the commissioner and Wisconsin courts. Under the bill, pharmacy benefit manager licenses may be limited, suspended, or revoked for the same reasons as for employee benefit plan administrator licenses, which include that the pharmacy benefit manager is unqualified; repeatedly or knowingly violates laws, rules, or commissioner's orders; endangers enrollees or the public; or has inadequate financial resources. After a pharmacy benefit manager's license is ordered suspended or revoked, the commissioner may allow the pharmacy benefit manager to continue to provide services for the purpose of providing continuity of care to existing enrollees. In addition to powers the commissioner has generally to implement and enforce insurance–related laws, the bill allows the commissioner to examine, audit, or accept an audit of a pharmacy benefit manager in the same manner as employee benefit plan administrators and insurers and to promulgate any rules to implement licensure of pharmacy benefit managers.

Pharmacy benefit manager regulation

Unless federal law requires otherwise, a pharmacy benefit manager is prohibited in the bill from retroactively denying a pharmacist's or pharmacy's claim unless the original claim was fraudulent, the payment of the original claim was incorrect, the pharmacy services were not rendered by the pharmacist or pharmacy, the pharmacist or pharmacy violated state or federal law, or the reduction is permitted by contract and is related to a quality program. The bill limits recovery for an incorrect payment to the amount that exceeds the allowable claim. The bill requires every pharmacy benefit manager to submit annual transparency reports containing information specified in the bill to the commissioner. The bill sets requirements on a pharmacy benefit manager; insurer; defined network plan, such as a health maintenance organization; or a self–insured governmental health plan that is conducting an audit of a pharmacist or pharmacy.

Certain health plans, or pharmacy benefit managers on behalf of health plans, may require a pharmacy to fulfill certification or accreditation requirements in order to participate in the plan's network of providers. The bill requires a pharmacy benefit manager or a representative of a pharmacy benefit manager to provide to a pharmacy, within 30 days of receipt of a written request from the pharmacy, written notice of the certification or accreditation requirements as a determinant of network participation. The bill prohibits a pharmacy benefit manager or representative from changing its accreditation requirements more frequently than once every 12 months.

Current law requires pharmacy benefit managers to agree in their contracts to make certain disclosures regarding prescription drug reimbursement, including updating maximum allowable cost pricing information for prescribed drugs or devices at least every seven business days, reimbursing pharmacies or pharmacists subject to the updated maximum allowable cost pricing, and modifying information in the maximum allowable cost information in a timely fashion. Pharmacy benefit managers currently must also include in each contract with a pharmacy a process to appeal, investigate, and resolve pricing disputes in accordance with the specifics in current law. These current law requirements are unchanged by the bill.

Disclosures to consumers; cost-sharing limitation

Under the bill, a health insurance policy or a governmental self–insured health plan may not, and a policy or plan must ensure that a pharmacy benefit manager does not, restrict a pharmacy from or penalize a pharmacy for informing an enrollee under the policy or plan of any differential between the out–of–pocket cost of a drug to the enrollee under the policy or plan and the cost an individual would pay for the drug without using insurance. Health insurance policies are referred to in the bill as disability insurance policies. The bill prohibits a policy, plan, or pharmacy benefit manager from requiring an enrollee under the policy or plan to pay more for a covered drug than either the cost–sharing amount for the prescription drug under the policy or plan or the amount the enrollee would pay for the drug without using insurance, whichever amount is lower.

The bill requires pharmacies to post a sign describing the pharmacist's ability to substitute a less expensive drug product equivalent or interchangeable biological product for the prescribed drug or biological product unless the consumer or the prescribing practitioner indicates otherwise. Under current law, a pharmacist is required to dispense either the prescribed drug or biological product or, if lower in price, a drug product equivalent or interchangeable biological product. The pharmacist is currently required to inform the consumer of the options available in dispensing the prescription. The bill requires each pharmacy to have available for the public a listing of the retail price, updated monthly or more often, of the 100 most commonly prescribed prescription drugs available for purchase at the pharmacy. The bill also requires pharmacies to make available for the public information on how to access a list, created by the Pharmacy Examining Board, of the 100 most commonly prescribed generic drugs with the corresponding brand name, and the federal Food and Drug Administration's list of currently approved interchangeable biological products, which the Pharmacy Examining Board currently has to provide a link to on its Internet site.

Drug substitution

The bill requires a health insurance policy, governmental self–insured health plan, or pharmacy benefit manager to provide advanced written notice to an enrollee of a formulary change that either removes a prescription drug from the formulary or reassigns a prescription drug to a higher benefit tier. A higher benefit tier is a tier with a higher deductible, copayment, or coinsurance than the tier the prescription drug had been assigned. The advanced notice required by the bill must be provided no fewer than 30 days before the expected formulary change, must include information on the procedure for the enrollee to request an exception to the formulary change, and need only be provided to those enrollees who are using the drug at the time the notification must be sent. A policy, plan, or pharmacy benefit manager is not required to provide advanced written notice if the prescription drug is no longer approved by the federal Food and Drug Administration; is the subject of a notice, guidance, warning, announcement, or other statement from the FDA relating to concerns about the safety of the drug; or is approved by the FDA for use without a prescription. A policy, plan, or pharmacy benefit manager is also not required to provide advanced written notice for the removal or reassignment of a prescription drug if the policy, plan, or pharmacy benefit manager adds to the formulary at the same or a lower benefit tier a generic prescription drug that is approved by the FDA for use as an alternative to the prescription drug or a prescription drug in the same pharmacologic class or with the same mechanism of action. A lower benefit tier has a lower deductible, copayment, or coinsurance than the prescription drug's current benefit tier.

The bill requires a pharmacist or pharmacy to notify an enrollee in a policy or plan if a prescription drug for which an enrollee is filling or refilling a prescription is removed from the formulary and the policy or plan or a pharmacy benefit manager acting on behalf of a policy or plan adds to the formulary at the same or a lower cost–sharing tier a generic prescription drug or a prescription drug in the same pharmacologic class or with the same mechanism of action. If an enrollee has had an adverse reaction to the prescription drug that is being substituted for an originally prescribed drug, the bill allows the pharmacist or pharmacy to extend the prescription order for the originally prescribed drug to fill one 30–day supply of the originally prescribed drug for the cost–sharing amount that applies to the prescription drug at the time of the substitution.

This proposal may contain a health insurance mandate requiring a social and financial impact report under s. 601.423, stats.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 40.51 (8) of the statutes is amended to read:

40.51 **(8)** Every health care coverage plan offered by the state under sub. (6) shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.729, 632.746 (1) to (8) and (10), 632.747, 632.748, 632.798, 632.83, 632.835, 632.85, 632.853, 632.855, 632.861, 632.867, 632.87 (3) to (6), 632.885, 632.89, 632.895 (5m) and (8) to (17), and 632.896.

SECTION 2. 40.51 (8m) of the statutes is amended to read:

40.51 **(8m)** Every health care coverage plan offered by the group insurance board under sub. (7) shall comply with ss. 631.95, 632.729, 632.746 (1) to (8) and (10), 632.747, 632.748, 632.798, 632.83, 632.835, 632.85, 632.853, 632.855, 632.861, 632.867, 632.885, 632.89, and 632.895 (11) to (17).

SECTION 3. 40.51 (15m) of the statutes is repealed.

SECTION 4. 66.0137 (4) of the statutes is amended to read:

66.0137 **(4)** SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or a village provides health care benefits under its home rule power, or if a town provides health care benefits, to its officers and employees on a self–insured basis, the self–insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.729, 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.798, 632.85, 632.853, 632.855, 632.861, 632.867, 632.87 (4) to (6), 632.885, 632.89, 632.895 (9) to (17), 632.896, and 767.513 (4).

SECTION 5. 120.13 (2) (g) of the statutes is amended to read:

120.13 **(2)** (g) Every self–insured plan under par. (b) shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.729, 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.798, 632.85, 632.853, 632.855, 632.861, 632.867, 632.87 (4) to (6), 632.885, 632.89, 632.895 (9) to (17), 632.896, and 767.513 (4).

SECTION 6. 185.983 (1) (intro.) of the statutes is amended to read:

185.983 **(1)** (intro.) Every voluntary nonprofit health care plan operated by a cooperative association organized under s. 185.981 shall be exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41, 601.42, 601.43, 601.44, 601.45, 611.26, 611.67, 619.04, 623.11, 623.12, 628.34 (10), 631.17, 631.89, 631.93, 631.95, 632.72 (2), 632.729, 632.745 to 632.749, 632.775, 632.79, 632.795, 632.798, 632.85, 632.853, 632.855, 632.861, 632.867, 632.87 (2) to (6), 632.885, 632.89, 632.895 (5) and (8) to (17), 632.896, and 632.897 (10) and chs. 609, 620, 630, 635, 645, and 646, but the sponsoring association shall:

SECTION 7. 450.13 (5m) of the statutes is created to read:

450.13 **(5m)** DISCLOSURES TO CONSUMERS. (a) Each pharmacy shall post in a prominent place at or near the place where prescriptions are dispensed a sign that clearly describes a pharmacist's ability under this state's law to substitute a less expensive drug product equivalent under sub. (1s) unless the consumer or the prescribing practitioner has indicated otherwise under sub. (2).

(b) The pharmacy examining board shall create a list of the 100 most commonly prescribed generic drug product equivalents, including the generic and brand names of the drugs, and provide, either directly or on the department's Internet site, the list to each pharmacy on an annual basis. Each pharmacy shall make available to the public information on how to access the list under this paragraph.

(c) Each pharmacy shall have available for the public a listing of the retail price, updated no less frequently than monthly, of the 100 most commonly prescribed prescription drugs, which includes brand name and generic equivalent drugs and biological products and interchangeable biological products, that are available for purchase at the pharmacy.

SECTION 8. 450.135 (8m) of the statutes is created to read:

450.135 **(8m)** DISCLOSURE TO CONSUMERS. (a) Each pharmacy shall post in a prominent place at or near the place where prescriptions are dispensed a sign that clearly describes a pharmacist's ability under this state's law to substitute a less expensive interchangeable biological product under sub. (2) unless the consumer or the prescribing practitioner has indicated otherwise under sub. (3).

SECTION 9. 450.135 (9) of the statutes is amended to read:

450.135 **(9)** LINKS TO BE MAINTAINED BY BOARD. The board shall maintain links on the department's Internet site to the federal food and drug administration's lists of all currently approved interchangeable biological products. Each pharmacy shall make available for the public information on how to access the federal food and drug administration's lists of all currently approved interchangeable biological products through the department's Internet site.

SECTION 10. 601.31 (1) (w) of the statutes is amended to read:

601.31 **(1)** (w) For initial issuance and for each annual renewal of a license as an administrator or pharmacy benefit manager under ch. 633, $100.

SECTION 11. 601.46 (3) (b) of the statutes is amended to read:

601.46 **(3)** (b) A general review of the insurance business in this state, including a report on emerging regulatory problems, developments and trends, including trends related to prescription drugs;

SECTION 12. 609.83 of the statutes is amended to read:

609.83 Coverage of drugs and devices. Limited service health organizations, preferred provider plans, and defined network plans are subject to ss. 632.853, 632.861, and 632.895 (16t) and (16v).

SECTION 13. 616.09 (1) (a) 2. of the statutes is amended to read:

616.09 **(1)** (a) 2. Plans authorized under s. 616.06 are subject to s. 610.21, 1977 stats., s. 610.55, 1977 stats., s. 610.57, 1977 stats., and ss. 628.34 to 628.39, 1977 stats., to chs. 600, 601, 620, 625, 627 and 645, to ss. 632.72, 632.755, ~~632.86~~ 632.861 and 632.87 and to this subchapter except s. 616.08.

SECTION 14. 632.86 of the statutes is repealed.

SECTION 15. 632.861 of the statutes is created to read:

632.861 Prescription drug charges. (1) DEFINITIONS. In this section:

(a) "Disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(b) "Enrollee" means an individual who is covered under a disability insurance policy or a self–insured health plan.

(c) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

(d) "Prescription drug" has the meaning given in s. 450.01 (20).

(e) "Prescription drug benefit" has the meaning given in s. 632.865 (1) (e).

(f) "Self–insured health plan" has the meaning given in s. 632.85 (1) (c).

(2) ALLOWING DISCLOSURES. (a) A disability insurance policy or self–insured health plan that provides a prescription drug benefit may not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the policy or plan from informing, or penalize such pharmacy for informing, an enrollee of any differential between the out–of–pocket cost to the enrollee under the policy or plan with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

(b) A disability insurance policy or self–insured health plan that provides a prescription drug benefit shall ensure that any pharmacy benefit manager that provides services under a contract with the policy or plan does not, with respect to

such policy or plan, restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the policy or plan from informing, or penalize such pharmacy for informing, an enrollee of any differential between the out–of–pocket cost to the enrollee under the policy or plan with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

(3) COST-SHARING LIMITATION. (a) A disability insurance policy or self–insured health plan that provides a prescription drug benefit or a pharmacy benefit manager that provides services under a contract with a policy or plan may not require an enrollee to pay at the point of sale for a covered prescription drug an amount that is greater than the lowest of all of the following amounts:

1. The cost–sharing amount for the prescription drug for the enrollee under the policy or plan.

2. The amount a person would pay for the prescription drug if the enrollee purchased the prescription drug at the dispensing pharmacy without using any health plan or health insurance coverage.

(4) DRUG SUBSTITUTION. (a) Except as provided in par. (b), a disability insurance policy that offers a prescription drug benefit, a self–insured health plan that offers a prescription drug benefit, or a pharmacy benefit manager acting on behalf of a disability insurance policy or self–insured health plan shall provide to an enrollee advanced written notice of a formulary change that removes a prescription drug from the formulary of the policy or plan or that reassigns a prescription drug to a benefit tier for the policy or plan that has a higher deductible, copayment, or coinsurance. The advanced written notice of a formulary change under this paragraph shall be provided no fewer than 30 days before the expected date of the removal or

reassignment and shall include information on the procedure for the enrollee to request an exception to the formulary change. The policy, plan, or pharmacy benefit manager is required to provide the advanced written notice under this paragraph only to those enrollees in the policy or plan who are using the drug at the time the notification must be sent according to available claims history.

(b) 1. A disability insurance policy, self–insured health plan, or pharmacy benefit manager is not required to provide advanced written notice under par. (a) if the prescription drug that is to be removed or reassigned is any of the following:

a. No longer approved by the federal food and drug administration.

b. The subject of a notice, guidance, warning, announcement, or other statement from the federal food and drug administration relating to concerns about the safety of the prescription drug.

c. Approved by the federal food and drug administration for use without a prescription.

2. A disability insurance policy, self–insured health plan, or pharmacy benefit manager is not required to provide advanced written notice under par. (a) if, for the prescription drug that is being removed from the formulary or reassigned to a benefit tier that has a higher deductible, copayment, or coinsurance, the policy, plan, or pharmacy benefit manager adds to the formulary a generic prescription drug that is approved by the federal food and drug administration for use as an alternative to the prescription drug or a prescription drug in the same pharmacologic class or with the same mechanism of action at any of the following benefit tiers:

a. The same benefit tier from which the prescription drug is being removed or reassigned.

b. A benefit tier that has a lower deductible, copayment, or coinsurance than the benefit tier from which the prescription drug is being removed or reassigned.

(c) A pharmacist or pharmacy shall notify an enrollee in a disability insurance policy or self–insured health plan if a prescription drug for which an enrollee is filling or refilling a prescription is removed from the formulary and the policy or plan or a pharmacy benefit manager acting on behalf of a policy or plan adds to the formulary a generic prescription drug that is approved by the federal food and drug administration for use as an alternative to the prescription drug or a prescription drug in the same pharmacologic class or with the same mechanism of action at any of the following benefit tiers:

1. The same benefit tier from which the prescription drug is being removed or reassigned.

2. A benefit tier that has a lower deductible, copayment, or coinsurance than the benefit tier from which the prescription drug is being removed or reassigned.

(d) If an enrollee has had an adverse reaction to the generic prescription drug or the prescription drug in the same pharmacologic class or with the same mechanism of action that is being substituted for an originally prescribed drug, the pharmacist or pharmacy may extend the prescription order for the originally prescribed drug to fill one 30–day supply of the originally prescribed drug for the cost–sharing amount that applies to the prescription drug at the time of the substitution.

SECTION 16. 632.865 (1) (a) of the statutes is renumbered 632.865 (1) (aw).

SECTION 17. 632.865 (1) (ae) and (ak) of the statutes are created to read:

632.865 **(1)** (ae) "Health benefit plan" has the meaning given in s. 632.745 (11).

(ak) "Health care provider" has the meaning given in s. 146.81 (1).

SECTION 18. 632.865 (1) (c) of the statutes is renumbered 632.865 (1) (c) (intro.) and amended to read:

632.865 **(1)** (c) (intro.) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription drug benefits on behalf of any of the following:

1. An insurer ~~or other.~~

3. Another entity that provides prescription drug benefits to residents of this state.

SECTION 19. 632.865 (1) (c) 2. of the statutes is created to read:

632.865 **(1)** (c) 2. A cooperative, as defined in s. 185.01 (2).

SECTION 20. 632.865 (1) (dm) of the statutes is created to read:

632.865 **(1)** (dm) "Prescription drug" has the meaning given in s. 450.01 (20).

SECTION 21. 632.865 (3) to (7) of the statutes are created to read:

632.865 **(3)** LICENSE REQUIRED. No person may perform any activities of a pharmacy benefit manager without being licensed by the commissioner as an administrator or pharmacy benefit manager under s. 633.14.

(4) ACCREDITATION FOR NETWORK PARTICIPATION. A pharmacy benefit manager or a representative of a pharmacy benefit manager shall provide to a pharmacy, within 30 days of receipt of a written request from the pharmacy, a written notice of any certification or accreditation requirements used by the pharmacy benefit manager or its representative as a determinant of network participation. A pharmacy benefit manager or a representative of a pharmacy benefit manager may change its accreditation requirements no more frequently than once every 12 months.

(5) RETROACTIVE CLAIM REDUCTION. Unless required otherwise by federal law, a pharmacy benefit manager may not retroactively deny or reduce a pharmacist's or pharmacy's claim after adjudication of the claim unless any of the following is true:

(a) The original claim was submitted fraudulently.

(b) The payment for the original claim was incorrect. Recovery for an incorrect payment under this paragraph is limited to the amount that exceeds the allowable claim.

(c) The pharmacy services were not rendered by the pharmacist or pharmacy.

(d) In making the claim or performing the service that is the basis for the claim, the pharmacist or pharmacy violated state or federal law.

(e) The reduction is permitted in a contract between a pharmacy and a pharmacy benefit manager and is related to a quality program.

(6) AUDITS OF PHARMACIES OR PHARMACISTS. (a) *Definitions.* In this subsection:

1. "Audit" means a review of the accounts and records of a pharmacy or pharmacist by or on behalf of an entity that finances or reimburses the cost of health care services or prescription drugs.

2. "Entity" means a defined network plan, as defined in s. 609.01 (1b), insurer, self–insured health plan, or pharmacy benefit manager or a person acting on behalf of a defined network plan, insurer, self–insured health plan, or pharmacy benefit manager.

3. "Self–insured health plan" has the meaning given in s. 632.85 (1) (c).

(b) *Procedures.* An entity conducting an on–site or desk audit of pharmacist or pharmacy records shall do all of the following:

1. If the audit is an audit on the premises of the pharmacist or pharmacy, notify the pharmacist or pharmacy in writing of the audit at least 2 weeks before conducting the audit.

2. Refrain from auditing a pharmacist or pharmacy within the first 5 business days of a month unless the pharmacist or pharmacy consents to an audit during that time.

3. If the audit involves clinical or professional judgment, conduct the audit by or in consultation with a pharmacist licensed in any state.

4. Limit the audit review to no more than 250 separate prescriptions. For purposes of this subdivision, a refill of a prescription is not a separate prescription.

5. Limit the audit review to claims submitted no more than 2 years before the date of the audit, unless required otherwise by state or federal law.

6. Allow the pharmacist or pharmacy to use authentic and verifiable records of a hospital, physician, or other health care provider to validate the pharmacist's or pharmacy's records relating to delivery of a prescription drug and use any valid prescription that complies with requirements of the pharmacy examining board to validate claims in connection with a prescription, refill of a prescription, or change in prescription.

7. Allow the pharmacy or pharmacist to document the delivery of a prescription drug or pharmacist services to an enrollee under a health benefit plan using either paper or electronic signature logs.

8. Before leaving the pharmacy after concluding the on–site portion of an audit, provide to the representative of the pharmacy or the pharmacist a complete list of the pharmacy records reviewed.

(c) *Results of audit.* An entity that has conducted an audit of a pharmacist or pharmacy shall do all of the following:

1. Deliver to the pharmacist or pharmacy a preliminary report of the audit within 60 days after the date the auditor departs from an on–site audit or the pharmacy or pharmacist submits paperwork for a desk audit. A preliminary report under this subdivision shall include claim–level information for any discrepancy reported, the estimated total amount of claims subject to recovery, and contact information for the entity or person that completed the audit so the pharmacist or pharmacy subject to the audit may review audit results, procedures, and discrepancies.

2. Allow a pharmacist or pharmacy that is the subject of an audit to provide documentation to address any discrepancy found in the audit within 30 days after the date the pharmacist or pharmacy receives the preliminary report.

3. Deliver to the pharmacist or pharmacy a final audit report, which may be delivered electronically, within 90 days of the date the pharmacist or pharmacy receives the preliminary report or the date of the final appeal of the audit, whichever is later. The final audit report under this subdivision shall include any response provided to the auditor by the pharmacy or pharmacist and consider and address the pharmacy's or pharmacist's response.

4. Refrain from assessing a recoupment or other penalty on a pharmacist or pharmacy until the appeal process is exhausted and the final report under subd. 3. is delivered to the pharmacist or pharmacy.

