Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dawn B. Crim, Secretary

PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI
Contact: Debra Sybell (608) 266-2112
January 30, 2020

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

9:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of January 3, 2020 (5-6)

C. Conflicts of Interest

D. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Annual Policy Review **(7)**
3) Election of Officers, Appointment of Liaisons and Alternates, and Delegation of Authorities **(8-16)**
4) 2020 Meeting Dates **(17)**
5) Board Members – Term Expiration Dates
   a. Franklin LaDien – 7/1/2020
   b. Anthony Peterangelo – 7/1/2023
   c. Philip Trapskin – 7/1/2021
   d. Michael Walsh – 7/1/2020
   e. Shana Weiss – 7/1/2023
   f. John Weitekamp – 7/1/2022
   g. Cathy Winters – 7/1/2021

E. 9:00 A.M. PUBLIC HEARING: Clearinghouse Rule 19-165, Relating to Storage (18-25)
1) Review and Respond to Public Hearing Comments and Clearinghouse Report

F. 9:00 A.M. PUBLIC HEARING: Clearinghouse Rule 19-164, Relating to Pharmacy Internships (18, 26-32)
1) Review and Respond to Public Hearing Comments and Clearinghouse Report

G. Administrative Rule Matters – Discussion and Consideration (33)

1) Review of 21 CFR 1305 (New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances) **(34-44)**
2) Pending or Possible Rulemaking Projects **(45)**

H. Presentation on 2019 Intergovernmental Working Meeting on Drug Compounding – Zachary Peters and Robert Eldridge, DLSC Staff – Discussion and Consideration

I. Pilot Program Matters – Discussion and Consideration

J. Legal Status of Cannabidiol – Discussion and Consideration

K. Request to List Multiple Office Locations on Physician Licenses – Update from Legal Counsel – Discussion and Consideration

L. Education and Examination Matters

1) MPJE Item Review and Related Matters **(46-51