5. Refrain from accruing or charging interest between the time the notice of the audit is given under par. (b) 1. and the final report under subd. 3. has been delivered.

6. Exclude dispensing fees from calculations of overpayments.

7. Establish and follow a written appeals process that allows a pharmacy or pharmacist to appeal the final report of an audit and allow the pharmacy or pharmacist as part of the appeal process to arrange for, at the cost of the pharmacy or pharmacist, an independent audit.

8. Refrain from subjecting the pharmacy or pharmacist to a recoupment or recovery for a clerical or record–keeping error in a required document or record, including a typographical or computer error, unless the error resulted in an overpayment to the pharmacy or pharmacist.

(d) *Confidentiality of audit.* Information obtained in an audit under this subsection is confidential and may not be shared unless the information is required to be shared under state or federal law and except that the audit may be shared with the entity on whose behalf the audit is performed. An entity conducting an audit may have access to the previous audit reports on a particular pharmacy only if the audit is conducted by the same entity.

(e) *Cooperation with audit.* If an entity is conducting an audit that is complying with this subsection in auditing a pharmacy or pharmacist, the pharmacy or pharmacist that is the subject of the audit may not interfere with or refuse to participate in the audit.

(f) *Payment of auditors.* A pharmacy benefit manager or entity conducting an audit may not pay an auditor employed by or contracted with the pharmacy benefit manager or entity based on a percentage of the amount recovered in an audit.

(g) *Applicability.* 1. This subsection does not apply to an investigative audit that is initiated as a result of a credible allegation of fraud or willful misrepresentation or criminal wrongdoing.

2. If an entity conducts an audit to which a federal law applies that is in conflict with all or part of this subsection, the entity shall comply with this subsection only to the extent that it does not conflict with federal law.

(7) TRANSPARENCY REPORTS. (a) Beginning on June 1, 2021, and annually thereafter, every pharmacy benefit manager shall submit to the commissioner a report that contains, from the previous calendar year, the aggregate rebate amount that the pharmacy benefit manager received from all pharmaceutical manufacturers but retained and did not pass through to health benefit plan sponsors and the percentage of the aggregate rebate amount that is retained rebates. Information required under this paragraph is limited to contracts held with pharmacies located in this state.

(b) Reports under this subsection shall be considered a trade secret under the uniform trade secret act under s. 134.90.

(c) The commissioner may not expand upon the reporting requirement under this subsection, except that the commissioner may effectuate this subsection.

SECTION 22. Chapter 633 (title) of the statutes is amended to read:

CHAPTER 633

EMPLOYEE BENEFIT PLAN

ADMINISTRATORS ~~AND~~, PRINCIPALS,

AND PHARMACY BENEFIT MANAGERS

SECTION 23. 633.01 (1) (intro.) and (c) of the statutes are amended to read:

633.01 **(1)** (intro.) "Administrator" means a person who directly or indirectly solicits or collects premiums or charges or otherwise effects coverage or adjusts or settles claims for ~~a~~ an employee benefit plan, but does not include the following persons if they perform these acts under the circumstances specified for each:

(c) A creditor on behalf of its debtor, if to obtain payment, reimbursement or other method of satisfaction from ~~a~~ an employee benefit plan for any part of a debt owed to the creditor by the debtor.

SECTION 24. 633.01 (2r) of the statutes is created to read:

633.01 **(2r)** "Enrollee" has the meaning given in s. 632.861 (1) (b).

SECTION 25. 633.01 (3) of the statutes is amended to read:

633.01 **(3)** "Insured employee" means an employee who is a resident of this state and who is covered under ~~a~~ an employee benefit plan.

SECTION 26. 633.01 (4) of the statutes is renumbered 633.01 (2g) and amended to read:

633.01 **(2g)** "~~Plan~~ Employee benefit plan" means an insured or wholly or partially self–insured employee benefit plan which by means of direct payment, reimbursement or other arrangement provides to one or more employees who are residents of this state benefits or services that include, but are not limited to, benefits for medical, surgical or hospital care, benefits in the event of sickness, accident, disability or death, or benefits in the event of unemployment or retirement.

SECTION 27. 633.01 (4g) of the statutes is created to read:

633.01 **(4g)** "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

SECTION 28. 633.01 (4r) of the statutes is created to read:

633.01 **(4r)** "Prescription drug benefit" has the meaning given in s. 632.865 (1) (e).

SECTION 29. 633.01 (5) of the statutes is amended to read:

633.01 **(5)** "Principal" means a person, including an insurer, that uses the services of an administrator to provide ~~a~~ an employee benefit plan.

SECTION 30. 633.01 (6) of the statutes is created to read:

633.01 **(6)** "Self–insured health plan" has the meaning given in s. 632.85 (1) (c).

SECTION 31. 633.04 (intro.) of the statutes is amended to read:

633.04 Written agreement required. (intro.) An administrator may not administer ~~a~~ an employee benefit plan in the absence of a written agreement between the administrator and a principal. The administrator and principal shall each retain a copy of the written agreement for the duration of the agreement and for 5 years thereafter. The written agreement shall contain the following terms:

SECTION 32. 633.05 of the statutes is amended to read:

633.05 Payment to administrator. If a principal is an insurer, payment to the administrator of a premium or charge by or on behalf of an insured employee is payment to the insurer, but payment of a return premium or claim by the insurer to the administrator is not payment to an insured employee until the payment is received by the insured employee. This section does not limit any right of the insurer against the administrator for failure to make payments to the insurer or an insured employee.

SECTION 33. 633.06 of the statutes is amended to read:

633.06 Examination and inspection of books and records. (1) The commissioner may examine, audit or accept an audit of the books and records of an administrator or pharmacy benefit manager as provided for examination of licensees under s. 601.43 (1), (3), (4) and (5), to be conducted as provided in s. 601.44, and with costs to be paid as provided in s. 601.45.

(2) A principal that uses an administrator may inspect the books and records of the administrator, subject to any restrictions set forth in ss. 146.81 to 146.835 and

in the written agreement required under s. 633.04, for the purpose of enabling the principal to fulfill its contractual obligations to ~~insureds~~ insured employees.

SECTION 34. 633.07 of the statutes is amended to read:

633.07 Approval of advertising. An administrator may not use any advertising for ~~a~~ an employee benefit plan underwritten by an insurer unless the insurer approves the advertising in advance.

SECTION 35. 633.09 (4) (b) 2. and 3. of the statutes are amended to read:

633.09 **(4)** (b) 2. To ~~a~~ an employee benefit plan policyholder for payment to a principal, the funds belonging to the principal.

3. To an insured employee, the funds belonging to the insured employee.

SECTION 36. 633.11 of the statutes is amended to read:

633.11 Claim adjustment compensation. If an administrator adjusts or settles claims under ~~a~~ an employee benefit plan, the commission, fees or charges that the principal pays the administrator may not be based on the employee benefit plan's loss experience. This section does not prohibit compensation based on the number or amount of premiums or charges collected, or the number or amount of claims paid or processed by the administrator.

SECTION 37. 633.12 (1) (intro.), (b) and (c) of the statutes are amended to read:

633.12 **(1)** (intro.) An administrator shall prepare sufficient copies of a written notice approved in advance by the principal for distribution to all ~~insureds~~ insured employees of the principal and either shall distribute the copies to the ~~insureds~~ insured employees or shall provide the copies to the principal for distribution to the ~~insureds~~ insured employees. The written notice shall contain all of the following:

(b) An explanation of the respective rights and responsibilities of the administrator, the principal and the ~~insureds~~ insured employees.

(c) A statement of the extent to which the employee benefit plan is insured or self–insured, and an explanation of the terms "insured" and "self–insured".

SECTION 38. 633.13 (1) and (3) of the statutes are amended to read:

633.13 **(1)** GENERAL. Except as provided in sub. (2), a person may not perform, offer to perform or advertise any service as an administrator or a pharmacy benefit manager unless the person has obtained a license under s. 633.14. A pharmacy benefit manager that also performs services as an administrator need only obtain an administrator license under s. 633.14.

(3) RESPONSIBILITIES OF PRINCIPAL. A principal may not use the services of an administrator unless the administrator furnishes proof of licensure under s. 633.14 or exemption under sub. (2). An insurer or a self–insured health plan may not use the services of a pharmacy benefit manager unless the pharmacy benefit manager furnishes proof of licensure under s. 633.14.

SECTION 39. 633.14 (2) (intro.) and (c) 1. and 3. and (3) of the statutes are amended to read:

633.14 **(2)** (intro.) The commissioner shall issue a license to act as an administrator or pharmacy benefit manager to a corporation, limited liability company or partnership that does all of the following:

(c) 1. That the corporation, limited liability company or partnership intends in good faith to act as an administrator or pharmacy benefit manager through individuals designated under subd. 3. in compliance with applicable laws of this state and rules and orders of the commissioner.

3. That for each employee benefit plan or prescription drug benefit to be administered, the corporation, limited liability company or partnership has designated or will designate an individual in the corporation, limited liability

company or partnership to directly administer the employee benefit plan or prescription drug benefit.

(3) The commissioner shall promulgate rules establishing the specifications that a bond supplied by an administrator or pharmacy benefit manager under sub. (1) (b) or (2) (b) must satisfy to guarantee faithful performance of the administrator or pharmacy benefit manager.

SECTION 40. 633.15 (1) (a), (1m), and (2) (a) 1., 2. and 3. and (b) 1. of the statutes are amended to read:

633.15 **(1)** (a) *Payment.* An administrator or pharmacy benefit manager shall pay the annual renewal fee under s. 601.31 (1) (w) for each annual renewal of a license by the date specified by a schedule established under par. (b).

(1m) SOCIAL SECURITY NUMBER, FEDERAL EMPLOYER IDENTIFICATION NUMBER OR STATEMENT. At an annual renewal, an administrator or pharmacy benefit manager shall provide his or her social security number, if the administrator is an individual unless he or she does not have a social security number, or its federal employer identification number, if the administrator or pharmacy benefit manager is a corporation, limited liability company or partnership, if the social security number or federal employer identification number was not previously provided on the application for the license or at a previous renewal of the license. If an administrator who is an individual does not have a social security number, the individual shall provide to the commissioner, at each annual renewal and on a form prescribed by the department of children and families, a statement made or subscribed under oath or affirmation that the administrator does not have a social security number.

(2) (a) 1. If an administrator or pharmacy benefit manager fails to pay the annual renewal fee as provided under sub. (1) or fails to provide a social security

number, federal employer identification number or statement made or subscribed under oath or affirmation as required under sub. (1m), the commissioner shall suspend the administrator's or pharmacy benefit manager's license effective the day following the last day when the annual renewal fee may be paid, if the commissioner has given the administrator or pharmacy benefit manager reasonable notice of when the fee must be paid to avoid suspension.

2. If, within 60 days from the effective date of suspension under subd. 1., an administrator or pharmacy benefit manager pays the annual renewal fee or provides the social security number, federal employer identification number or statement made or subscribed under oath or affirmation, or both if the suspension was based upon a failure to do both, the commissioner shall reinstate the administrator's or pharmacy benefit manager's license effective as of the date of suspension.

3. If payment is not made or the social security number, federal employer identification number or statement made or subscribed under oath or affirmation is not provided within 60 days from the effective date of suspension under subd. 1., the commissioner shall revoke the administrator's or pharmacy benefit manager's license.

(b) 1. Except as provided in pars. (c) to (e), the commissioner may revoke, suspend or limit the license of an administrator or pharmacy benefit manager after a hearing if the commissioner makes any of the following findings:

a. That the administrator or pharmacy benefit manager is unqualified to perform the responsibilities of an administrator or pharmacy benefit manager.

b. That the administrator or pharmacy benefit manager has repeatedly or knowingly violated an applicable law, rule or order of the commissioner.

c. ~~That~~ If the licensee is an administrator, that the administrator's methods or practices in administering ~~a~~ an employee benefit plan endanger the interests of ~~insureds~~ insured employees or the public, or that the financial resources of the administrator are inadequate to safeguard the interests of ~~insureds~~ insured employees or the public.

SECTION 41. 633.15 (2) (b) 1. d. of the statutes is created to read:

633.15 **(2)** (b) 1. d. If the licensee is a pharmacy benefit manager, that the pharmacy benefit manager's methods or practices in administering a prescription drug benefit endanger the interests of enrollees or the public, or that the financial resources of the pharmacy benefit manager are inadequate to safeguard the interests of enrollees or the public.

SECTION 42. 633.15 (2) (b) 2. of the statutes is amended to read:

633.15 **(2)** (b) 2. A person whose license has been revoked under subd. 1. may apply for a new license under s. 633.14 only after the expiration of 5 years from the date of the order revoking the administrator's or pharmacy benefit manager's license, unless the order specifies a lesser period.

SECTION 43. 633.15 (2) (f) of the statutes is created to read:

633.15 **(2)** (f) The commissioner, after ordering a suspension or revocation under this subsection, may allow a pharmacy benefit manager to continue to provide services for the purpose of providing continuity of care in prescription drug benefits to existing enrollees.

SECTION 44. 633.16 of the statutes is amended to read:

633.16 Regulation. Nothing in this chapter gives the commissioner the authority to impose requirements on ~~a~~ an employee benefit plan that is exempt from state law under 29 USC 1144 (b).

SECTION 45. Nonstatutory provisions.

(1) PHARMACY BENEFIT MANAGER; COMPLIANCE DATE. A pharmacy benefit manager that is not required to be licensed as an administrator is not required to be licensed under s. 633.14 and a pharmacy benefit manager is not required to comply with s. 632.865 (3) to (7) until the effective date of this subsection, unless the commissioner of insurance specifies a later date on which registration or compliance is required.

SECTION 46. Initial applicability.

(1) For policies and plans containing provisions inconsistent with this act, this act first applies to policy or plan years beginning on the effective date of this subsection.

(END)

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:
Kassandra Walbrun	1/6/2021
	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?
1/28/2021	☒ Yes ☐ No	Administrative Rule Matters – Discussion and Consideration 1. Development of 2021 Biennial Report under s. 227.29, Wis. Stats. 2. Pending and Possible Rules a. Phar 2 (Emergency and Permanent Rule)

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

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

1. Discuss findings of Rules Committee and development of draft report

2a. Discuss status of emergency rule and potential for permanent rule

11) Authorization

Kassandra Walbrun *1/6/2021*

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

Philip Trapskin
Chairperson

Franklin LaDien
Vice Chairperson

Cathy Winters
Secretary

PHARMACY EXAMINING BOARD

4822 Madison Yards Way
PO Box 8366
Madison WI 53708-8366

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

March 22, 2019

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: Report Submitted in Compliance with s. 227.29 (1), Stats.

Dear Senator Nass and Representative Ballweg:

This report has been prepared and submitted in compliance with s. 227.29 (1), Stats.

I. Unauthorized rules, as defined in s. 227.26 (4) (a):

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules are unauthorized.

II. Rules for which the authority to promulgate has been restricted:

After careful review of the Board's administrative rules, the Board has determined that no promulgated rules have restricted authority.

III. Rules that are obsolete or that have been rendered unnecessary:

Rule	**Description of why the rule is obsolete or has been rendered unnecessary.**	**Action taken to address or reason for not taking an action**
Phar 5.02	It is no longer necessary for a pharmacist to notify the Board in writing of a name or address change. The change is typically done electronically.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several obsolete and unnecessary provisions, particularly in the areas of technology.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

IV. Rules that are duplicative of, superseded by, or in conflict with another rule, a state statute, a federal statute or regulation, or a ruling of a court of competent jurisdiction:

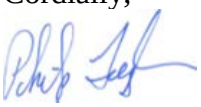
Rule	Citation or the text of the statute, regulation, or ruling.	Action taken to address or reason for not taking an action
Phar 11.01	Procedures for disciplinary proceedings. Procedures for disciplinary proceedings before the board are set forth in ch. SPS 2. This provision is unnecessary.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 12.04	Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985). The referenced federal statute has been superseded.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.

V. Rules that are economically burdensome:

Rule		**Action taken to address or reason for not taking an action**
Phar 6.04	Floor design, professional service area, and prescription counter space are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board will be drafting a scope to address all actions identified in this report not already being addressed in a current rule promulgation project.
Phar 6.07	Storage requirements are economically burdensome and do not correspond with the evolving types of pharmacies.	The Board is currently drafting a rule to update this section.
Phar 6.075	Temperature and humidity requirements were based upon nationally accepted standards. Stakeholders informed the Board of challenges and burdens in meeting these provisions.	The Board is currently drafting a rule to update this section.
Ch. Phar 7	This chapter has not had a comprehensive review in over 15 years. There are several provisions which are economically burdensome.	The Board is currently working on an entire rewrite of this chapter to reflect current pharmacy standards and practice, and reduce the regulatory impact on pharmacies without negatively impacting public safety.

Thank you.

Cordially,



Philip Trapskin
Chairperson

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 EMERGENCY RULES

The statement of scope for this rule, SS 135-20, was approved by the Governor on October 16, 2020, published in Register 778A3 on October 19, 2020, and approved by the Pharmacy Examining Board on December 3, 2020.

This emergency rule was approved by the Governor on *.

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 2.05 (3), relating to endorsement requirements for pharmacists.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Pharmacy Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is:

On March 25, 2020, the Pharmacy Examining Board granted a variance of s. 450.03 (1), Stats., pursuant to s. 450.02 (3m) (b), Stats., to allow pharmacists who are licensed in good standing in other states, United States territories and the District of Columbia to practice pharmacy in the state of Wisconsin without a Wisconsin license. The purpose of the variance was to compensate for a shortage of pharmacy staff during the pandemic. The variance was in effect for 90 days. Subsequently, the provisions of the variance were superseded by Emergency Order #16 and it was rescinded on April 3, 2020. Then 2019 Act 185 was signed into law which expired on June 10, 2020. On June 4, 2020, the Board reviewed and reissued the variance until August 1, 2020. On July 23, 2020, the Pharmacy Board determined that the requirements of s. 450.02 (3m) (b), Stats., were met and extended the variance for another 90 days.

The Pharmacy Examining Board has received information from stakeholders that there remains a shortage of pharmacy staff and an inability to receive a license due to the impact the pandemic has had on the availability of the multi-state pharmacy jurisprudence examination. The Board determines that the preservation of the public health and safety necessitates an emergency rule to temporarily suspend the requirement that applicants who hold a license in another state take the multi-state pharmacy jurisprudence examination with Wisconsin as primary state.

ANALYSIS

Statutes interpreted: Section 450.05, Stats.

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

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides that each examining 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.

Section 450.02 (2), Stats., provides that the Board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05, Stats.

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

Related statutes or rules:

Section 450.05, Stats., specifies the requirements for licensure as a pharmacist on the basis of licensure as a pharmacist in another state.

Plain language analysis:

The proposed emergency rule temporarily suspends the requirement that applicants for a pharmacist license who hold a license in another state take the multi-state pharmacy jurisprudence examination.

Summary of, and comparison with, existing or proposed federal statutes and regulations:

None.

Comparison with rules in adjacent states:

Illinois:

Rules of the Illinois Department of Financial and Professional Regulation specify the licensure requirements for an applicant who is currently licensed as a pharmacist under the laws of another U.S. jurisdiction or another country (68 Ill. Adm. Code 1330.350). The requirements include successful passage of the Illinois multi-state pharmacy jurisprudence examination.

Iowa:

Rules of the Iowa Board of Pharmacy specify the requirements for an applicant for license transfer who is currently licensed as a pharmacist in another state or territory of the United States (657 IAC 2.9). The requirements include successful completion of the multi-state pharmacy jurisprudence examination, Iowa edition.

Michigan:

Rules of the Michigan Board of Pharmacy specify the requirements for an applicant for licensure by endorsement (Mich Admin Code, R 338.475). The requirements include successful completion of the Michigan multi-state pharmacy jurisprudence examination.

Minnesota:

Rules of the Minnesota Board of Pharmacy specify the requirements for an applicant for licensure as a pharmacist on the basis of licensure as a pharmacist in another state (Minnesota Rules, part 6800.1300). The requirements include successful completion of the Minnesota version of the multi-state pharmacy jurisprudence examination.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board has received information from stakeholders that there remains a shortage of pharmacy staff and an inability to receive a license due to the impact the pandemic has had on the availability of the multi-state pharmacy jurisprudence examination. The Board determined that the preservation of public health and safety necessitates an emergency rule to temporarily suspend the requirement that applicants for a pharmacist license who hold a license in another state take the multi-state pharmacy jurisprudence examination.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

As the proposed emergency rule temporarily suspends the requirement that applicants for a pharmacist license who hold a license in another state take the multi-state pharmacy jurisprudence examination, there is no anticipated effect on small business.

Fiscal estimate:

This proposed emergency rule will not have a fiscal impact.

Effect on small business:

The proposed emergency rule does not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Dale Kleven, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone (608) 261-4472; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Dale Kleven, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be submitted by the date and time at which the public hearing on this emergency rule is conducted. Information as to the place, date, and time of the public hearing will be published on the Legislature's website and in the Wisconsin Administrative Register.

TEXT OF RULE

SECTION 1. Phar 2.05 (3) is repealed.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect upon publication in the official state newspaper, pursuant to s. 227.22 (2) (c), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Pharmacy Examining Board is approved for submission to the Governor.

Dated December 10, 2020 Agency _____

Chairperson
Pharmacy Examining Board

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:
Kimberly Wood, Program Assistant Supervisor-Adv on behalf of Jameson Whitney, Legal Counsel.	1/22/2021 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?
1/28/2021	☒ Yes ☐ No	Public Agenda Request: Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration

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 ☒ No	N/A

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

The Board should review the attached requests regarding the proposed MOU and provide advice to the State of Wisconsin on whether participation is warranted.

11) Authorization

Kimberly Wood *1/22/2021*

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.

Women's International Pharmacy
Custom Compounded Prescriptions for Men and Women

July 9, 2020

Wisconsin Pharmacy Examining Board
Department of Safety and Professional Services
4822 Madison Yards Way
Madison WI 53705

RE: Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration.

Dear Members of the Board,

We represent Women's International Pharmacy (WIP), a retail pharmacy specializing in compounding patient-specific medications containing bioidentical hormones for women and men. We are a local Madison, Wisconsin-based business that was founded in 1985 and currently has approximately 60 employees. WIP is nationally-recognized for its compounded hormone medications and its services are utilized by prescribers nationwide. Thousands of patients, both in Wisconsin and around the country, rely on WIP for individualized compounded hormone medications. WIP is licensed in, and dispenses patient-specific compounded medications to, all 50 states, the District of Columbia, Puerto Rico and Guam.

As you may be aware, as part of the Drug Quality and Security Act of 2013 (DQSA), FDA was tasked with developing a memorandum of understanding (MOU) with the States that addresses the interstate *distribution* of inordinate amounts of compounded drugs and provides for appropriate investigation of complaints relating to compounded drugs *distributed* interstate. FDA has now finalized that MOU and it is currently under review by the United States Office of Management and Budget (OMB). OMB will determine the financial impact of the MOU and whether it meets the requirements of the federal Paperwork Reduction Act. If OMB approves the MOU, it will be released to the States to either sign or reject. The MOU will go into effect 365 days, i.e. one year, from the date upon which it is released to the States for signature.

The MOU is exceedingly problematic for two main reasons. First, if a particular State chooses ***not*** to enter into the MOU, the DQSA provides that compounding pharmacies in that State cannot distribute compounded medication out of the State in excess of five percent (5%) of the total prescription orders dispensed or distributed by that pharmacy. In other words, if a State declines to enter into the MOU with FDA, resident compounding pharmacies in that State will be

almost entirely restricted to in-state commerce and will not be able to meaningfully participate in interstate commerce. Resident compounding pharmacies, especially those who serve patients throughout the country like WIP, will see an immediate and disastrously detrimental decline in business. Resident compounding pharmacies will have no choice but to cut staff, downsize pharmacy facility size, space, and equipment, and eliminate most, if not all, compounding, thereby resulting in significant lost revenue. It goes without saying that this will have a profoundly negative impact on the State economy, pharmacy practices, and patient health.

Second, even if a State chooses to enter into the MOU with FDA, the terms of the MOU are burdensome for both State boards of pharmacy and the retail pharmacies they regulate, and the consequences of complying with the MOU are frustratingly unclear for regulators, pharmacies, and patients.

As a threshold matter, despite the fact that the DQSA directs FDA to regulate the *distribution* of compounded medication by way of the MOU, FDA has defined the term *distribution* for purposes of the MOU to include patient-specific dispensing, thereby allowing FDA to regulate the amount of compounded medication a pharmacy dispenses *and* distributes interstate.[1] The MOU then places a 50-percent threshold on all compounded drugs that leave a pharmacy by defining "inordinate amounts of compounded human drug products" as follows:

> **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

MOU at App. A (footnote omitted). Although not a hard cap, the MOU clearly establishes that compounding pharmacies will incur increased FDA scrutiny if more than 50 percent of their business is conducted out of state.

[1] "**Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded." MOU at App. A (emphasis in original). FDA ignores the fact that the terms "dispense" and "distribute" are universally-recognized distinct activities in pharmacy practice and is using the MOU as an opportunity to extend the reach of its regulatory authority to include patient-specific dispensing.

Per the MOU, the burden to police whether a compounding pharmacy has met this "50 percent threshold" falls to the States. States that sign on to the MOU must, on an annual basis, identify, "using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [State], pharmacies that distribute inordinate amounts of compounded human drug products interstate." MOU § III.b.2 at 5. If a pharmacy is identified as having distributed inordinate amounts interstate, States must provide additional information to FDA, including prescription data, licensing information, inspection observations, and the States into which the pharmacy distributed compounded medication. MOU § III.b.3 at 5. In addition, for those States that have identified a pharmacy to have met the "50-percent threshold," the MOU provides that within 30 days of such identification, States must notify FDA and provide FDA with *seven* categories of information about that particular pharmacy. MOU § III.c.1.b at 7.

The States' obligations under the MOU are entirely unfunded. Each State that signs on to the MOU will need to allocate resources sufficient to comply with the terms of the MOU and where those resources will come from is a mystery. Many States may simply pass that burden on to the compounding pharmacies, which will inevitably cause economic harm. All pharmacies located in States that sign the MOU will, at a minimum, have to gather and provide information to their home States in order for those States to establish whether such pharmacies have distributed compounded drugs in what FDA deems to be inordinate amounts. If such pharmacies are found to have reached the "50-percent threshold", that data-gathering and reporting increases significantly. Given the extent of information required under the MOU, pharmacies like WIP will need to hire additional staff to handle the data-gathering and reporting requirements, and/or will be forced to reallocate staff whose time would be better served focusing on the preparation of compounded medications to meet patient needs.

Furthermore, what FDA intends to do with the information obtained from States, such as whether FDA will conduct increased inspections or take enforcement action against pharmacies so identified, is unclear. Compounding pharmacies like WIP are entirely in the dark as to what will come next if they are deemed to have distributed in "inordinate amounts." This regulatory uncertainty, coupled with the increased data-gathering and reporting burden, may deter pharmacies from reaching the "50-percent threshold," thereby reducing patient access to compounded medication when pharmacies curtail interstate dispensing of compounded drugs.

Finally, and perhaps most alarming, even if a State signs the MOU, it permits a State to terminate its participation with just 60 days' notice. State pharmacy board and licensing departments often change on an annual basis, which would mean a State's position on whether to continue its participation could change annually. Compounding pharmacies have no control over a State's decision to terminate its participation under the MOU. As a result, compounding pharmacies' economic livelihoods, and patient access to the medications they dispense, could change in just two months.

The MOU could be approved by OMB and released to the States for signature any day now. It is abundantly clear that FDA has put States and compounding pharmacies, between a rock and a hard place. Regardless of which path the States choose, businesses and patients suffer. Accordingly, we respectfully request that the Wisconsin Pharmacy Examining Board perform the following actions to ensure the continued operations of compounding pharmacies in this State and, most importantly, patient access to compounded medications:

1. Share what your authority is as a Board to sign or not to sign the MOU;

2. Express concern and displeasure to the FDA and OMB over the terms of the MOU. Several States have already done so, including Arizona, Texas and South Carolina (examples attached);

3. If OMB approves the MOU, we ask that the Board sign the MOU. When faced with the prospect of a 5% limit on interstate distribution and dispensing, the MOU, despite its glaring flaws, is the only viable option to preserve patient access to much needed medications and avoid significant economic injury; and

4. Lastly, if the Board signs the MOU, we ask that the Board craft regulations designed to prevent the unilateral termination of the MOU on 60 days' notice, including allowing for sufficient notice and comment from resident compounding pharmacies like WIP before termination.

Thank you for your consideration and please contact us with any questions.

Sincerely,

Gina Besteman, R.Ph.
Director of Compounding and Dispensing

Michelle Violi, Pharm. D.
Dispensing Pharmacists Manager

Women's International Pharmacy
2 Marsh Ct
Madison WI 53718
800-699-8144

Enclosures: 4

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

    1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

[3] To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

(i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

(ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

facility in which they were compounded during that same calendar year.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information
    1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

        a. Complaints:

            i. Name and contact information of the complainant, if available;

            ii. Name and address of the pharmacy that is the subject of the complaint;

            iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

            iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

            v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

        b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

    a. Name and contact information of the complainant or notifier;

    b. Name and address of the physician that is the subject of the complaint or notification; and

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only "in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed" by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

[9] The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

June 5, 2020

Mr. Russel Vought
Director
Office of Management and Budget (OMB)
725 17the Street, NW
Washington, DC 20503

[Submitted electronically to www.reginfo.gov/public/do/PRAMain]

RE: OMB Control Number 0910-0800 (Docket No. FDA-2018-N-3065)

Dear Director Vought:

The undersigned organizations represent thousands of pharmacy compounding professionals who continue to have serious concerns with the Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the [insert State] Board of Pharmacy and the U.S. Food and Drug Administration ("the MOU"). We write to you today regarding the FDA's recent submission of the MOU to OMB for review under the Paperwork Reduction Act of 1995 (PRA).

Three of our organizations (APhA, APC *formerly* IACP, and NCPA) each commented separately on our substantive concerns about the various draft versions of the MOU and have commented jointly in July of 2019 on the most recent draft MOU that was released in September of 2018. The comments of our individual organizations to the September 2018 draft MOU, as well as the joint comment our organizations submitted to that draft are included here for your review.

The final MOU includes a few recommendations from our organizations in relation to the requirements on states (e.g., increasing the reporting threshold from 30% to 50%), However, as you will see, the main substantive concern our organizations and many other stakeholders have is that the previous draft MOU, as well as the final MOU now before you, redefine the key statutory term "distribution" to include the patient-specific "dispensing" of compounded drugs in a way that is inconsistent with the statutory language of Section 503A of the Food, Drug and Cosmetic Act (FDCA) and that will lead to serious access problems for patients who rely on out-of-state pharmacies for their compounded medications.

Today, we write to you to express concern with the fact that FDA's analysis supporting the proposed information collection burden for the final MOU was inadequate to meet the requirements of the Paperwork Reduction Act and should therefore be rejected by OMB and sent back to FDA.

The main purpose of FDA's information collection estimate associated with the MOU was to determine the level of information collection burden on state boards of pharmacy and other state regulatory agencies that would result from the MOU's requirements for investigation, reporting and recordkeeping of adverse event reports involving pharmacies shipping compounded drugs interstate. This information is critical in the context of this particular MOU because the level of burden the MOU's requirements place on states relates directly to the number of states that will sign the MOU. States that sign the MOU will be required to finance the additional staffing needed to gather intrastate and interstate dispensing and distribution data from all compounding pharmacies in their state and evaluate that data to determine which pharmacies trigger the MOU's reporting requirements. States that sign the MOU will further be required to investigate adverse event reports, report data to the FDA, and maintain records. Pharmacies in states that are unable or unwilling to sign the MOU are statutorily prohibited from "distributing" more than five percent of their compounded drugs interstate. Because FDA has redefined the key term "distribution" to include traditional patient-specific "dispensing" of compounded drugs, patients who rely on out-of-state pharmacies in states that do not sign the MOU will see their access to the compounded medications they need greatly restricted. Therefore, it is critical that that FDA conduct a thorough, transparent and accurate assessment of the collection of information to ascertain the true burden of the MOU on each individual state, as well as a detailed and complete assessment of the likelihood that each individual state will sign.

In the MOU the FDA directs states to use "surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available" to determine which pharmacies in their state have distributed more than 50 percent of their compounded drugs out of state. For purposes of their proposed information collection for OMB review, it appears FDA did not survey the individual state boards of pharmacy and other state regulatory agencies that will be impacted by the MOU, but rather, chose to use anecdotal evidence gleaned from the public comments to establish hypothetical averages of the numbers of adverse event reports states will receive and the resulting reporting and recordkeeping manpower burden on the states. Our organizations have confirmed the National Association of Boards of Pharmacy (NABP) is currently in the process of surveying member Boards on the MOU with initial results expected in mid-June. At a minimum, FDA should wait to include this data in any reformulated final MOU. In addition, FDA's proposed information collection does not adequately consider the substantial manpower and resources of the MOU's inspection requirements on the states.

From this incomplete information collection estimate, FDA makes the assumption that 45 states will sign the MOU. Yet, in their comments to the draft MOU, the NABP indicated that at as many as 20 states had serious concerns with the administrative burden and unfunded mandates the MOU would create and were unlikely to sign. The final MOU makes minor changes to the previous draft, increasing to five days from the previously proposed three days states have for reporting adverse events to the FDA. This final MOU also expands from six months to one year the time states are given to consider whether to sign the MOU. FDA also cites the yet-to-be-developed "information sharing network" as an additional improvement to the previous draft. It is our understanding that this "information sharing network," which FDA has contracted with NABP to develop, has not been finalized and will not enter into beta testing until at least the fourth quarter of this year. As such, state boards of pharmacy may very well not have access to this information, on which FDA's incomplete burden analysis relies heavily, before they have to determine whether to sign the MOU.

It is highly unlikely that those minor concessions to the concerns being raised by the states will translate into 45 states signing the MOU. We believe that FDA's inaccurate assessment of the collection of information on the MOU has led to a substantial underestimation of the burden that will be placed on

states that sign and, therefore, a substantial overestimation of the number of states that will sign it. As discussed above, the likely refusal of many states to sign the MOU will have a profoundly negative impact upon patients who rely on out-of-state pharmacies for their compounded drugs. Further, FDA estimates that one state will terminate its participation in the MOU each year. If the burden to the states is as inconsequential as FDA predicts, it is unclear why FDA predicts this contraction in participation, especially given the serious penalties on pharmacies within that state and on patient access to medications if the MOU is not continued.

For these reasons, our organizations believe OMB should not approve FDA's information collection estimates under the PRA related to the MOU and require FDA to conduct a true, transparent evaluation of the collection of information that involves a detailed survey of each state that will produce accurate data for the states, pharmacy stakeholders, patients and the general public about the impact of the MOU. As the negative impact on patients served by out-of-state pharmacies in states that do not sign the MOU will be substantial, FDA should be directed to continue working with stakeholders on a final MOU that all states will commit to sign. As you will see from the enclosed joint comments submitted by our organizations in July of 2019, we suggested revisions that could be made to the requirements on states as well as an alternative definition of "distribution" for purposes of the MOU that we believe would have led to most if not all states signing the MOU, with broad stakeholder support. Unfortunately, FDA has yet to formally respond to these consensus recommendations.

Thank you in advance for your consideration of our request. Should you have questions, please do not hesitate to contact APC Legislative and Regulatory Counsel David Pore at dpore@hslawmail.com and APhA Senior Director Regulatory Policy Michael Baxter at mbaxter@aphanet.org.

Sincerely,

American Pharmacists Association
Alliance for Pharmacy Compounding
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

Commented [STS1]: Congress clearly expressed its intent that the MOU would address interstate **distribution** of inordinate amounts of compounded drug products. Nowhere does Congress reference any intention to limit the amount of compounded drug products that can be dispensed to patients pursuant to patient-specific prescriptions. As noted below, for purposes of this MOU, FDA has now redefined "distribution" to include any drug that leaves a pharmacy by any means other than by being picked up in-person by the patient at the pharmacy. As a result, drugs mailed directly to a patient based upon a patient-specific prescription would be considered "distribution," not "dispensing."

Commented [STS2]: Consistent with their established meanings, Congress refers to dispensing and distributing as separate and distinct actions and provides for the combined total of dispensed and distributed drug products to serve as the denominator for the 5% limit on interstate **distribution**.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

Commented [STS3]: To the extent a state's established investigatory policies and procedures conflict with the requirements of this MOU, the requirements of this MOU will control and the state will be forced to revise its existing policies and procedures and associated staffing to conform to the requirements of the MOU.

[3] To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

Commented [STS4]: 3-year record keeping requirement for states. Unfunded mandate.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

Commented [STS5]: 5-business day deadline for states to provide notice to FDA of a complaint (substantiated or not) of a serious adverse drug experience or serious product quality issue related to a drug distributed outside the state. Unfunded mandate.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days after receiving the complaint.

Commented [STS6]: This notice requirement related to compounding by physicians applies to *any* adverse drug experience and *any* product quality issue and is not limited to serious adverse drug experiences or serious product quality issues.

Commented [STS7]: 5-business day deadline. Unfunded mandate.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

   (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

   (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

Commented [STS8]: FDA's new definition of "distribute" includes any drug "sent out" of the pharmacy, including drugs that are sent directly to a patient pursuant to a patient-specific prescription (historically, "dispensing"). This is a new definition created by the FDA for this MOU that contradicts the established meanings of "distribute" and "dispense" and the intent of Congress.

Commented [STS9]: FDA's new definition of "dispense" includes only those drugs that are picked up by the patient in-person at the pharmacy. Nowhere in any federal (or state) statute, rule, or regulation is the term "dispense" defined so narrowly. This is a new definition created by the FDA for this MOU that contradicts the established meanings of "distribute" and "dispense" and the intent of Congress.

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

Commented [STS10]: Unfunded mandate required of states annually. The number of pharmacies triggering this reporting requirement will likely be much higher under the FDA's new definitions of "distribute" and "dispense," than under the established meanings of those terms.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

Commented [STS11]: Unfunded mandate required of states annually. The number of pharmacies triggering this reporting requirement will likely be much higher under the FDA's new definitions of "distribute" and "dispense," than under the established meanings of those terms.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

Commented [STS12]: 30-business day deadline. Unfunded mandate.

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

Commented [STS13]: 30-business day deadline, which is triggered by *any* physician who distributes *any amount* of *any kind of* compounded drugs interstate. Unfunded mandate.

c. Submission and Disclosure of Information

1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

Commented [STS14]: Unfunded mandate. Who will compile this information for each state? Who will review this information for each state and determine which pharmacies trigger the reporting requirement? Who will then prepare the reports for each state and then submit the reports to the FDA? How many additional staff members with each state be required to hire and at what cost?

a. Complaints:

i. Name and contact information of the complainant, if available;

ii. Name and address of the pharmacy that is the subject of the complaint;

iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

   a. Name and contact information of the complainant or notifier;

   b. Name and address of the physician that is the subject of the complaint or notification; and

Commented [STS15]: 21 USC § 353 is the section of the FD&C Act immediately preceding 21 USC § 353a (503A) -- the enabling statute under which FDA is proposing this MOU. Paragraph (e)(4)(E) of that section defines "wholesale distribution" and expressly excludes from the definition "the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use." At the time Congress added 503A to the FD&C Act in 1997, it was common practice for pharmacies to distribute small quantities of compounded drugs to physicians for "office use," pursuant to state law. Congress' establishment of the 5% limit on interstate distribution is evidence of Congress' intent to allow pharmacies to continue to engage in interstate office-use distribution up to 5% of their total production *even if their states refuse to sign the MOU.* The creation of 503B outsourcing facilities in 2013 allowed for registered facilities to engage in office-use distribution without limit, but it did not affect the limited office-use distribution allowed by pharmacies under 503A. FDA's efforts to prohibit pharmacies from engaging in limited office-use distribution is another example of FDA's overreach under the FD&C Act and its disregard for historical norms and Congressional intent.

Commented [STS16]: Unfunded mandate. Moreover, this reporting requirement, triggered by the interstate distribution of *any* amount of *any kind* of compounded drugs (sterile or non-sterile) by a physician, will have a chilling effect on compounding by physicians and will limit patient access to necessary medications.

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

Commented [STS17]: What will be the terms of this separate agreement? Will that agreement also include new definitions that contradict terms' established meanings? What if a state refuses to enter into a separate agreement with FDA to allow FDA to share the confidential information of its pharmacies and citizens?

Commented [STS18]: As with this MOU, FDA has shown that it will interpret those laws and regulations in whatever manner suits its current interests.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

Commented [STS19]: The MOU itself is a product of FDA's efforts to exceed the statutory and regulatory authority afforded to it by the FD&C Act.

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

Commented [STS20]: To the contrary, this MOU infringes upon states' rights to regulate compounding pharmacies within their state, the rights of pharmacies to engage in interstate commerce if the state in which they are located refuses to sign the MOU, and patients' access to drugs compounded in other states that do not sign the MOU.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only "in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed" by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

Commented [STS21]: Termination will not only affect pharmacies that engage in interstate distribution, but it will also affect the individual patients and practitioners in other states who will no longer have access to the compounded drugs due to the 5% cap on interstate distribution, which term as now defined by FDA includes drugs mailed directly to patients pursuant to a patient-specific prescription.

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

Commented [STS22]: The established meaning of "distribution" is to deliver a drug, other than by administering or dispensing. The established meaning of "dispense" is to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner. The method of delivery has never impacted either definition. However, FDA has now created a new, nearly all-encompassing definition of "distribution" that only excludes drugs handed to the patient in-person at the pharmacy. In doing so, FDA is attempting to strip states of their historical authority to regulate the dispensing of drugs by pharmacies directly to patients via other delivery methods.

[9] The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

Commented [STS23]: It is noteworthy that, in this MOU, FDA is similarly attempting to create a new definition for "inordinate amounts," which definition it acknowledges to be in direct conflict with Congress' express definition of that same term in the same section of the FD&C Act.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

Arizona State Board of Pharmacy

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
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Talking Points on FDA Final MOU – FDA Underestimates Problems with Implementation

1. FDA estimates that 45 states will sign the MOU. This expectation is unrealistic. The National Association of Boards of Pharmacy (NABP) submitted comments to the FDA stating that at least 20 states indicated they will likely not sign because of either unfunded mandates or problems with the definition of distribution which includes dispensing. This definition of distribution is in conflict with state laws and the NABP model Pharmacy Act that defines distribution and dispensing as separate activities.

2. If fewer states sign, this will create problems for both pharmacies in those states and patients that these pharmacies serve as they would be limited to filling prescriptions across state lines to 5 percent of their total volume. Many pharmacies specialize in serving patients such as autistic children, women with hormonal imbalances, organ transplantation patients, individuals with pain management issues, and many other specialty groups. Many compounding pharmacies have a regional or national clientele, and the limits of the MOU if a state doesn't sign would be disastrous.

3. FDA projects that one state will terminate its participation in the MOU each year. This means that in 10 years, by FDA's estimate no more than 35 states will be party to the agreement.

4. With 60-days notice, either a state or the FDA can withdraw from the MOU. This creates tremendous uncertainty that adversely affects both pharmacies in that state and patients throughout the country.

5. State boards of pharmacy are dealing with the health care crisis created by COVID-19. They do not have the time or resources to consider the MOU at this time. State budgets have been hard hit by a decline of revenues as a result of COVID-19, and do not have the additional resources that implementing the final MOU requires.

6. FDA's analysis on the impact on state boards of pharmacy is based primarily on coordination with an "information sharing network" it has contracted NABP to develop. This network has not been developed, and it is unknown as to when it will be completed. A final network could take several years to complete, especially given the challenges of the current situation with COVID-19. Because of this, the cost to the states to comply far exceeds the estimated cost projected by FDA.

7. FDA states that the requirements of the final MOU are not an unfunded mandate because states don't have to sign it. However, given the penalties to pharmacies and patients that would result from a state not signing, every state will be obligated to devote resources to seeing if the MOU can be signed. If they do sign, they must absorb the additional cost especially since the "information sharing network" touted by FDA does not yet exist.

8. NABP has been tasked with creating the information sharing network. As such, NABP is a covered entity under HIPAA. FDA is not. Sharing potentially protected health information with FDA, therefore, would be a HIPAA violation that could adversely affect NABP and the individual states utilizing the information sharing platform.

South Carolina
Department of Labor, Licensing and Regulation

Board of Pharmacy

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Henry D. McMaster
Governor

Emily H. Farr
Director

June 15, 2020

[Submitted Electronically to www.reginfo.gov/public/do/PRAMain]

The Honorable Russell T. Vought
Acting Director
United States Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: OMB Control Number 0910-0800, Docket No. FDA-2018-N-3065

Dear Director Vought:

The South Carolina Board of Pharmacy ("Board") respectfully submits the following concerns regarding the information collection submitted to OMB by the FDA for review under the Paperwork Reduction Act dealing with the final standard memorandum of understanding "(MOU") provided for by section 503A of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") ("final standard MOU").

Initially, the Board notes that it was not formally surveyed or otherwise directly contacted regarding the FDA's collection of information on the MOU. Instead, it appears from the notice of the collection of information filed with OMB that FDA has based their estimates of how many states will sign the MOU and the resulting burdens on these states on the limited number of comments it received from state boards to the docket in the federal register. The Board believes that the FDA's estimates on the number of adverse event reports and the number of pharmacies that will trigger the 50% threshold on distributing and dispensing drugs out of state are significantly lower than will be borne out. To that end, the Board believes that a more detailed collection of information by the FDA, to include surveying individual states in writing, would demonstrate this underestimation.

Additionally, the FDA's estimates regarding the number of states that will enter into the agreement, as well as the burden on these states, are almost certainly inaccurate due to the FDA's redefining of the term "distribution" in the final standard MOU. By extending the definition of "distribution" beyond its common usage in the industry, as well as its definition in most state laws, the FDA has also underestimated the economic impact on pharmacies located in states that do not sign the final standard MOU, as well as the impact on the out-of-state patients of these pharmacies. As such, the FDA must implement a much more thorough collection of information.

Finally, the FDA's estimate that 45 states will sign the final standard MOU likely results from an inadequate consideration of individual state laws that may prohibit a state from entering into the MOU. For example, many states have provisions that make private the investigations of its licensees and/or permittees. These potential barriers and the potential downstream effects on pharmacies located in states that may be prohibited by law from entering into an MOU serve as additional reasons why the FDA must engage in a more thorough collection of information.

For these reasons, the Board respectfully submits that OMB should not approve the MOU under the Paperwork Reduction Act and should require FDA to first do a true collection and reporting of information by surveying each state about the burden and impact the MOU would have on that state if it were to sign the MOU. Thank you in advance your consideration.

Sincerely,

Eric J. Strauss, Pharm.D.
Chair, South Carolina Board of Pharmacy

TEXAS STATE BOARD OF PHARMACY

June 15, 2020

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Submitted via: https://www.regulations.gov/comment?D=FDA-2018-N-3065-0046

RE: Comments on Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability (OMB Control Number 0920-0800; Docket ID: FDA-2018-N-3065)

Dear Director Vought:

This letter is to express concerns with the information collection that has recently been submitted to Office of Management and Budget (OMB) by the Food and Drug Administration (FDA) for review under the Paperwork Reduction Act dealing with the "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between [insert State of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (MOU). The MOU will require substantial inspection, data tracking, reporting and recordkeeping requirements on boards of pharmacy and other agencies in states that sign the MOU, so the FDA estimates of the burden for those requirements are critical.

The Texas State Board of Pharmacy has not been formally surveyed or otherwise directly contacted regarding FDA's collection of information for the MOU. Instead, the notice of the collection of information filed with OMB suggests that FDA has based their estimates of both how many states will sign the MOU and what the burden on those states will be on a handful of comments from state boards. From these comments, FDA estimates the average numbers for how many adverse event reports states will receive and how many pharmacies will trigger the 50% threshold on out-of-state distributing and dispensing drugs, which then requires tracking, reporting and recordkeeping. An accurate information collection by FDA would have involved actually surveying states in writing, and as result, the lack of accurate information may have resulted in a serious underestimation of the burden the MOU will have for boards. The estimate of the number of states that will sign the MOU could also be inflated. The burden on larger states that sign the MOU, like Texas, will undoubtedly be several times greater than the averages in FDA's estimates.

FDA disagrees with comments they received that the MOU amounts to an unfunded mandate because it is "voluntary". However, FDA's defines the term "distribution" in the MOU to include patient specific dispensing. As a result, if a state does not sign, the economic impact on pharmacies and the healthcare impact on their out-of-state patients would be considerable. It would be critical that FDA conduct a comprehensive collection of information on the MOU so that OMB, as well state boards of pharmacy, state legislatures, pharmacy stakeholders and the public can have a more complete picture of what state resources will be necessary to meet the MOU's requirements.

We also have specific concerns regarding the content of two sections of the MOU.

1. Section III.a.5 provides:

> As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network5 or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).

This provision should be changed to require the submission as soon as possible, but no later than 5 business days after *discovering* that a complaint involves a serious adverse drug experience or serious product quality issue. Complaints are often submitted without complete information regarding the circumstances, including whether the incident involved a serious adverse drug experience or serious product quality issue and whether drug product compounded at a pharmacy and distributed outside the State. As written this section would potentially require the agency to report a complaint before identifying that the complaint met the requirements for reporting.

2. Section III.b.3.d provides:

> 3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
>
> . . .
>
> d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

This section is confusing and in conflict with the stated purpose of the MOU. If a pharmacy distributes compounded human drug products without valid prescription orders for individually identified patients, then it would be compounding drugs as a 503B outsourcing

facility and would fall outside the scope of the MOU which states that it does not apply to 503B facilities. Further, the Texas State Board of Pharmacy does not regulate outsourcing facilities.

I appreciate the opportunity to provide comments. Thank you for your consideration of our input. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Allison Vordenbaumen Benz, R.Ph., M.S
Executive Director/Secretary

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0030]

Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (final standard MOU). The final standard MOU describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

DATES: The announcement of the MOU is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. FDA is withdrawing its revised draft standard MOU that published on September 10, 2018 (83 FR 45631), as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit electronic comments on the final standard MOU to Docket No. FDA-2015-N-0030. Submit written comments on the final standard MOU to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the final standard MOU to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft document.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993-0002, 240-402-4078.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following sections of the FD&C Act: (1) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act). Another condition to qualify for the exemptions listed in section 503A of the FD&C Act is that the drug is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.

Section 503A(b)(3)(B) of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i).

FDA is withdrawing the revised draft standard MOU entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration," which was issued in September 2018 (2018 revised draft standard MOU). The 2018 revised draft standard MOU is superseded by the final standard MOU.

II. Previous Efforts to Develop a Standard MOU

In the *Federal Register* of January 21, 1999 (64 FR 3301), FDA announced the availability for public comment of a draft standard MOU, developed in consultation with NABP (1999 draft standard MOU). Over 6,000 commenters submitted comments on the 1999 draft standard MOU. Because of litigation over the constitutionality of the advertising, promotion, and solicitation provision in section 503A of the FD&C Act,[1] the draft standard MOU was not completed. In 2013, section 503A of the FD&C Act was amended by the Drug Quality and Security Act (DQSA) (Pub. L. 113-54) to remove the advertising, promotion, and solicitation provisions that were held unconstitutional, and FDA took steps to implement section 503A, including to continue to develop the standard MOU. In the *Federal Register* of February 19, 2015 (80 FR 8874), FDA withdrew the 1999 draft standard MOU and issued the 2015 draft standard MOU for public comment. FDA received more than 3,000 comments on the 2015 draft standard MOU. In the *Federal Register* of September 10, 2018 (83 FR 45631), FDA withdrew the 2015 draft standard MOU and issued the 2018 revised draft standard MOU for public comment. FDA received 38 comments during the comment period on the 2018 revised draft standard MOU. By this notice, FDA is withdrawing the 2018 revised draft standard MOU and issuing a final standard MOU, which the Agency developed in consultation with NABP for use by the States in complying with section 503A(b)(3)(B).

III. Final Standard MOU

In consultation with NABP, FDA has developed a final standard MOU. FDA considered the comments submitted on the 2015 draft standard MOU and 2018 revised draft standard MOU,

[1] The conditions of section 503A of the FD&C Act originally included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002. See *Thompson v. Western States Med. Ctr*., 535 U.S. 357 (2002).

as well as comments on the MOU provisions it received in connection with a draft guidance on section 503A of the FD&C Act entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (2013 draft 503A guidance) (see 78 FR 72901, December 4, 2013). Below, FDA has summarized and discussed key provisions of the final standard MOU and, where appropriate, summarized changes that the Agency made in the final standard MOU. Drug products intended for veterinary use, repackaged drug products, biological products subject to licensure through a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), and drug products compounded by outsourcing facilities under section 503B of the FD&C Act are not the subject of the final standard MOU.

A. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

The final standard MOU provides that a State Board of Pharmacy or other appropriate State agency that enters into the MOU agrees to:

- Investigate complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy in the State and distributed outside the State. Investigations performed by the State Board of Pharmacy or other appropriate State agency under this MOU will include taking steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained. Investigations will be performed pursuant to the State Board of Pharmacy's or other appropriate State agency's established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of the MOU;

- If the complaint is substantiated, take action that the State Board of Pharmacy or other appropriate State agency considers to be appropriate and warranted, in accordance with and as permitted by State law, to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur;
- Maintain records of the complaints it receives regarding adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State Board of Pharmacy or other appropriate State agency receives notice of the complaint. The State Board of Pharmacy or other appropriate State agency will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
- Notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov as soon as possible, but no later than 5 business days, after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a human drug product compounded at a pharmacy and distributed outside the State, and provide FDA with certain information about the complaint, including the following: name and contact information of the complainant, if available; name and address of the pharmacy that is the subject of the complaint; and a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

- Share with FDA, as permitted by State law, the results of the investigation of a complaint after the State Board of Pharmacy or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue. This information includes the following: the State Board of Pharmacy's or other appropriate State agency's assessment of whether the complaint was substantiated, if available; and a description and the date of any actions the State Board of Pharmacy or other appropriate State agency has taken to address the complaint;
- Notify the appropriate regulator of physicians within the State of complaints of which the State Board of Pharmacy or other appropriate State agency receives that involve an adverse drug experience or product quality issue relating to human drug products compounded by a physician and distributed outside the State. The State Board of Pharmacy or other appropriate State agency will also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov as soon as possible, but no later than 5 business days, after receiving the complaint of the following information, if available: name and contact information of the complainant; name and address of the physician that is the subject of the complaint; and description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

The types of complaints of compounded drug products that should be investigated include any adverse drug experience and product quality issues. Even non-serious adverse drug experiences and product quality issues can be indicative of problems at a compounding facility that could result in product quality defects leading to serious adverse drug experiences if not corrected. For example, inflammation around the site of an injection can indicate drug product

contamination from inadequate sterile practices at the compounding pharmacy. If the pharmacy or physician has inadequate sterile practices, other more serious contamination could result in serious adverse drug experiences.

The final standard MOU does not include specific directions to the State Boards of Pharmacy or other appropriate State agencies relating to how to conduct their investigation of complaints. Rather, as recommended by comments submitted to FDA previously, the details of such investigations are left to the State Board of Pharmacy's or other appropriate State agency's discretion. For example, a State Board of Pharmacy or other appropriate State agency may review an incoming complaint describing an adverse drug experience and determine that such a complaint does not warrant further investigation. In other cases, a State Board of Pharmacy or other appropriate State agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

The State Board of Pharmacy or other appropriate State agency signing the final standard MOU would agree to notify FDA about certain complaints and provide FDA with certain information about the complaints so FDA could investigate the complaints itself, or take other appropriate action. The 2018 revised draft standard MOU provided that notification would occur as soon as possible, but no later than 3 business days of receipt of the complaint. The final standard MOU provides that notification will occur as soon as possible, but no later than 5 business days after the State Board of Pharmacy or other appropriate State agency receives the complaint. This period will continue to facilitate early Federal/State collaboration on serious adverse drug experiences and serious product quality issues that have the potential to affect patients in multiple States, while providing for notification in a timeframe that is more feasible for the State Boards of Pharmacy or other appropriate State agencies. FDA increased the time

for notifying FDA in the final standard MOU in response to comments expressing concern about having sufficient time to process complaints and notify FDA. We note that FDA has staff on call 24 hours a day to receive information in emergency situations.

Comments on the 2015 draft MOU expressed concern with certain provisions regarding States entering into the MOU and agreeing to take action not permitted by State law or implying that, after taking action, the State made a legal determination that a complaint had been resolved. The revised draft standard MOU clarified that the State should investigate and take action that the State considers to be appropriate with respect to the complaint in accordance with and as permitted by State law. FDA also clarified that, by signing the MOU, the State agrees to take steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained rather than make definitive determinations of risk or confirm containment. The final standard MOU retains these revisions that addressed the concerns from comments on the 2015 draft.

B. *Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate*

For purposes of the final standard MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they are compounded during that same calendar year (Fig. 1). This concept is called the 50 percent threshold.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies that enter into the MOU will agree to:

- On an annual basis, identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the State Board of Pharmacy or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate.
- For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the State Board of Pharmacy or other appropriate State agency will identify, using data submitted to the Information Sharing Network or other available mechanisms, during that same calendar year:
    - The total number of prescription orders for sterile compounded human drug products distributed interstate;

- The names of States in which the pharmacy is licensed;
- The names of States into which the pharmacy distributed compounded human drug products; and,
- Whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

- Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, the State Board of Pharmacy or other appropriate State agency will notify FDA, by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the following information:
  - Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;
  - The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;
  - The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they are compounded during that same calendar year;
  - Total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;
  - Total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

- The names of States in which the pharmacy is licensed as well as the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and
- Whether the State Board of Pharmacy or other appropriate State agency inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescriptions for individually identified patients during that same calendar year.

- If the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, it will notify the appropriate regulator of physicians within the State. The State Board of Pharmacy or other appropriate State agency will, within 30 days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

Section 503A of the FD&C Act reflects Congress' recognition that compounding may be appropriate when it is based on receiving a valid prescription order or notation approved by the prescribing practitioner for an identified individual patient. However, drug products compounded under section 503A are not required to demonstrate that they are safe or effective, have labeling that bears adequate directions for use, or conform to CGMP. Congress, therefore, imposed strict limitations on the distribution of drug products compounded under section 503A to protect the public health and the integrity of the drug approval process.

In particular, Congress did not intend for compounders operating under these statutory provisions to grow into conventional manufacturing operations making unapproved drugs,

operating a substantial proportion of their business interstate, without adequate oversight. Although other provisions of the FD&C Act (e.g., the adulteration provisions regarding drugs prepared, packed, or held under insanitary conditions) apply to drugs compounded by State-licensed pharmacies and physicians that may qualify for the exemptions under section 503A of the FD&C Act, and although FDA may take action in appropriate cases against compounders whose drugs violate these provisions or that operate outside of the conditions in section 503A, Congress recognized that these compounders are primarily overseen by the States. However, if a substantial proportion of a compounder's drug products are distributed outside a State's borders, adequate regulation of those drug products poses significant challenges to State regulators. States face logistical, regulatory, and financial challenges inspecting compounders located outside of their jurisdiction. In addition, if a compounder distributes drug products to multiple States, it can be very difficult to gather the scattered information about possible adverse drug experiences or product quality issues associated with those drug products, connect them to the compounder, and undertake coordinated action to address a potentially serious public health problem.

Therefore, as a baseline measure, section 503A(b)(3)(B)(ii) of the FD&C Act limits the distribution of compounded drug products outside of the State in which they are compounded to 5 percent of the total prescription orders dispensed or distributed by a licensed pharmacist, pharmacy, or physician. It then directs FDA, in consultation with NABP, to develop a standard MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in and distributed outside such State. Development of the standard MOU involves FDA describing what inordinate amounts means and providing a mechanism for

addressing distribution of inordinate amounts of compounded human drug products interstate, as long as the State agrees to appropriately investigate complaints relating to drug products compounded in and distributed out of the State. The 5 percent limitation in section 503A(b)(3)(B)(ii) does not apply to drug products compounded in a State that has entered into the standard MOU under section 503A(b)(3)(B)(i).

In the 2015 draft standard MOU, FDA proposed that distribution interstate up to a 30 percent limit would not be inordinate, and that States entering into the MOU would agree to take action regarding pharmacists, pharmacies, or physicians that distribute inordinate amounts of compounded drug products interstate. FDA received a number of comments indicating that certain pharmacies, such as pharmacies located near State borders and home infusion pharmacies, distribute more than 30 percent of their compounded human drug products to patients interstate because, for example, the patients are located in another nearby State, or because few pharmacies compound a particular drug product to treat an uncommon condition for patients dispersed throughout the country. The comments noted that the proposed definition of inordinate amounts and the proposed provision in which States agree to take action could prevent such pharmacies from fulfilling patients' medical needs for the drug products that they supply. Other comments expressed concern about instances in which pharmacies are located near a State border and distribute compounded drug products to the other side of that border. FDA also received general comments questioning the Agency's basis for the 30 percent limit and indicating that it was too low. Some comments suggested that FDA increase the limit, including a suggestion to increase it to 50 percent.

The 2018 revised draft standard MOU addressed these comments in two respects. First, it removed the provision in the 2015 draft standard MOU that States agree to take action with

respect to the distribution of inordinate amounts of compounded human drug products interstate. Second, it changed what is considered "inordinate amounts" from a 30 percent limit to a 50 percent threshold. In the final standard MOU, the States are not agreeing to take action with respect to distribution of inordinate amounts of compounded human drug products interstate, but, instead, to notify FDA of pharmacies that have distributed an inordinate amount of compounded human drug products interstate. The Agency does not intend to take action against a pharmacy located in a State that has entered into the MOU solely because the pharmacy has exceeded the threshold for inordinate amounts. Rather, the State Board of Pharmacy or other appropriate State agency entering into the final standard MOU agrees to collect further information on pharmacies that have distributed inordinate amounts interstate and provide this information to FDA to help inform Agency inspectional priorities. The State Board of Pharmacy or other appropriate State agency also agrees to notify FDA and the appropriate state regulator of physicians if it becomes aware of physicians distributing any amount of compounded human drug products interstate.

We note that States generally have day-to-day oversight responsibilities over State-licensed pharmacies, pharmacists, and physicians. In general, FDA considers a State-licensed pharmacy or physician to be primarily overseen by the State, which is responsible both for regulation of the compounder and protection of its citizens who receive the compounded drug products. However, as discussed above, if a substantial proportion of a compounder's drug products is distributed outside a State's borders, adequate regulation of those drugs poses significant challenges to State regulators. In such cases, although State oversight continues to be critical, additional oversight by FDA may afford an important public health benefit.

As stated above, the final standard MOU uses 50 percent as the threshold beyond which the amount of compounded human drug products distributed interstate by a pharmacy would be

considered inordinate. The 50 percent threshold is the threshold that, with regard to pharmacies, triggers an information identification and reporting obligation once it is reached. The Agency believes that more than 50 percent is an appropriate measure of "inordinate amounts" because it marks the point at which pharmacies are distributing the majority of their compounded human drug products interstate, and the regulatory challenges associated with interstate distributors discussed above become more pronounced. At this point, the risk posed by the distribution practices of the compounder may weigh in favor of additional Federal oversight in addition to State oversight.

FDA recognizes that, in some cases, pharmacies may distribute more than 50 percent of a small quantity of compounded human drug products to contiguous States. Although such pharmacies have exceeded the inordinate amounts threshold in the final standard MOU, FDA would consider other information, such as the number of patients that will receive the compounded human drug products, if available, when assessing the pharmacy's priority for risk-based inspection. Accordingly, when a State Board of Pharmacy or other appropriate State agency identifies a pharmacy that distributes an inordinate amount of compounded human drug products interstate, the final standard MOU provides that the State entity will supply the Agency with certain information as described above. In addition, if the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the State entity will notify both the appropriate regulator of physicians within the State and FDA. FDA intends to use this information to prioritize its oversight of compounders based on risk, focusing on those that appear likely to distribute large volumes of compounded human drug products, particularly when the distribution

is to multiple States, the drug products are intended to be sterile, and there is information about a lack of valid prescriptions for individually identified patients.

The calculation of inordinate amounts in the final standard MOU, with clarifying changes to the language, is the same as the calculation proposed in the 2018 revised draft standard MOU, with the exception of a change in the timeframe used in the calculation from 1 month to 1 year and removing drugs compounded by physicians from the calculation made by the State Board of Pharmacy or other appropriate State agency. The 2015 draft standard MOU provided that a compounder is considered to have distributed an inordinate amount of compounded drug products interstate if the number of units of compounded drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such compounder during that calendar month. FDA received comments noting that because the calculation includes both compounded and non-compounded drug products, in many cases, a substantial factor in whether a compounder has distributed an inordinate amount of compounded drug products interstate is whether the compounder offers non-compounded drug products. For example, under that policy, many specialty compounding pharmacies that engage in distribution of compounded human drug products interstate and only distribute compounded drug products would be able to distribute fewer compounded drug products interstate before reaching an inordinate amount than a pharmacy that also fills prescriptions for non-compounded drug products, even if both pharmacies produced the same amount of compounded drug products. After considering the public comments, FDA does not believe that including non-compounded drug products within the calculation of inordinate amounts would help address the public health concerns associated with sending compounded human drug products interstate that

Congress sought to address in section 503A(b)(3)(B) of the FD&C Act. Non-compounded drug products were excluded from the calculation of inordinate amounts in the 2018 revised draft MOU. This final standard MOU maintains this exclusion.[2] FDA removed drug products compounded by physicians from the inordinate amount calculation to clarify that the State Board of Pharmacy or other appropriate State agency signing the MOU does not agree to gather information about the distribution of compounded drug products interstate by physicians or to calculate inordinate amounts of drug products compounded by a physician and distributed interstate. Instead, the State Board of Pharmacy or other appropriate State agency signing the MOU agrees that if it becomes aware that a physician is distributing any amount of compounded human drug products interstate it will notify the State authority that regulates physicians and FDA. This focus on States calculating inordinate amounts of pharmacy compounding reflects FDA's understanding and feedback from State regulators that the distribution interstate of compounded drug products mainly involves pharmacy compounders.

FDA received comments on the 2018 revised draft MOU expressing concern about calculating inordinate amounts by calendar month. After considering these comments and recognizing the possibility for significant monthly fluctuations, we have provided for annual calculation of inordinate amounts in the final standard MOU.

This 50 percent threshold does not function as a limit on the distribution of compounded human drug products interstate, but, instead, is a threshold for triggering information gathering about pharmacy distribution of compounded drugs by the State Board of Pharmacy or other

[2] FDA also intends to exclude non-compounded drugs from the calculation of the 5 percent limit in section 503A(b)(3)(B)(ii).

appropriate State agency and provision to FDA. The information gathered will be considered by the Agency for the purpose of helping to inform its risk-based inspection priorities.

C. Definitions

Appendix A retains the definitions of "adverse drug experience," "serious adverse drug experience," "product quality issue," and "serious product quality issue" from the 2018 revised draft standard MOU.

To clarify the meaning of "distribution of inordinate amounts of compounded drug products interstate," the proposed definition of "distribution" in the 2018 revised draft standard MOU has been omitted and "distribution of compounded human drug products interstate" and "inordinate amounts" are defined. "Distribution of compounded human drug products interstate" means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded. A pharmacy has distributed an "inordinate amount" of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (1) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (2) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

We received a number of comments on the 2015 draft standard MOU and the 2018 revised draft standard MOU stating that distributing and dispensing are mutually exclusive activities, such that if a drug product is distributed, it is not also dispensed, and vice versa. Some

comments asserted, in particular, that a compounded drug product should not be considered to be "distributed" when it is provided pursuant to a prescription. Other stakeholders, however, agreed with the inclusion of drug products provided pursuant to a prescription within the definition of "distribution" and maintained that this interpretation was important to protect the public health.

After considering these comments and the public health objectives of section 503A(b)(3)(B) of the FD&C Act, FDA considers that when a drug is picked up at the facility in which it was compounded, dispensing, but not distribution, occurs for purposes of 503A(b)(3)(B).

FDA believes that in-person dispensing, where the transaction between the compounder and the patient is completed at the facility in which the drug product was compounded, is appropriately overseen, primarily, by the State outside the context of the MOU, regardless of whether the compounded drug product subsequently leaves the State. Such an intrastate, local transaction generally indicates a close connection among the patient, compounder, and prescriber. By contrast, transactions by mail often have a less direct nexus among the patient, compounder, and prescriber than in-person pick-ups and would be considered "distribution."

Drugs dispensed in-person that are later taken out of State will not contribute to reaching the threshold for inordinate amounts under the final MOU. Nor will complaints associated with compounded drug products dispensed this way and subsequently taken out of State be subject to the complaint investigation provisions of the final MOU. FDA expects that, in practice, the State in which the initial transaction occurred would handle such complaints. The State may, in its discretion, notify FDA of the complaint.

FDA is not persuaded by comments urging the Agency to interpret "distribution" and "dispensing" to be entirely separate activities for purposes of section 503A(b)(3)(B) of the

FD&C Act. These comments recommend using definitions for these terms used elsewhere in the FD&C Act and FDA regulations, and generally conclude that distribution does not include the transfer of a drug pursuant to a prescription.

The conditions in section 503A, including section 503A(b)(3)(B), must be interpreted consistent with the prescription requirement in section 503A(a) of the FD&C Act. If we were to interpret the word "distribution" to apply only if a drug is provided without a prescription, it would mean that drug products compounded under section 503A of the FD&C Act are excluded from regulation under the MOU and the 5 percent limit, because to qualify for the exemptions under section 503A, a compounder must obtain a valid prescription order for an individually identified patient. For the reasons stated previously in this document, we believe this would achieve the opposite of what Congress intended. A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient."

Nor is there anything to suggest that Congress understood "distributed" and "dispensed" to be mutually exclusive categories rather than overlapping categories for purposes of section 503A. Section 503A(b)(3)(B) of the FD&C Act does not define "distribution" to exclude dispensing, which Congress has done elsewhere when that was its intention.[3] The definition

[3] In other (non-compounding) contexts, where it would further a regulatory purpose, Congress and the Agency have specifically defined "distribute" to exclude dispensing. See, for example, section 581(5) of the FD&C Act (21 U.S.C. 360eee(5)), which applies to Title II of the DQSA, and 21 CFR 208.3, which applies to 21 CFR part 208. Section 503A of the FD&C Act does not contain a similar definition, or a similar specific direction to exclude dispensing from the meaning of distribution. We also note that these definitions were adopted for provisions that focus on conventionally manufactured drug products, which assign different obligations to dispensers than to wholesalers, packagers, or other intermediaries in light of the different role that dispensers play with respect to product labeling and the drug distribution chain. In contrast, section 503A of the FD&C Act focuses on

proposed by comments would write an exclusion for dispensing, in its entirety, into the statute where Congress did not. Indeed, with respect to comments suggesting that drugs dispensed pursuant to prescriptions could not also be "distributed," we note that, in section 503A(b)(3)(B), Congress specifically contemplated that prescription orders could be "distributed" when it directed the Agency to count the number of prescription orders that pharmacists and prescribers distributed.

IV. Other Issues

A. Authority of State Boards of Pharmacy or other Appropriate State Agencies

The 2018 revised draft standard MOU proposed that "States" would be the signatories of the MOU. In the final standard MOU, FDA clarifies the State party to the agreement, which is described as the "State Board of Pharmacy or other appropriate State agency." FDA received comments expressing concerns that the State entity signing the MOU (e.g., the State Board of Pharmacy) may not have regulatory authority over physician compounding and could not agree to the MOU provisions regarding physicians as they appeared in the 2018 revised draft standard MOU. With regard to physician compounding, FDA has revised certain provisions from the 2018 revised draft standard MOU. Under the final standard MOU, a State Board of Pharmacy or other appropriate State agency would enter into the MOU on behalf of the State and agree to (1) notify FDA and the appropriate regulator of physicians within the State when it receives a complaint about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if it becomes

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compounded drugs, and the reasons for defining "distribution" to exclude dispensing in Title II of the DQSA or part 208 do not apply.

aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State.

B. Physician Compounding

It is FDA's understanding that physicians who compound drugs generally do so for their own patients, within their own professional practice, and provide them intrastate. FDA believes that, generally, physicians are not engaged in compounding that results in routine distribution of compounded drug products interstate.

Additionally, several comments advised that State Boards of Pharmacy do not oversee physician compounding and would not be able to agree to the provisions under the 2018 revised draft standard MOU with respect to oversight of physician compounding (collecting additional information to identify whether a physician compounder is distributing inordinate amounts of compounded drug products interstate, etc.). Accordingly, under the final standard MOU, State Boards of Pharmacy or other appropriate State agencies would agree to (1) notify FDA and the appropriate regulator of physicians within the State when they receive complaints about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if they become aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State. The information provided to FDA will help inform Agency inspectional priorities with respect to physicians who compound human drug products and provide information to State regulators of physicians for appropriate action.

C. Development of a Standard MOU

A number of comments on the 1999 draft standard MOU, the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft MOU suggested that FDA negotiate

MOUs with individual States, rather than develop a standard MOU. Section 503A of the FD&C Act requires the Agency to develop a standard MOU for use by the States. Furthermore, it would be impractical to develop an individualized MOU with every State, and creating individualized MOUs would create a patchwork of regulation of distribution of compounded human drug products interstate by compounders seeking for their drug products to qualify for the exemptions under section 503A of the FD&C Act. This would be confusing to the healthcare community, as well as regulators.

D. Exemptions from the Provisions Related to Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate

Some comments on the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft standard MOU requested that we consider exempting certain drug products or types of compounding entities from the threshold in the MOU and the 5 percent limit. For example, some comments recommended that we exempt nonsterile products.

American consumers rely on the FDA drug approval process to ensure that medications have been evaluated for safety and effectiveness before they are marketed in the United States. Drugs made by compounders, including those made at outsourcing facilities, are not FDA-approved. This means that they have not undergone premarket review of safety, effectiveness, or manufacturing quality. Therefore, when an FDA-approved drug is commercially available, FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug product unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

In section 503A of the FD&C Act, Congress enacted several conditions to differentiate compounders from conventional manufacturers and provided that only if the compounders meet those conditions can they qualify for the exemptions from the drug approval requirements in section 505 of the FD&C Act. One of those conditions relates to limitations and other measures to address distribution of compounded drug products interstate, and FDA intends to enforce those provisions to differentiate compounding that qualifies for the exemptions from conventional manufacturing in the guise of compounding that does not and will apply the conditions to all types of drugs and all categories of compounding.

E. Information Sharing Between the State Boards of Pharmacy or Other Appropriate State Agencies and FDA

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies will agree to notify FDA of a complaint relating to a compounded human drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue and provide information about those experiences and issues. The final standard MOU also provides that State Boards of Pharmacy or other appropriate State agencies will notify FDA if they identify a pharmacy that has distributed inordinate amounts of compounded human drug products interstate. In addition, State Boards of Pharmacy or other appropriate State agencies will notify FDA and the appropriate regulator of physicians within the State if the State entity becomes aware of a physician who is distributing any amount of compounded human drug products interstate, or if the State entity receives a complaint involving an adverse experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State.

FDA has entered into a cooperative agreement with NABP to establish an information sharing network that is intended to, in part, facilitate State information reporting to FDA by State Boards of Pharmacy or other appropriate State agencies that enter into the MOU with FDA addressing distribution of compounded drugs interstate.[4] The goal of this information-sharing and research initiative is to improve the management and sharing of information available to State regulators and FDA regarding State-licensed compounders and the distribution of compounded human drug products interstate to support better and more targeted regulation and oversight of compounding activities to help reduce risk to patients. This information will be important to help States to focus their limited resources on compounders for which they have primary oversight responsibility that present the greatest risk. It will also facilitate FDA's ability to determine when additional Federal oversight is warranted, such as when a large-scale compounder distributes drug products to multiple States, potentially causing significant and widespread harm if its products are substandard. FDA expects that the information sharing network will be designated by FDA for purposes of the MOU to collect, assess, and allow review and sharing of information pursuant to the MOU. FDA regularly posts, on its compounding website, information about enforcement and other actions related to compounders that violate the FD&C Act, and it is obligated to share certain information with States under section 105 of the DQSA. In addition to these measures, FDA is taking steps to proactively share information with States about complaints that it receives regarding compounded drug products, consistent with Federal laws governing information disclosure.

F. Enforcement of the 5 Percent Limit on Distribution of Compounded Human Drug Products Out of the State in Which They Are Compounded

[4] See RFA-FD-19-025, available at https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-19-025.html.

In the 2013 draft 503A guidance, FDA stated that it does not intend to enforce the 5 percent limit on distribution of compounded human drug products outside of the State in which they are compounded until 90 days after FDA has finalized a standard MOU and made it available to the States for their consideration and signature. Most comments on the 2013 draft 503A guidance that raised this issue said this period was too short but did not recommend a specific alternative. A few comments recommended a different timeframe, one recommending 120 days and another recommending 365 days. The 1997 Senate Committee Report for the Food and Drug Administration Modernization Act suggests that a 180-day period for States to decide whether to sign might be appropriate.[5] In the notice of availability for the 2018 revised draft standard MOU, consistent with the 2015 draft standard MOU, the Agency proposed a 180-day period after the final standard MOU is made available for signature before FDA will enforce the 5 percent limit in States that have not signed the MOU, and invited public comment on whether this was an appropriate timeframe. Some commenters on the 2018 revised draft standard MOU stated that more time may be necessary because some States may be required to enact new laws and promulgate new regulations before entering the MOU. Therefore, in response to these comments, FDA is providing a 365-day period for States to decide whether to sign the MOU before FDA intends to begin enforcing the 5 percent limit in States that do not sign. It is FDA's understanding that this extended timeframe corresponds to a full legislative cycle for most States and should, therefore, afford sufficient time for States to modify their laws and regulations, if necessary.

[5] "[U]ntil the State . . . enters into a memorandum of understanding (MOU) with the Secretary or 180 days after the development of the standard MOU, whichever comes first, the [section 503A] exemption shall not apply if inordinate quantities of compounded products are distributed outside of the State in which the compounding pharmacy or physician is located." (U.S. Senate Committee Report)

V. Paperwork Reduction Act of 1995

This MOU refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information have been approved under OMB control number 0910-0800.

VI. Electronic Access

Persons with access to the internet may obtain the final standard MOU at either https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, or https://www.regulations.gov.

Dated: October 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-23687 Filed: 10/26/2020 8:45 am; Publication Date: 10/27/2020]

Women's International Pharmacy
Custom Compounded Prescriptions for Men and Women

July 9, 2020

Wisconsin Pharmacy Examining Board
Department of Safety and Professional Services
4822 Madison Yards Way
Madison WI 53705

RE: Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State Boards of Pharmacy and the U.S. Food and Drug Administration.

Dear Members of the Board,

We represent Women's International Pharmacy (WIP), a retail pharmacy specializing in compounding patient-specific medications containing bioidentical hormones for women and men. We are a local Madison, Wisconsin-based business that was founded in 1985 and currently has approximately 60 employees. WIP is nationally-recognized for its compounded hormone medications and its services are utilized by prescribers nationwide. Thousands of patients, both in Wisconsin and around the country, rely on WIP for individualized compounded hormone medications. WIP is licensed in, and dispenses patient-specific compounded medications to, all 50 states, the District of Columbia, Puerto Rico and Guam.

As you may be aware, as part of the Drug Quality and Security Act of 2013 (DQSA), FDA was tasked with developing a memorandum of understanding (MOU) with the States that addresses the interstate *distribution* of inordinate amounts of compounded drugs and provides for appropriate investigation of complaints relating to compounded drugs *distributed* interstate. FDA has now finalized that MOU and it is currently under review by the United States Office of Management and Budget (OMB). OMB will determine the financial impact of the MOU and whether it meets the requirements of the federal Paperwork Reduction Act. If OMB approves the MOU, it will be released to the States to either sign or reject. The MOU will go into effect 365 days, i.e. one year, from the date upon which it is released to the States for signature.

The MOU is exceedingly problematic for two main reasons. First, if a particular State chooses ***not*** to enter into the MOU, the DQSA provides that compounding pharmacies in that State cannot distribute compounded medication out of the State in excess of five percent (5%) of the total prescription orders dispensed or distributed by that pharmacy. In other words, if a State declines to enter into the MOU with FDA, resident compounding pharmacies in that State will be

almost entirely restricted to in-state commerce and will not be able to meaningfully participate in interstate commerce. Resident compounding pharmacies, especially those who serve patients throughout the country like WIP, will see an immediate and disastrously detrimental decline in business. Resident compounding pharmacies will have no choice but to cut staff, downsize pharmacy facility size, space, and equipment, and eliminate most, if not all, compounding, thereby resulting in significant lost revenue. It goes without saying that this will have a profoundly negative impact on the State economy, pharmacy practices, and patient health.

Second, even if a State chooses to enter into the MOU with FDA, the terms of the MOU are burdensome for both State boards of pharmacy and the retail pharmacies they regulate, and the consequences of complying with the MOU are frustratingly unclear for regulators, pharmacies, and patients.

As a threshold matter, despite the fact that the DQSA directs FDA to regulate the *distribution* of compounded medication by way of the MOU, FDA has defined the term *distribution* for purposes of the MOU to include patient-specific dispensing, thereby allowing FDA to regulate the amount of compounded medication a pharmacy dispenses *and* distributes interstate.[1] The MOU then places a 50-percent threshold on all compounded drugs that leave a pharmacy by defining "inordinate amounts of compounded human drug products" as follows:

> **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.

MOU at App. A (footnote omitted). Although not a hard cap, the MOU clearly establishes that compounding pharmacies will incur increased FDA scrutiny if more than 50 percent of their business is conducted out of state.

[1] "**Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded." MOU at App. A (emphasis in original). FDA ignores the fact that the terms "dispense" and "distribute" are universally-recognized distinct activities in pharmacy practice and is using the MOU as an opportunity to extend the reach of its regulatory authority to include patient-specific dispensing.

Per the MOU, the burden to police whether a compounding pharmacy has met this "50 percent threshold" falls to the States. States that sign on to the MOU must, on an annual basis, identify, "using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [State], pharmacies that distribute inordinate amounts of compounded human drug products interstate." MOU § III.b.2 at 5. If a pharmacy is identified as having distributed inordinate amounts interstate, States must provide additional information to FDA, including prescription data, licensing information, inspection observations, and the States into which the pharmacy distributed compounded medication. MOU § III.b.3 at 5. In addition, for those States that have identified a pharmacy to have met the "50-percent threshold," the MOU provides that within 30 days of such identification, States must notify FDA and provide FDA with *seven* categories of information about that particular pharmacy. MOU § III.c.1.b at 7.

The States' obligations under the MOU are entirely unfunded. Each State that signs on to the MOU will need to allocate resources sufficient to comply with the terms of the MOU and where those resources will come from is a mystery. Many States may simply pass that burden on to the compounding pharmacies, which will inevitably cause economic harm. All pharmacies located in States that sign the MOU will, at a minimum, have to gather and provide information to their home States in order for those States to establish whether such pharmacies have distributed compounded drugs in what FDA deems to be inordinate amounts. If such pharmacies are found to have reached the "50-percent threshold", that data-gathering and reporting increases significantly. Given the extent of information required under the MOU, pharmacies like WIP will need to hire additional staff to handle the data-gathering and reporting requirements, and/or will be forced to reallocate staff whose time would be better served focusing on the preparation of compounded medications to meet patient needs.

Furthermore, what FDA intends to do with the information obtained from States, such as whether FDA will conduct increased inspections or take enforcement action against pharmacies so identified, is unclear. Compounding pharmacies like WIP are entirely in the dark as to what will come next if they are deemed to have distributed in "inordinate amounts." This regulatory uncertainty, coupled with the increased data-gathering and reporting burden, may deter pharmacies from reaching the "50-percent threshold," thereby reducing patient access to compounded medication when pharmacies curtail interstate dispensing of compounded drugs.

Finally, and perhaps most alarming, even if a State signs the MOU, it permits a State to terminate its participation with just 60 days' notice. State pharmacy board and licensing departments often change on an annual basis, which would mean a State's position on whether to continue its participation could change annually. Compounding pharmacies have no control over a State's decision to terminate its participation under the MOU. As a result, compounding pharmacies' economic livelihoods, and patient access to the medications they dispense, could change in just two months.

The MOU could be approved by OMB and released to the States for signature any day now. It is abundantly clear that FDA has put States and compounding pharmacies, between a rock and a hard place. Regardless of which path the States choose, businesses and patients suffer. Accordingly, we respectfully request that the Wisconsin Pharmacy Examining Board perform the following actions to ensure the continued operations of compounding pharmacies in this State and, most importantly, patient access to compounded medications:

1. Share what your authority is as a Board to sign or not to sign the MOU;

2. Express concern and displeasure to the FDA and OMB over the terms of the MOU. Several States have already done so, including Arizona, Texas and South Carolina (examples attached);

3. If OMB approves the MOU, we ask that the Board sign the MOU. When faced with the prospect of a 5% limit on interstate distribution and dispensing, the MOU, despite its glaring flaws, is the only viable option to preserve patient access to much needed medications and avoid significant economic injury; and

4. Lastly, if the Board signs the MOU, we ask that the Board craft regulations designed to prevent the unilateral termination of the MOU on 60 days' notice, including allowing for sufficient notice and comment from resident compounding pharmacies like WIP before termination.

Thank you for your consideration and please contact us with any questions.

Sincerely,

Gina Besteman, R.Ph.
Director of Compounding and Dispensing

Michelle Violi, Pharm. D.
Dispensing Pharmacists Manager

Women's International Pharmacy
2 Marsh Ct
Madison WI 53718
800-699-8144

Enclosures: 4

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Preparing for FDA's Compounding MOU

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FDA's Compounding MOU Raises Questions Among Boards of Pharmacy

The impending implementation of the Food and Drug Administration (FDA) "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products" (MOU) has introduced many questions among the state boards of pharmacy.

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Questions Include:

- When will the MOU be finalized?
- What obligations will it place on the boards of pharmacy?
- How will it impact state oversight of 503A pharmacies?
- What information will be required to collect and share?
- What IT and personnel resources will be needed?
- What mechanism will be used to collect, manage, and share information?
- When does a board need to share complaints regarding compounders with the FDA?

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What Information Must Boards of Pharmacy Flag for FDA?

Per the MOU, boards must identify for FDA:

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate*
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate

*The distribution of inordinate amounts interstate is a threshold for the board of pharmacy to identify and report certain information to FDA, not a limit on the distribution of compounded products interstate.

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What Information Must Boards Flag for FDA?

- Boards will determine if a pharmacy is compounding inordinate amounts using either:
  - Surveys, or
  - reviews of records during inspections, or
  - information-sharing network (NABP's system), or
  - other available mechanisms
- The MOU does not require the board to input compounding pharmacy data into the information-sharing network.
- The MOU allows the board to meet its obligation to determine compounding of inordinate amounts solely through use of the information-sharing network.

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NABP Develops System for Collecting and Sharing Information Specified in the MOU

- The information-sharing network is being developed using a grant provide by FDA to NABP for a pilot project to build the network and evaluate its accuracy and usefulness
- FDA recognized there is no centralized system to collect and share data from compounding pharmacies distributing interstate, and thus the grant was established
- FDA is eager to partner with NABP and boards to protect patients from high-risk compounders
- FDA agrees the network will be a key to assisting boards in their efforts to comply with the MOU, understanding the lack of board resources

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How is NABP Building the New Information Sharing System?

- NABP is adapting its existing NABP e-Profile Connect data management system to meet the needs of the new information-sharing network
- e-Profile Connect provides state boards of pharmacy with information on each individual pharmacist, technician, student/intern, and facility in the system
- With this framework already in place, NABP is adapting the system to enable the collection, management, and sharing of information pertaining to compounders

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Implementation Begins with Pilot Project

- Development of the new information-sharing network began in June 2020 as part of a three-year pilot project
- Implementation of the network is expected to begin in early 2021 with the collection of information from compounding pharmacies
- Boards of pharmacy will have access to this information and the ability to supplement it
- Subsequently, NABP will evaluate the usability of the network and the accuracy of the information collected during the pilot and present a final analysis to FDA

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How Will the Project Meet the Goal of Improving Compounding Pharmacy Oversight?

- Enable the collection, management, and sharing of information regarding compounding pharmacies in the US
- Provide boards of pharmacy with a tool to report compounding pharmacy information to FDA, giving access to data that will inform oversight determinations
- Enable boards of pharmacy to better prioritize their resources to address compounding pharmacies that pose the highest risk to patients
- Foster better, more targeted oversight of compounding pharmacies

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System Will Provide New Capabilities for Boards of Pharmacy

- Expands current e-profile connect system
- Adds data fields outlined in the MOU to the pharmacy facility profiles found in the e-profile connect system
- Allows boards and pharmacies to enter data
- Boards will be able to review and annotate information provided by licensees, and upload documents, including complaints and inspection forms

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System Will Identify Certain Data for FDA

- The system will notify boards about pharmacies whose submitted data show that they are distributing inordinate amounts of compounded human drugs interstate
- And it will require boards of pharmacy to approve the submission of such data to FDA prior to it being transmitted
- It will also require the affirmative approval by a board prior to the submission to FDA of any complaint

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What Information Will Be Collected From Pharmacies?

Regarding the distribution or dispensing of compounded human drug products, the system will collect the following information from the pharmacy:

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
  - Human drug compounding – sterile
  - Human drug compounding – nonsterile
  - Patient-specific compounding
  - Non-patient-specific compounding

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If a Pharmacy Is Compounding Sterile or Nonsterile Human Drug Products, the Following Information Will Also Be Collected or Calculated:

- Number of prescription orders for compounded drugs the pharmacy sent out
- Number of prescription orders for compounded drugs dispensed at the facility
- Total number of prescription orders for compounded drugs sent out or dispensed at the facility*
- Total number of prescription orders for compounded drugs distributed interstate
- Percentage of compounded drugs distributed interstate*

*Calculated by the system

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Also to Be Collected:

- Number of prescription orders for sterile compounded drugs distributed interstate
- Names of states in which pharmacy is licensed
- Names of states into which pharmacy distributed compounded drugs during the year
- Whether compounded drugs are distributed without patient-specific prescriptions

If the board has the compounding pharmacy data referenced here, the board will be able enter it into the facility's e-profile.

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Notifying FDA of Inordinate Amounts

Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drugs interstate during the identified calendar year, and upon approval by the board, the system will provide FDA with the following information about such pharmacies:

1. Name and address of the pharmacy
2. The number of prescription orders for compounded human drugs that the pharmacy sent out of (or caused to be sent out of) the facility in which the drugs were compounded
3. The number of prescription orders for compounded human drugs that were dispensed (e.g. picked up by the patient) at the facility in which they were compounded

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Notifying FDA of Inordinate Amounts

4. The total number of prescription orders for compounded human drugs distributed interstate
5. The total number of prescription orders for sterile compounded human drugs distributed interstate
6. The names of the states in which the pharmacy is licensed
7. The names of the states in which the pharmacy distributed compounded human drugs
8. Whether the board inspected for and found during its most recent inspection that the pharmacy distributed compounded human drugs without valid prescription orders for individually identified patients

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Notifying FDA of Pharmacy Complaints

Regarding complaints involving a serious adverse drug experience or serious product quality issue related to human drug products compounded by a pharmacy and distributed outside the state, the board will enter into the system:

1. Name and contact information of the complainant, if available
2. Name and address of pharmacy that is the subject of complaint
3. Description of complaint, including description of any compounded human drug product that is the subject of complaint
4. The board's assessment of whether the complaint was substantiated, if available
5. Description of any actions the board has taken to address the complaint
6. Copy of complaint or other relevant documents (optional upload)

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Notifying FDA of Pharmacy Complaints

Transmission of complaint information from system to FDA:

- As soon as possible after, but no later than five business days after receiving the complaint, and upon approval by the board, the system will provide FDA with the information found in items 1 – 3.
- After the board concludes its investigation of the compliant, and upon approval by the board, the system will provide FDA with the information found in items 4 – 5.

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Notifying FDA of Physician Complaints

Regarding complaints involving an adverse drug experience or product quality issue related to human drug products compounded by a physician, or regarding the distribution of any amount of human drug products compounded by a physician and distributed outside a state, the board will enter into the system:

1. Name and contact information of the complainant or notifier
2. Name and address of the physician who is the subject of the complaint or notification
3. A description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

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Notifying FDA of Physician Complaints

Transmission of Physician Complaint Information from system to FDA:

- Regarding complaints against physicians, as soon as possible but no later than five business days after receiving the complaint, and upon approval by the board, the system will transmit such complaint to FDA. In addition, the board must notify the state regulator of physicians.

Transmission of Physician Notification Information from system to FDA:

- Regarding the distribution of any amount of compounded products interstate by a physician, within 30 business days of identification of such physician, and upon approval by the board, the system will transmit this information to FDA. In addition, the board must notify the state regulator of physicians.

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Collection of Data From Pharmacies Will Be Through Two Pathways

1. Requesting compounding data through any application for one of our pharmacy accreditation programs *except* for the DMEPOS program, or through the VPP inspection application. The pharmacy will pay the regular accreditation or inspection application fee.
2. The data fields will be available through the pharmacy's e-profile. The pharmacy will set up an e-profile or access its already-established e-profile, then insert the data. There is no charge for this.

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How will NABP Encourage Pharmacies to Volunteer Requested Information?

- All pharmacies seeking accreditation will voluntarily submit the requested information – regardless of whether their primary intent is to participate in the pilot project
- Compounding pharmacies can enter the requested information outside of the accreditation application process
- All pharmacies submitting the requested data will have the opportunity to receive a VPP inspection at no cost to them.

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System Provides Transparency to Support Data-Driven Policy Decisions

- Boards of pharmacy and FDA will gain a better understanding of the interstate distribution of compounded drugs, including significant compliance issues
- Boards of pharmacy and FDA will be better positioned to advance public health protections associated with compounded drugs
- Boards of pharmacy will gain an ongoing means of reporting information relating to compounding pharmacies to FDA
- FDA will gain improved visibility to determine whether additional federal oversight is warranted

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Ultimately the Information-Sharing Network Will Reduce Patient Risk

- Boards will be able to better prioritize their limited resources to address compounding pharmacies posing the highest risk to patients
- The system will foster better and more targeted regulation and oversight of compounding pharmacies to reduce risk to patients

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Feedback from Boards Has Been Positive

- Vast majority of boards are in the process of determining whether to sign the MOU.
- Several boards have said they will surely sign the MOU.
- Some boards have said they do currently require or are considering requiring pharmacies to report data to the system.
- Very few have said they will not sign the MOU.
- NABP is in conversations with several boards about sharing compounding pharmacy data they already collect.

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Informational Resources

NABP's new website has a page dedicated to this project

- Background and details on the project
- Link to MOU
- FAQs
- Slide deck

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Thank You!

Arizona State Board of Pharmacy

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Talking Points on FDA Final MOU – FDA Underestimates Problems with Implementation

1. FDA estimates that 45 states will sign the MOU. This expectation is unrealistic. The National Association of Boards of Pharmacy (NABP) submitted comments to the FDA stating that at least 20 states indicated they will likely not sign because of either unfunded mandates or problems with the definition of distribution which includes dispensing. This definition of distribution is in conflict with state laws and the NABP model Pharmacy Act that defines distribution and dispensing as separate activities.

2. If fewer states sign, this will create problems for both pharmacies in those states and patients that these pharmacies serve as they would be limited to filling prescriptions across state lines to 5 percent of their total volume. Many pharmacies specialize in serving patients such as autistic children, women with hormonal imbalances, organ transplantation patients, individuals with pain management issues, and many other specialty groups. Many compounding pharmacies have a regional or national clientele, and the limits of the MOU if a state doesn't sign would be disastrous.

3. FDA projects that one state will terminate its participation in the MOU each year. This means that in 10 years, by FDA's estimate no more than 35 states will be party to the agreement.

4. With 60-days notice, either a state or the FDA can withdraw from the MOU. This creates tremendous uncertainty that adversely affects both pharmacies in that state and patients throughout the country.

5. State boards of pharmacy are dealing with the health care crisis created by COVID-19. They do not have the time or resources to consider the MOU at this time. State budgets have been hard hit by a decline of revenues as a result of COVID-19, and do not have the additional resources that implementing the final MOU requires.

6. FDA's analysis on the impact on state boards of pharmacy is based primarily on coordination with an "information sharing network" it has contracted NABP to develop. This network has not been developed, and it is unknown as to when it will be completed. A final network could take several years to complete, especially given the challenges of the current situation with COVID-19. Because of this, the cost to the states to comply far exceeds the estimated cost projected by FDA.

7. FDA states that the requirements of the final MOU are not an unfunded mandate because states don't have to sign it. However, given the penalties to pharmacies and patients that would result from a state not signing, every state will be obligated to devote resources to seeing if the MOU can be signed. If they do sign, they must absorb the additional cost especially since the "information sharing network" touted by FDA does not yet exist.

8. NABP has been tasked with creating the information sharing network. As such, NABP is a covered entity under HIPAA. FDA is not. Sharing potentially protected health information with FDA, therefore, would be a HIPAA violation that could adversely affect NABP and the individual states utilizing the information sharing platform.

MOU Update

June 2020

Belmar™
PHARMA SOLUTIONS

MOU—What is it?

- FDA Guidance, required by statute, that will control the quantity of compounds “put into interstate commerce”
  - If the state we dispense from becomes party to MOU, we can ship uninterrupted, but report all shipments once 50% threshold of RX’s going outside state is surpassed
  - If the state we dispense from DOES NOT become a party to MOU, # of compounds “put into interstate commerce” is limited to 5% of RX volume
  - Final guidance expected mid-June 2020, states have 365 days to become party, before enforcement begins (anticipated effective date July 1, 2021)
  - Applies to 503a ONLY

MOU—Our Strategy

- Squash current draft guidance before it becomes “final” using Office of Management & Budget cost review (will know result by 6/15/2020)
- Lobby legislators to both appeal to OMB (squash) and to FDA (delay) that “now is not the time to add unfunded mandates on states
- Appeal to FDA for enforcement discretion once MOU becomes effective
- Litigate
- Convince (lobby) CO, FL to adopt MOU
- Multi-facility Supply chain network approach

Squash & Lobby re: current draft guidance

- OMB is reviewing current draft and that is only reason current draft is not "final"
- We are appealing to OMB on the basis of "new facts" which mean the draft is either (1) too costly to implement at this time, (2) FDA has made factual misrepresentations or (3) materially new terms are introduced
  - COVID's effect on state budgets
  - FDA indicates "45 states" intend to sign (we know that is not true)
  - FDA added a new provision that allows a state to withdraw from MOU with 60 days notice – making reliance by impacted businesses on the MOU very risky
- Same messaging being delivered to our industry friends in congress, including Pence's staff

Appeal to FDA for enforcement discretion

- FDA will not delay implementation again
- We are conversing with FDA compounding head, re: enforcement discretion
  - Beginning when it goes live, we would voluntarily report what we ship via interstate commerce regardless of what our states do
  - This could buy us time to convince states to participate
  - Asking for delay (or enforcement discretion) in implementation of final MOU (2 years)
  - Risk of obtaining any enforcement discretion if we are party to litigation

Litigate

- Group of 7 compounders seeking to obtain motion for summary judgement blocking implementation of current draft
  - May also include a challenge to original statue
- Compliant filed as soon as 6-16-2020
- Motion for summary judgement filed 3-4 weeks after Complaint
- Argument strategy to be discussed on call
- $35-40K per participant
- IF FDA loses and appeals, an additional $50-70K per participant

Adoption at State level

- Work with BOP's in CO, FL, AZ, TX
  - AZ, CO, FL have indicated no desire to adopt
  - States view this as unfunded mandate
  - PA is only state that has indicated intent to sign (to our knowledge)
    - Lobbied by Marwood and Lee Rosebush on behalf of Pentec (DW Healthcare)
  - This approach is problematic due to 60 day back-out clause

Multi-facility Supply Chain network

- Build compounding facilities in key compounding states (#7-10 big states)
  - Compounding-only capabilities, sterile and non-sterile
  - 1 call center supporting all “compounding” centers
  - We would build these facilities, size depends upon revenue opportunity
  - Greatly simplifies state licensing (1-5 states per facility)
  - Make as much compounded product in 503b and distribute to A’s
    - Limited formulary
  - Increases barriers to entry for larger players, (but helps mom & pops)
  - Until we build it and then a state agrees to become party to MOU
  - Employing this strategy would result in a 35% decrease in 503A business based upon today’s business pattern in CO and FL. An undetermined amount can be made up by 503B to A compounding

Wood, Kimberly - DSPS

From: Kristen Youngdahl <Kristen@belmarpharmacy.com>
Sent: Tuesday, June 09, 2020 12:56 PM
To: O'Neill - DORA, Mark
Cc: Dmitry Kunin - DORA; Dave Hill
Subject: RE: MOU - FDA
Attachments: 12_10_18 Comment to FDA re_ MOU - FINAL.PDF

Hi Mark and Dmitry,

We would like CO to be a party to the MOU however does the board have the authority to sign the MOU? That is our primary question. If the board does not know what is the process? We currently employ approximately 100 people and we are a growing Colorado business.

Below are answers to your questions:

1. If the board would be willing to write a letter and submit it to the FDA on or before June 15, 2020, that would be great. Comments close on this date.
2. Distribution vs. dispensing (FDA uses this language interchangeably) Please see the attached PDF from our comment submission 2018. This lays out the framework for the dispensing vs. distributing language. Below is the MOU with highlighted dispensing and distribution.
    a. The drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such a State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded, in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B) of the FD&C Act).
3. The AZ letter that we sent would be the template for a letter, however please change in anyway CO deems fit. The letter should not be verbatim to match AZ.
4. Attached are the comments submitted during the last comment period 2018. Currently we are working with the same group but our comments are not finished yet.

Happy to discuss further. Do you know if this item will be discussed at the next board meeting. If so when is the next meeting? Belmar would like to be present.

Sincerely,

Kristen Youngdahl, PharmD
Belmar Pharmacy
Pharmacy: (800) 525-9473 | (303) 763-5533
Pharmacy Fax: (866) 415-2923 | (303) 763-9712

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From: O'Neill - DORA, Mark
Sent: Wednesday, June 3, 2020 6:38 AM
To: Kristen Youngdahl
Cc: Dmitry Kunin - DORA
Subject: MOU - FDA

Hello,

Thank you for the documents.

I read through the proposed MOU, and I have a couple of questions.

1. I see that the final date to submit comments to the FDA is June 15, 2020. Are you requesting that the Board submit a final FDA comment by that date?

2. I didn't see the confusion in the MOU itself about distribution vs. dispensing. I admit that the document is long and involved. Could you point out this discrepancy for me?

3. Do you have a template version of a letter that you would like the Board to review? I think the Board staff would like to see what you and Dave would say.

4. Did you and Dave already submit a comment? Could you send me a copy of it?

Thanks a lot.

--
Mark O'Neill, R.Ph.
Pharmaceutical Inspector

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December 10, 2018

VIA ELECTRONIC SUBMISSION

Dockets Management Staff (HFA-305)
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments to Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food And Drug Administration

To Whom It May Concern:

We write on behalf of a coalition of approximately 154 registered compounding pharmacies who serve several hundred thousand patients throughout the country every month. These pharmacies, like so many others, will be directly impacted by the Memorandum of Understanding ("*MOU*") currently proposed by the U.S. Food & Drug Administration ("*FDA*"). *See* Sept. 10, 2018 Notice at 83 FR 45631. Accordingly, we appreciate the opportunity to submit comments regarding the MOU and hope that FDA will take these comments into consideration when finalizing the MOU for submission to the States. As set forth below, the MOU as currently proposed will have a profoundly negative impact on compounding pharmacies, physicians, and patients across the country. We strongly recommend FDA withdraw the proposed MOU and work with representatives of compounding pharmacies to formulate a version that works best for patients, physicians, and pharmacies.

As a threshold matter, we sincerely appreciate the considerable steps FDA took in revising the 2015 draft MOU in light of stakeholder feedback. FDA's efforts here have not gone unnoticed and FDA's recognition of the concerns raised by compounding pharmacies, physicians and patients across the country is commendable. However, although the current proposed MOU is an improvement on the 2015 draft, serious deficiencies remain that require consideration and correction.[1] Specifically, the current draft MOU fails for the following reasons:

- Despite the complete lack of authority, FDA continues to define "distribution" to include patient-specific dispensing. This expansive definition fails even the most basic scrutiny as (1) the language of Section 503A does not allow for it; (2) Congress has repeatedly defined the terms separately in other similar statutes; and (3) the practice of pharmacy considers the terms "distribution" and "dispensing" to mean separate things. If FDA is permitted to

[1] In addition to the issues raised in this comment, we note that the increase in the distribution threshold from 30% to 50% does not, in fact, solve the concerns raised by the 30% threshold in the 2015 draft MOU. FDA has increased the distribution threshold to 50%, however, it has also narrowed what is included in that threshold to compounded products. Thus, the 50% threshold does not dramatically increase the level of distribution permitted by compounding pharmacies under the MOU.

define "distribution" to include patient-specific dispensing, then Section 503A becomes an illegal delegation of Congressional authority;

- FDA fails to provide any notice or guidance as to what will happen to compounding pharmacies once they are deemed to have distributed inordinate amounts of compounded medication interstate. This lack of guidance does not withstand the bounds of basic due process as regulated entities are entitled to have fair notice of the standards by which FDA will enforce statutes and regulations;

- The Tenth Amendment and the anti-commandeering doctrine prohibits Congress from conscripting State officials to carry out federal regulatory programs. Congressional direction empowering FDA to commandeer State officials to investigate complaints related to the distribution of compounded drugs interstate, therefore, is unconstitutional. The MOU, in turn, which not only directs States to investigate complaints but also obligates States to carry out a wide range of information gathering and oversight activities on FDA's behalf, violates the Tenth Amendment and the anti-commandeering doctrine.

As a result of the above concerns, we strongly encourage FDA to reconsider and withdraw its current draft of the MOU in order to work with stakeholders, State regulatory bodies, physicians, and patients to develop an MOU that allows patients access to the compounded medications and complies with FDA's governing statute as well as all applicable constitutional principles.

1. Congress Did Not Give FDA The Authority To Regulate The Practice Of Dispensing Through The MOU.

Despite repeated challenges from industry stakeholders, FDA continues to define "distribution" in the MOU to include dispensing. The plain language of Section 503A, definitions of distribution in similar statutes, and the nature of the practice of pharmacy as a whole, demonstrate that the terms "distribution" and "dispensing" mean separate and mutually exclusive things. Congress did not give FDA the authority to regulate patient-specific ***dispensing*** through the MOU. Moreover, if "distribution" can be interpreted to include patient-specific dispensing, Congressional direction to craft an MOU that addresses distribution becomes an illegal delegation of Congressional authority.

(a) <u>In Section 503A, Congress Only Granted FDA The Power To Create An MOU Governing "Distribution" Not "Dispensing."</u>

The plain language of Section 503A does not support FDA's inclusion of "dispensing" in the definition of "distribution." Rather, Section 503A explicitly states that the MOU should only address the "***distribution*** of inordinate amounts of compounded drug products interstate." 21 U.S.C. § 353a(3)(B)(i) (emphasis added). Section 503A ***does not authorize*** FDA to address dispensing in the MOU.

First, as noted by numerous industry stakeholders in their comments to the 2015 draft MOU, it is plainly evident from the language of Section 503A that Congress meant the terms "distribution" and "dispensing" to mean two separate things. Section 503A specifically states that, when drafting the MOU, FDA is to address the "***distribution*** of inordinate amounts of compounded drug products interstate…."

21 U.S.C. §353a(b)(3)(B)(i) (emphasis added). But as to those States that decline to enter into the MOU, Congress provided that compounding pharmacies operating within that State cannot exceed "5 percent of the total prescription orders ***dispensed or distributed*** by such pharmacy or physician." 21 U.S.C. § 353a(b)(3)(B) (emphasis added). Thus, contrary to FDA's statement in the *Federal Register* that there is nothing "to suggest that Congress understood distributed and dispensed to be mutually exclusive categories," 83 FR 45636, the language of Section 503A clearly demonstrates that Congress recognized that the words "dispense" and "distribute" are separate and distinct concepts.

To interpret the two terms as meaning the same thing would render the term "dispensed" in Section 503A(b)(3)(B) completely meaningless. Congress would not refer to the two terms separately in one part of Section 503A if it intended the terms to mean the same thing, or if one was to be treated as a subset of the other. FDA's attempt to equate the terms "distribution" and "dispensing" is a complete violation of the plain language of Section 503A, and FDA's effort to regulate patient-specific dispensing through the MOU exceeds the scope of its authority.

Moreover, construing "distribution" to cover patient-specific dispensing is inconsistent with the structure of Section 503A, which applies the term "distribution" to compounding for office use, i.e., compounding pursuant to a non-patient-specific order by a physician who needs compounded drugs in his or her office to administer directly to patients. Section (3)(B) of Section 503A establishes two categories of permissible activity for Section 503A pharmacies: dispensing and distribution. 21 U.S.C. § 353a(b)(3)(B)(ii). Section (3)(B) then limits the interstate "distribution" of compounded medications to 5% of total prescription orders dispensed or distributed, and permits FDA to develop an MOU to further address the interstate "distribution" of compounded medications above and beyond 5%. Limiting FDA's authority over "distribution" to office use—and even then only where such distribution is either "inordinate" or in a State which has not adopted the MOU—would best serve the clear statutory dichotomy between "dispensing" and "distribution."

Thus, contrary to FDA's argument in the *Federal Register,* it is entirely consistent with the language of Section 503A to define "distribution" to apply to a compounded drug that is provided pursuant to a physician's order but without a patient-specific prescription. 83 FR 45636. Section 503A does in fact contemplate that medications may be compounded based on the pharmacy's relationship with the prescribing practitioner and dispensed pursuant to an office use order where permitted by State law prior to the receipt of a patient name. Notably, Section 503A does not indicate ***when*** the pharmacy must obtain the patient name and does not state ***how*** a compounded medication can leave a pharmacy after it has been compounded, allowing these activities to remain governed by State law. As a result, Section 503A contemplates "distribution" activities, like office use.[2] To construe "distribution" to exclude dispensing activities would still leave FDA with the ability to regulate non-patient-specific compounded medications ***distributed*** interstate through the MOU.

[2] In addition, the legislative history of the DQSA clearly indicates that Congress did not intend the DQSA to only contemplate patient-specific prescriptions and to eliminate office use compounding even where permitted by State law. *See* 159 Cong. Rec. S8072 (Senate ed. Nov. 18, 2013) (statement of Sen. Alexander) ("The legislation does not change current law on office use compounding or repackaging."); *id.* at S8073 (statement of Sen. Boozman) ("Office-use compounding and repackaging is acceptable under Arkansas law. Nothing in this law changes that.").

We note that FDA has revised the definition of distribution to exclude dispensing that occurs at the facility in which the drug was compounded. As FDA stated in the *Federal Register*, FDA "intend[s] to consider that when a drug is picked up in this way, dispensing, but not distribution, occurs for purposes of calculating 'inordinate amounts' under the MOU…." *See* 83 FR 45635. Again, although we sincerely appreciate the efforts FDA has made to recognize the issues associated with its definition of distribution, FDA's decision to exclude a certain category of dispensing activity from the definition of "distribution" simply serves to confirm that "dispensing" and "distribution" are wholly separate activities which are mutually exclusive. By recognizing that there is a certain type of dispensing that falls outside the scope of "distribution," i.e. when a patient physically picks up a prescription from a pharmacy, FDA concedes that "dispensing" activities are wholly separate from "distribution." There is no other way to interpret this revision.[3]

(b) Congress Has Repeatedly And Explicitly Distinguished Between The Terms "Dispense" And "Distribute."

Furthermore, contrary to FDA's suggestion in the *Federal Register*, the absence of definitions for the terms "distribution" and "dispensing" in Section 503A does not somehow render the terms indistinguishable. *See* 83 FR 45636 at n.4. In fact, the opposite is true. Title II of the DQSA, for example, was enacted ***at the same time*** as Title I of the DQSA (which includes Section 503A) and expressly defines "dispense" and "distribute" to mean separate things. Title II of the DQSA, more commonly referred to as "Track and Trace," outlines steps to build an electronic, interoperable nationwide pharmaceutical "track and trace" system to identify and trace certain prescription drugs as they are distributed in the United States to deter drug counterfeiting. Congress defined "distribute" or "distribution" in Title II of the DQSA to expressly ***exclude*** patient-specific dispensing:

> [T]he sale, purchase, trade, delivery, handling, storage, or receipt of a product, and ***does not include the dispensing of a product pursuant to a patient-specific prescription*** executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

21 U.S.C. § 581(5) (emphasis added). Congress' treatment of "dispensing" and "distribution" as mutually exclusive categories in Title II of the DQSA necessarily indicates that Congress intended to do the same in Section 503A of the DQSA. Title II was passed by Congress as part of the same statute as Title I. It makes no sense to interpret "dispensing" and "distribution" as being wholly exclusive of each other in Title II of the DQSA, but interchangeable in Title I of the DQSA (i.e. Section 503A), especially where Congress did not so specifically state.

Congress has also defined the terms "dispense" and "distribute" differently in another similar statutory scheme. The Controlled Substances Act ("CSA") addresses the manufacture, importation,

[3] We note further that FDA's revised definition of "distribution" to exclude one type of dispensing is impractical and unsound. FDA has not accounted for how this exception would work in the real world. What if the patient is too sick to pick up the medication? Can a relative or other agent of the patient pick up the medication on the patient's behalf? What if the patient is infirm and has no ability to pick up the medication? Will the infirm patient simply not have access to the medication from the specialized compounding pharmacy? Where does the line between dispensing and distribution begin and end? This lack of demarcation is all the more reason why the activities encompassing "dispensing" should not be subsumed into "distribution."

possession, use, and distribution of certain drug substances with the potential for abuse, and applies equally to drug manufacturers and drug compounders. The CSA defines "dispense" and "distribute" to mean two different things, and expressly excludes the act of dispensing from the definition of "distribute." 21 U.S.C. § 802(10)-(11). Specifically, the CSA defines the term "distribute" to mean "to deliver (***other than by administering or dispensing***) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical." 21 U.S.C. § 802(11) (emphasis added). Thus, in a similar statute to DQSA applicable to the drug industry, Congress has defined "distribution" to expressly ***exclude*** dispensing.

(c) FDA's Interpretation Of Section 503A Departs From The Recognized Industry Understanding Of "Dispensing" And "Distribution."

Moreover, FDA's definition of "distribution" in the MOU is a radical departure from how this activity is understood in pharmacy practice. Pharmacists routinely recognize that the act of "dispensing" in the context of pharmacy practice is wholly different from the act of "distribution." This distinction is reflected in the National Association of Boards of Pharmacy Model State Pharmacy Act (the "*Model Act*"), which is designed to provide State Boards of Pharmacy with model language that may be used when developing State pharmacy laws or board rules for the respective States. *See* NABP Model Act at p.15, https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/. The Model Act defines the term "dispense" as:

> [T]he interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation, final Verification, and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.

Id. at Art. I., Sec. 105(q2). The term "distribution," on the other hand, is defined as:

> [T]o sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term ***does not include***:
>
> (1) ***To Dispense*** or Administer;
>
> (2) Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or
>
> (3) Providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of hospital or another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.

Id. at Art. I, Sec. 105(s2). States and state boards of pharmacy are encouraged by NABP, therefore, to recognize the terms "distribution" and "dispensing" are mutually exclusive in the practice of pharmacy and formulate regulations and policies reflecting that difference.

Yet, in the present case, FDA's interpretation of Section 503A ignores the practice of pharmacy's recognized distinction between "distribution" and "dispensing," and instead defines "distribution" to include patient-specific dispensing in the context of the MOU. FDA clings to this definition of "distribution" despite the clear direction from Congress that in crafting the MOU, FDA is to consult with NABP to develop the MOU. 21 U.S.C. § 353a(b)(3). To define "distribution" to include "dispensing" is an abrupt departure from industry understanding and creates needless confusion for compounding pharmacies across the nation.

(d) FDA's Interpretation Of "Distribution" Is An Unconstitutional Delegation Of Legislative Authority By Congress, Violating The Canon Of Constitutional Avoidance.

Finally, if "distribution" means, as FDA contends, "that a compounder has sent a drug product out of the facility in which the drug was compounded," Congress's direction to develop an MOU addressing "distribution" lacks the necessary intelligible principle to guide FDA in the exercise of its authority. *See* MOU at Appendix A. Such a standardless transfer of legislative power to FDA would violate Article I of the United States Constitution. Binding authority prevents interpretation of the statute in this fashion.

It is well-settled that, "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988). "This cardinal principle has its roots in Chief Justice Marshall's opinion for the Court in *Murray* v. *The Charming Betsy,* 2 Cranch 64, 118 (1804), and has for so long been applied by this Court that it is beyond debate." *Id*. In interpreting statutes then, courts will "not lightly assume that Congress intended to infringe constitutionally protected liberties or usurp power constitutionally forbidden it." *Id*. Instead, "where a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter." *Jones v. United States*, 526 U.S. 227, 240 (1999) (citation omitted).

The Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const., Art. I, § 1. Congress cannot delegate any part of its legislative power to a federal agency except pursuant to the principle of separation of powers found in Sections 1 and 8 of Article 1 of the Constitution. *United States v. Chicago, M., St. P. & P.R. Co*., 282 U.S. 311, 324 (1931); *Whitman*, 531 U.S. at 472-73 ("legislative power" consists of decision-making authority without any "intelligible principle to which the person or body authorized . . . is directed to conform"). Congress must, therefore, provide an intelligible principle to guide—and limit—the actions of federal agencies, "even if the agency believes it possesses expertise or policy views superior to Congress's." *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 406 (1928). Federal agencies, in turn, must always act within the bounds of the constraints provided by Congress. "The Constitution gives ***Congress*** the legislative power to set policy in the first instance, and agencies then must act within those statutory boundaries — even if the agency believes it possesses expertise or policy views superior to Congress's." *Ctr. for Biological Diversity v. EPA*, 722 F.3d 401, 414 (D.C. Cir. 2013) (Kavanaugh, J., concurring) (emphasis added).

FDA's expansive definition of "distribution" in the MOU creates just the type of "grave and doubtful constitutional questions" that the doctrine of constitutional avoidance was intended to avoid. Congress has delegated to FDA the authority to draft an MOU that "addresses the distribution of inordinate amounts of compounded drug products interstate." 21 U.S.C. § 353a(b)(3)(B). For the reasons already stated, the text and structure of Section 503A and the DQSA as a whole mandate the conclusion that Congress did not intend "distribution" to encompass patient-specific dispensing. If, however, the statute admits to more than one meaning, and Congress ***could*** have intended to give FDA carte blanche to determine what constitutes "distribution," that delegation lacks the necessary "intelligible principles" to guide FDA in its drafting of the MOU.

The purpose of an intelligible principle is to make sure it is not "impossible in a proper proceeding to ascertain whether the will of Congress has been obeyed." *Yakus v. United States*, 321 U.S. 414, 426 (1944). Nowhere in Section 503A does Congress explain what, if anything, it means when it directs FDA to address "distribution" of certain quantities of drugs interstate and, thus, one cannot determine whether the definition that FDA adopts here actually conforms to the limits laid down by Congress. The only limitation placed on FDA by Section 503A to regulate compounding pharmacies by the MOU is its own judgment. FDA, taking the baton and running with it, has promulgated an MOU with the maximum possible reach into areas of traditional State regulation and concern, which as part of the FDCA are backed by new, harsh criminal consequences for compounding pharmacies and pharmacists for violating the MOU. *See Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1988) (noting that concerns about delegation are implicated whether the delegation "make[s] crimes of acts never before criminalized"). FDA's expansive definition of "distribution" effectively encompasses the entire conduct of compounding pharmacies, reaching well beyond what Congress could have contemplated in enacting Section 503A.

Applying constitutional avoidance to narrow overly broad readings of statutory delegations such as FDA's interpretation of Section 503A is wholly consistent with the development of the non-delegation doctrine. *Mistretta*, 488 U.S. at 373 n.7 ("In recent years, our application of the non-delegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional."); *see International Union, UAW v. OSHA*, 938 F.2d 1310, 1316-17 (D.C. Cir. 1991) (collecting cases supporting this proposition). Doing so shows respect for Congress by not assuming that it intended to violate the Constitution in enacting legislation. *Edward J. DeBartolo Corp.*, 485 U.S. at 575.

Here, assuming some ambiguity in Section 503A, we are left with two "fairly possible" constructions of the scope of FDA's power. *See Crowell v. Benson*, 285 U.S. 22, 62 (1932) ("[T]his Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided."). The first, wherein the term "distribution" excludes "dispensing," comports with the text of both Section 503A and the DQSA, as well as Congress's historical aversion to unduly interfering with State oversight and responsibility concerning the practice of pharmacy. *See South Carolina v. Regan*, 465 U.S. 367, 398 (1984) (looking at act's legislative history and purpose to determine that the alternative constitutional reading was plausible). The second, adopted by FDA, would create a serious constitutional concern that Congress has unconstitutionally delegated its legislative authority to FDA without an intelligible principal to guide it. The canon of constitutional avoidance requires adoption of the former construction and to avoid the latter. *Jones*, 526 U.S. at 240.

For all of the aforementioned reasons, FDA does not have authority to define the term "distribution" to include "dispensing" and, therefore, cannot regulate the practice of dispensing by way of the MOU. We encourage FDA to withdraw the MOU and reconsider its definition of "distribution" to comport with the plain language of Section 503A and industry understanding of the meaning of the term, and to ensure compliance with the canon of constitutional avoidance.[4]

2. FDA Fails To Set Standards By Which It Intends To Enforce Its Interpretation Of The Meaning Of Distribution Of Inordinate Amounts Of Compounded Drug Products Interstate.

Even assuming that FDA's interpretation of "distribution of inordinate amounts of compounded drugs interstate" withstands scrutiny, FDA has failed to provide any sort of guidance as to the penalties that may result once compounding pharmacies are deemed to have distributed in inordinate amounts. Accordingly, FDA has given itself unfettered discretion to enforce its interpretation in a subjective and discriminatory fashion. FDA's failure to provide sufficient notice of how it intends to enforce its interpretation of "distribution of inordinate amounts of compounded drug products interstate" against compounding pharmacies is a blatant violation of the Due Process Clause of the Fifth Amendment.

A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (citing *Connally v. General Constr. Co.,* 269 U.S. 385, 391 (1926) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law")). This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. *See United States v. Williams,* 553 U.S. 285, 304 (2008). A conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement. *Fox*, 567 U.S. at 253. Because agencies are given great deference in construing statutes and even greater deference in construing their own regulations, it is important that regulated parties not be subject to penalties unless they "know with ascertainable certainty an agency's interpretation." *Id*. at 251 (quotation marks omitted).

The MOU fails to provide any insight whatsoever into the potential penalties that may be imposed on compounding pharmacies deemed to have distributed compounded medication in inordinate amounts.

[4] We wish to further note that the concerns raised by the definition of "distribution" extends to patients across the country. By attempting to regulate dispensing through the MOU, FDA runs the serious risk of limiting patient access to much needed medication. Even though FDA has increased the threshold for what it considers to be "inordinate amounts" from 30% to 50%, there is still a risk patients will be denied the right to use the compounding pharmacy of their choice and/or the pharmacy their physician determines is best to prepare their compounded medication. The pharmacies represented herein compound and dispense unique preparations requiring a high level of expertise. Their pharmacists and staff undergo extensive training and attend medical conferences related to the various therapies utilized in the patient populations they most often treat. These pharmacies have, therefore, earned national reputations and the trust of many unique patients, their families, and physicians (many of which are located out of State). A 50% threshold on distribution (and, accordingly, dispensing) will force compounding pharmacies to turn away many out of State patients, necessarily compromising patient health. Congress did not give FDA authority to disrupt patient-specific dispensing in this manner.

FDA has indicated in the *Federal Register* only that "FDA may take action in appropriate cases against compounders that violated these provisions [of the MOU]," that the information provided by the States "will help inform inspectional priorities," and that:

> [t]he Agency believes that more than 50 percent is an appropriate measure of "inordinate amounts" because it marks the point at which pharmacies and physicians are distributing the majority of their compounded drug products interstate, and the regulatory challenges associated with interstate distributors discussed above become more pronounced. ***At this tipping point, the risk posed by the distribution practices of the compounder may weigh in favor of additional Federal oversight in addition to State oversight***.

See 83 FR 45635 (emphasis added). These vague statements fail to provide any certainty as to the potential ramifications for exceeding the 50% threshold and, accordingly, FDA appears to have complete freedom to enforce its interpretation of "distribution of inordinate amounts of compounded drug products interstate" in a subjective and arbitrary fashion.

It is essential that FDA define what will happen to compounding pharmacies once they reach the "tipping point" because violations of Section 503A expose compounding pharmacies to civil and criminal penalties. Section 503A is crafted as an exemption to the FDCA, wherein, if compounding pharmacies comply with the requirements set forth in Section 503A, they are exempt from the remainder of the FDCA, including its civil and criminal penalties. 21 U.S.C. § 353a. If a compounding pharmacy is deemed to have violated the MOU, in theory, FDA would have the authority to shut down the compounding pharmacy, and begin civil or criminal proceedings. All that FDA has offered as guidance here is that compounding pharmacies will be subject to "additional Federal oversight" after they reach the "tipping point." This vague pronouncement suggests that even if deemed to have exceeded the 50% threshold, compounding pharmacies will be able to continue to distribute compounded medication interstate even though, technically, they will be in violation of the MOU. At what point, then, will "additional Federal oversight" end and enforcement proceedings begin? Where is the line and when will compounding pharmacies reach it? As it stands, FDA has given itself carte blanche to arbitrarily apply the MOU, which will inevitably lead to inconsistencies in enforcement and confusion and uncertainty for compounding pharmacies, physicians and patients.[5]

For the above reasons, we request that FDA provide standards as to what will happen to compounding pharmacies once they exceed the 50% threshold, so as to avoid subjective and potentially discriminatory enforcement of the MOU.

[5] The Supreme Court has recognized and permitted pre-enforcement action with respect to an agency's promulgation of regulations, especially in those instances where the "impact of the regulations upon the petitions is sufficiently direct and immediate as to render the issue appropriate for judicial review." *See Abbot Laboratories v. Gardner*, 387 U.S. 136, 152-53 (1967). *Abbot Laboratories* was a pre-enforcement action brought by 37 individual drug manufacturers and the Pharmaceutical Manufacturers Association challenging FDA regulations related to labeling. FDA had not yet taken any action with respect to the regulations. Nevertheless, the Supreme Court held that the action was ripe for judicial review because the regulations had the status of law, violations of them carried heavy civil and criminal sanctions, FDA had direct authority to enforce the regulations, and the impact on the regulated industry with respect to the regulations would be direct and immediate.

3. The MOU, As Required By The Enabling Provision Of Section 503A, Violates The Tenth Amendment And The Anti-Commandeering Doctrine By Directing State Officials To Carry Out A Broad Federal Regulatory Program.

Finally, Congressional direction to FDA to craft an MOU with the States, wherein State officials are directed to carry out a regulatory program on behalf of the federal government, violates the Tenth Amendment and the anti-commandeering doctrine. The MOU, in turn, which conscripts State officials to carry out a wide array of regulatory activities for the benefit of FDA, is unconstitutional.

The Tenth Amendment confirms that all legislative power not conferred on Congress by the Constitution is reserved for the States. To that end, "Congress may not simply 'commandeer the legislative process of the States by directly compelling them to enact and enforce a federal regulatory program.'" *New York v. United States*, 505 U.S. 144, 161 (1992). "Where a federal interest is sufficiently strong to cause Congress to legislate, it must do so directly; it may not conscript state governments as its agents." *Id*. at 178. Adherence to the anti-commandeering principle is important for several reasons, including that the rule serves as "one of the Constitution's structural safeguards of liberty," *Printz v. United States*, 521 U.S. 898, 921 (1997), that the rule promotes political accountability, and that the rule prevents Congress from shifting the costs of regulation to the States. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S.Ct. 1461, 1475-76 (2018).

The Supreme Court has repeatedly struck down federal laws and regulations designed to direct State action. For example, *New York v. United States* concerned a federal law that required a State, under certain circumstances, either to "take title" to low-level radioactive waste or to "regulat[e] according to the instructions of Congress." 505 U.S. at 175. In enacting this provision, Congress issued orders to either the legislative or executive branch of State government (depending on the branch authorized by State law to take the actions demanded). Either way, the Supreme Court held, the provision was unconstitutional because "the Constitution does not empower Congress to subject state governments to this type of instruction." *Id*., at 176.

The Supreme Court applied the same principles to a federal statute requiring State and local law enforcement officers to perform background checks and related tasks in connection with applications for handgun licenses. *Printz*, 521 U.S. 898. Holding this provision unconstitutional, the Supreme Court put the point succinctly: "The Federal Government" may not "command the States' officers, or those of their political subdivisions, to administer or enforce a federal regulatory program." *Id*., at 935. This rule applies, the Supreme Court held, not only to State officers with policymaking responsibility but also to those assigned more mundane tasks. *Id*., at 929–930.

Here, Section 503A directs FDA to enter into an MOU with the States that "provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State." 21 USC § 353a(b)(3)(B)(i). Empowered by Congress, FDA has crafted an MOU that requires States to carry out a wide-range of regulatory activities on behalf of the federal government. First, the MOU instructs those States that sign on to the MOU to investigate complaints related to the compounding of drug products distributed interstate by compounding pharmacies, determine whether there is a public risk to health, and take action (if consistent with State law) against those pharmacies if warranted under the circumstances. If the complaint involves a "serious adverse drug

experience" or "serious product quality issue," the State must notify FDA within 3 business days, provide FDA with a litany of information regarding the compounding pharmacy in question, and then update FDA on the results of any investigation or action taken against the compounding pharmacy. The State must maintain records of the complaint, any investigations and any action taken against the offending compounding pharmacy for 3 years.

In addition to investigatory duties, the current draft of the MOU has expanded the scope of State obligations and now requires State officials to gather extensive data on FDA's behalf from compounding pharmacies in the State and to identify for FDA those compounding pharmacies that are distributing inordinate amounts of compounded drug products interstate. *See* MOU at Sections III.a and III.c. In other words, the ***State*** is tasked with making the determination of whether a compounding pharmacy has violated the Section 503A prohibition on the distribution of inordinate amounts interstate. *See* MOU at III.b.2. Once a compounding pharmacy has been identified by a State official as distributing inordinate amounts of compounded drug products interstate, per the MOU, the State official must then collect *additional* information from the offending compounding pharmacy regarding the distribution and dispensing of drugs both within and outside of the State. This information includes data on:

- The number of prescription orders "distributed or dispensed" within the State[6];
- The number of prescription orders distributed outside the State;
- The number of prescription orders for sterile products distributed outside the State;
- The number of States receiving compounding products from the compounding pharmacy; and
- Whether the compounding pharmacy is distributing compounded medication for office use.

See MOU at III.c.1.b. The State official must notify FDA within 30 days of identifying a compounding pharmacy within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate and provide FDA with the information gathered from that pharmacy. *See* MOU at III.b.5.

Congressional direction to FDA to conscript State officials to investigate complaints related to the distribution and dispensing of compounded drugs interstate is a plain violation of the Tenth Amendment. Like the laws deemed unconstitutional in *New York* and *Printz*, Congress may not commandeer the legislative process of the States by compelling them, through an MOU, to carry out a federal regulatory program. The MOU as currently drafted not only directs State officials to investigate complaints related to the distribution and dispensing of compounded drugs, it also directs ***State officials*** to interpret the MOU and determine which of its resident pharmacies have distributed compounded medication in "inordinate amounts." In other words, FDA through the MOU seeks to effectively deputize State officials to carry out federal law. Such direction is unconstitutional and a blatant violation of the anti-commandeering doctrine.

[6] Yet another example of FDA's recognition that the terms "dispense" and "distribute" are mutually exclusive terms. *See* MOU at Section III.c.1.b.ii.

FDA may argue that, regardless of whether the MOU requires State officials to carry out a federal regulatory program, the MOU is voluntary and, therefore, not "commandeering" within the meaning of *New York* and *Printz*. Congress does provide an alternative to the MOU in Section 503A wherein, if a State does not sign on to the MOU, compounding pharmacies in that State may not distribute in quantities that "exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy." 21 U.S.C. § 353a(b)(3)(B)(ii). Congress has not provided any standard for FDA to determine whether a compounding pharmacy exceeds the 5% threshold. FDA, likewise, has not taken the initiative to explain how it intends to police this 5% threshold. Accordingly, Congress and FDA appear to have left it to the States to ensure that compounding pharmacies comply with this provision. Otherwise, FDA would have no way of enforcing the 5% limitation. Thus, even if States choose not to enter the MOU, they are still required to expend State resources and time to carry out a federal regulatory program and enforce federal law.[7]

Supreme Court precedent is clear that Congress may not burden the States with executing a federal regulatory program. Congressional direction to FDA to do just that via Section 503A is, accordingly, unconstitutional, and FDA's sweeping attempt to fashion a broad federal regulatory program to be policed by the States is a violation of the Tenth Amendment and the anti-commandeering doctrine.[8] As a result, we strongly urge FDA to withdraw and reconsider the current draft of the MOU.

4. Conclusion

We strongly encourage FDA to reconsider the MOU as currently drafted in light of the points raised above. In addition to these substantive changes, we ask FDA to reconsider its proposal to State

[7] It must also be noted that because there is no "choice" with respect to a State's participation in this federal regulatory program, and because this program appears to be entirely unfunded, Congress and FDA may have effectively imposed an impermissible *unfunded* mandate on the States in violation of the Unfunded Mandate Reform Act ("*UMRA*"). *See* Unfunded Mandate Reform Act of 1995, 2 U.S.C.A. § 1501, *et seq*. The UMRA is a federal law that seeks to minimize the imposition of federal unfunded mandates, i.e., new standards or requirements imposed by the federal government on the States without adequate funding and in a manner that may displace other essential State governmental priorities. By law, federal agencies considering imposing huge financial burdens on States, must proffer an extensive cost-benefit analysis that weighs both the financial impact on the States as well as the unfunded mandate's effect on health and safety. *Id.* § 1532(a)(2). FDA has yet to reach out to States potentially burdened by the MOU, and has yet to provide evidence of such an analysis. Without an understanding of the true costs involved, States will be burdened with significantly increased costs for compliance monitoring and reporting and will be forced to use their own limited resources to comply with the MOU – resources that will have to be taken away from other vital State interests.

[8] We note, moreover, that the MOU subjects State officials tasked with overseeing the practice of medicine to the same requirements. FDA has no authority to regulate the practice of medicine by way of the MOU. Congress has traditionally held that the practice of medicine is to be regulated by the States and that it was not Congress's intent for the FDCA to preempt State regulation of the profession. FDA has consistently recognized Congress' position on this matter and has accepted that it may not regulate or interfere with the practice of medicine. In fact, FDA declined, as recently as September 2018, to regulate the practice of medicine when it comes to compounded drugs. As noted in the recently released FDA draft guidance on insanitary conditions at compounding facilities:

> FDA generally does not intend to take action under section 501(a)(2)(A) against a physician who is compounding or repackaging a drug product, or who is mixing, diluting, or repackaging a biological product, provided that such activities occur in the physician's office where the products are administered or dispensed to his own patients.

FDA Draft Guidance For Industry: *Insanitary Conditions at Compounding Facilities* (September 2018) at n.3. Thus, to the extent FDA seeks to regulate the practice of medicine through the MOU, we wish to remind FDA that it may not do so.

enforcing Section 503A's 5% limitation 180 days after the final standard MOU is made available to the States for signature. Application of a blanket 180-day period, without consideration of when the MOUs are actually signed, will create an unworkable situation. For example, a blanket 180-day period does not accommodate for the reality that States may need more than 180 days to consider and execute the MOU, or that States may sign the MOU on different dates. If one State signs an MOU immediately while another State waits 180 days, compounding pharmacies will be left without a clear understanding as to what rules apply in the intervening period between the date an MOU is executed in one State and the expiration of the 180-day period. To avoid these and other related issues, we strongly encourage FDA to adopt a single date on which all MOUs will become effective (regardless of when the MOU is signed) and on which FDA will start enforcing Section 503A's 5% limitation. We recommend that this date be 90 days after the last State notifies FDA as to whether or not it will sign onto the MOU.

We thank you for the opportunity to submit these comments.

Sincerely,

Rachael G. Pontikes

Rachael G. Pontikes

RGP:jw

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0800--Revision

This information collection supports Agency implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For efficiency of Agency operations, we are revising the information collection currently approved under OMB control number 0910-0800 pertaining to human drug compounding and section 503B of the FD&C Act (21 U.S.C. 355b) to include reference to Agency guidance regarding section 503A of the FD&C Act (21 U.S.C. 355a), and to also include information collection that we attribute to a final standard memorandum of understanding (MOU) provided for by section 503A ("final standard MOU"). Finally, we are revising the title of the information collection from "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act" to "Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act." As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources.

Agency Guidance Regarding Section 503A

We are revising the information collection to include reference to the guidance entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food,

Drug, and Cosmetic Act." The guidance is available from our website at: https://www.fda.gov/media/94393/download. The guidance was issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for comment at any time. The guidance communicates FDA's intention with regard to enforcement of section 503A of the FD&C Act to regulate entities that compound drugs and notes that parts of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement and explains how the provisions will be applied pending those consultations and rulemaking. Although the guidance does not include recommended information collection, we are including the guidance as a supplemental reference for respondents.

The Final Standard MOU

We are also revising the information collection to include information collection associated with the standard MOU pursuant to the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) found in section 503A of the FD&C Act. Section 503A of the FD&C Act describes the conditions under which certain drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician are exempt from certain sections of the FD&C Act. One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such a State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the

State in which they are compounded, in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B) of the FD&C Act).

Section 503A(b)(3)(B) of the FD&C Act directs FDA, in consultation with the National Association of Boards of Pharmacy (NABP), to develop a standard MOU for use by States in complying with the provision that references an MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in the State and distributed outside such State. Accordingly, we have developed the document entitled, "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [Insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration," available in docket number FDA-2018-N-3065, which is available at: https://www.regulations.gov/docket?D=FDA-2018-N-3065.

For purposes of this analysis, FDA assumes that 45 States will sign the standard MOU with FDA.

Under section III.a of the final standard MOU, the State Board of Pharmacy (BOP) or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to StateMOU@fda.hhs.gov as soon as possible, but no later than 5 business days, after receiving a complaint relating to a human drug product compounded at a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue. The notification will include the following information: (1) the name and contact information of the complainant, if available; (2) the name and address of the pharmacy that is the subject of the complaint; and (3) a description of the complaint, including a

description of any compounded human drug product that is the subject of the complaint. After the State BOP or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the State BOP or other appropriate State agency will share with FDA the results of the investigation as permitted by State law. The information will include: (1) the State BOP or other appropriate State agency's assessment of whether the complaint was substantiated, if available and (2) a description and date of any actions the State BOP or other appropriate State agency has taken to address the complaint. In addition, the State BOP or other appropriate State agency will maintain records of the complaints they receive, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State BOP or other appropriate State agency receives notice of the complaint. The State BOP or other appropriate State agency will maintain these records for at least 3 years, beginning on the date of final action on a complaint or the date of a decision that the complaint requires no action.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and will notify FDA by email at StateMOU@fda.hhs.gov or by submission to an information sharing network as soon as possible, but no later than 5 business days, after receiving any complaint relating to a drug product compounded by a physician and distributed outside the State involving an adverse drug experience or product quality issue. The information will include, if available: (1) the name and contact information of the complainant; (2) the name and address of the physician that is the subject of the complaint; and (3) a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

In the *Federal Register* of September 10, 2018 (83 FR 45631), we published a 60-day notice requesting public comment on the proposed collection of information. We note that in the final MOU we changed the title from "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration" to "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or other appropriate State Agency] and the U.S. Food and Drug Administration." A number of comments were received. Most comments focused on State resource issues including whether the extent, nature, and frequency of information collection and sharing was overly burdensome and whether or not the information collection imposed an unfunded mandate on State agencies. In consideration of the comments, FDA has made the following changes to the MOU:

- we have increased the time period, from 3 days to 5 business days, to communicate information about complaints that involve serious adverse drug experiences or serious product quality issues relating to a human drug product compounded at a pharmacy and complaints that involve adverse drug experiences or product quality issues relating to a human drug product compounded by a physician;
- we have increased the amount of time after the final standard MOU is available for signature from 180 days to 365 days before FDA intends to enforce the 5 percent limit in States that have not signed the final standard MOU; and
- we have coordinated with NABP to develop an information-sharing network to help reduce the information collection and sharing burden on the State BOPs or other appropriate State agencies.

We disagree that the information collections in the MOU create unfunded mandates. Entering into the MOU is voluntary. We believe the proposed collection of information satisfies the statutory objectives of providing FDA with the information it needs through the least burdensome means available. None of the comments received provided alternative figures to the burden estimates proffered, and we therefore estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State BOP or other appropriate State agency notifies FDA of compounding complaints	45	3	135	0.5 (30 minutes)	67.5
State BOP or other appropriate State agency identifies pharmacies that distribute inordinate amounts of compounded human drugs interstate using surveys or inspections or data submitted to an information sharing network	45	145	6,525	1	6,525
State BOP or other appropriate State agency notifies FDA of the distribution of inordinate amounts of compounded human drug products	45	44	1,980	0.5 (30 minutes)	990
State BOP or other appropriate State agency notifies FDA and appropriate State regulator of physicians about physicians who distribute compounded human drug products interstate	45	5	225	0.5 (30 minutes)	112.5
State BOP or other appropriate State agency notifies FDA of a new liaison to the MOU	13	1	13	0.2 (12 minutes)	2.6
State BOP or other appropriate State agency notifies FDA of its intent to terminate participation in the MOU	1	1	1	0.2 (12 minutes)	0.2
Total					7,697.8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State BOP or other appropriate State Agency Recordkeeping for 3 Years of Compounding Complaints about Drug Products Compounded at a Pharmacy	45	2	90	1	90

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Compounding MOU between FDA and State BOP or other appropriate State Agencies	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
State BOP or other appropriate State agency notifies pharmacies that compound human drugs, and the State authority that licenses or regulates physicians that its participation in the MOU has terminated	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our knowledge of State regulation of compounding practices and related complaints, we estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies ("No. of Respondents" in table 1, row 2) will notify FDA within 5 business days of receiving any complaint relating to a human drug product compounded by a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue or any complaint relating to a drug product compounded by a physician and distributed outside the State involving any adverse drug experience or product quality issue. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 3 complaints it receives ("No. of Responses per Respondent" in table 1, row 2), for a total of 135 notifications of complaints sent to FDA ("Total Annual Responses" in table 1, row 2). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response ("Average Burden per Response" in table 1, row 1), for a total of 67.5 hours ("Total Hours" in table 1, row 2).

We also estimate that a total of approximately 45 State BOPs or other appropriate State agencies ("No. of Recordkeepers" in table 2) will prepare and maintain records for 3 years of the complaints they receive, investigations of complaints, and any State action taken or response to complaints involving drug products compounded at a pharmacy and distributed outside the State.

We estimate that each State BOP or other appropriate State agency will receive annually approximately 2 complaints about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy and will prepare and maintain approximately 1 record per each complaint the State BOP or other appropriate State agency receives, for a total of 2 records per State BOP or other appropriate State agency ("No. of Records per Recordkeeper" in table 2), and a total of 90 records annually across all States ("Total Annual Records" in table 2). We further estimate that preparing and maintaining these records will take approximately 1 hour per record ("Average Burden per Recordkeeping (in hours)" in table 2), for a total of 90 hours ("Total Hours" in table 2).

Under section III.b of the final standard MOU, on an annual basis, the State BOP or other appropriate State agency will identify, using surveys, reviews of records during inspections, data submitted to an information sharing network, or other mechanisms available to the State BOP or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate by collecting information regarding the number of prescription orders for compounded human drug products distributed interstate during any calendar year and the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they are compounded during that same calendar year. If a pharmacy has been identified as distributing inordinate amounts of compounded human drug products interstate, the State BOP or other appropriate State agency will also collect information regarding: (1) the total number of prescription orders for sterile compounded human drug products distributed interstate; (2) the

names of States in which the pharmacy is licensed; (3) the names of States into which the pharmacy distributed compounded human drug products; and (4) whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

The State BOP or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to StateMOU@fda.hhs.gov within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, as described in the final standard MOU. The notification will include the name and address of the pharmacy and the information that the State BOP or other appropriate State agency collected, described in the previous paragraph.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA by submission to an information sharing network or by sending an email to StateMOU@fda.hhs.gov within 30 business days of identifying a physician that has distributed compounded human drug products interstate.

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies ("No. of Respondents" in table 1, row 3) will identify pharmacies that distribute inordinate amounts of compounded human drug products interstate. We estimate that each State agency will perform surveys or inspections of 145 pharmacies or use the information sharing network to identify this information ("No. of Responses per Respondent" in table 1, row 3). We estimate that this will take approximately 1 hour per response ("average burden per response" in table 1, row 3), for a total of 6,525 hours ("Total Hours" in table 1, row 3). We estimate that annually a total of 45 State BOPs or other appropriate State agencies ("No. of Respondents" in table 1, row 4) will find that a pharmacy has distributed inordinate amounts of compounded

human drug products interstate and notify FDA of this finding. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 44 findings it makes ("No. of Responses per Respondent" in table 1, row 4), for a total of 1,980 notifications ("Total Annual Responses" in table 1, row 4). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response ("Average Burden per Response" in table 1, row 4), for a total of 990 hours ("Total Hours" in table 1, row 4).

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies ("No. of Respondents" in table 1, row 5) will become aware of physicians that distribute compounded human drug products interstate. We estimate that each State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA annually of approximately five physicians that distribute compounded human drug products interstate ("No. of Responses per Respondent" in table 1, row 5), for a total of 225 notifications of physicians that distribute compounded human drug products interstate sent to FDA ("Total Annual Responses" in table 1, row 5). We estimate that preparing and submitting this information to us as described in the MOU will take approximately 0.5 hours per response ("Average Burden per Response" in table 1, row 1), for a total of 112.5 hours ("Total Hours" in table 1, row 5).

Under section V of the final standard MOU, a State BOP or other appropriate State agency may designate a new liaison to the MOU by notifying FDA's liaison in writing. If a State BOP or other appropriate State agency's liaison becomes unavailable to fulfill its functions under the MOU, the State BOP or other appropriate State agency will name a new liaison within 2 weeks and notify FDA.

We estimate that annually a total of approximately 13 State BOPs or other appropriate State agencies ("No. of Respondents" in table 1, row 5) will notify FDA of a new liaison to the MOU. We estimate that each State BOP or other appropriate State will submit to FDA annually approximately 1 notification of a new liaison ("No. of Responses per Respondent" in table 1, row 6), for a total of 13 notifications of a new liaison ("Total Annual Responses" in table 1, row 6). We estimate that preparing and submitting each notification as described in the MOU will take approximately 0.2 hours per response ("Average Burden per Response" in table 1, row 6), for a total of 2.6 hours ("Total Hours" in table 1, row 6).

Under section VI of the revised final standard MOU, a State BOP or other appropriate State agency may terminate its participation in the MOU by submitting to FDA a 60 calendar day notice of termination.

We estimate that annually a total of approximately one State BOP or other appropriate State agency ("No. of Respondents" in table 1, row 7) will notify FDA that it intends to terminate its participation in the MOU. We estimate that this State BOP or other appropriate State agency will submit to FDA annually approximately one notification of termination ("No. of Responses per Respondent" in table 1, row 7), for a total of one notification ("Total Annual Responses" in table 1, row 7). We estimate that preparing and submitting the notification as described in the MOU will take approximately 0.2 hours per notification ("Average Burden per Response" in table 1, row 7), for a total of 0.2 hours ("Total Hours" in table 1, row 7).

We estimate that annually a total of approximately one State BOP or other appropriate State agency ("No. of Respondents" in table 3, row 2) will notify pharmacists and the State authority that licenses or regulates physicians that its participation in the MOU has terminated. We estimate that this State BOP or other appropriate State agency will distribute approximately

one notification of termination ("No. of Responses per Respondent" in table 1, row 7), for a total of one notification ("Total Annual Responses" in table 3, row 2). We estimate that preparing and submitting the notification as described in the MOU will take approximately 1 hour per notification ("Average Burden per Response" in table 3, row 2), for a total of 1 hour ("Total Hours" in table 3, row 2).

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-10336 Filed: 5/13/2020 8:45 am; Publication Date: 5/14/2020]

State of Wisconsin
Department of Safety & Professional Services
AGENDA REQUEST FORM

1) Name and title of person submitting the request: Kimberly Wood, Program Assistant Supervisor-Adv on behalf of Jameson Whitney, Legal Counsel.	2) Date when request submitted: 1/22/2021 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?
1/28/2021	☒ Yes ☐ No	Variances: **1)** Review, Discussion and Consideration of All Current Variances **2)** Review, Discussion and Consideration of Any Proposed Variances a. Variance on Consulting and Delivery b. Pharmacy Society of Wisconsin Request for Variance to Supervision Requirements for Pharmacy Students c. Variance Requests Received After Preparation of the Agenda

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 ☒ No	N/A

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

Jameson Whitney, Legal Counsel will review with the Board the status of its existing variances, discuss any issues related to these matters. Additionally, the Board should discuss its previous variance regarding consulting and delivery and should consider the new variance proposed by PSW and any other requests that may be submitted in the interim.

Recent Board variances relating to COVID-19 can be found on the DSPS COVID-19 Information page:
https://dsps.wi.gov/Pages/NewsMedia/COVIDInformation.aspx

11) Authorization

Kimberly Wood	*1/22/2021*
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.

Pharmacy Society of Wisconsin

TO: Wisconsin Pharmacy Examining Board
FROM: Sarah Sorum, PharmD
CEO / Executive Vice President
Pharmacy Society of Wisconsin
DATE: January 16, 2021
SUBJECT: Variance Request per 450.02(3m)

Pharmacy professionals serve as a crucial asset and partner in the fight against COVID-19 and the administration of the COVID-19 vaccine. Under current law, pharmacy students may only administer vaccines if a licensed pharmacist supervises them. Many public health departments, health systems, and academic institutions are hosting vaccination clinics with physicians, nurse practitioners, physician assistants, or registered nurses – not pharmacists – on site.

We are requesting a variance to 450.035(2g) as follows:

> ***A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine unless he or she acts under the direct supervision of a licensed healthcare provider whose scope of practice includes vaccine administration ~~pharmacist~~ and he or she and, if the supervising healthcare provider is a pharmacist, the supervising pharmacist have successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in vaccination storage, protocols, administration technique, emergency procedures, and record keeping and, if the supervising healthcare provider is a pharmacist, the supervising pharmacist has satisfied the requirements specified in sub. (2t).***

The skill set of immunizing is a technical one not unique to one's healthcare profession, thus could be overseen by another healthcare professional authorized to immunize. Providing more flexibility to student pharmacists by allowing supervision by other healthcare providers when providing vaccinations is an effective way to disseminate the vaccine. While many student pharmacists are already playing an active role in vaccine administration, enlisting all of our willing, ready, and able pharmacy students to collaborate with other healthcare providers will exponentially increase vaccination opportunities. There are more than 700 pharmacy student immunizers in Wisconsin – allowing them to serve their community by administering COVID-19 vaccines in more settings can increase our immunization administration in Wisconsin significantly.

Thank you very much for your consideration of this variance request. Please do not hesitate to reach out with any questions.

Sincerely,

Sarah Sorum, PharmD
CEO / Executive Vice President
Pharmacy Society of Wisconsin

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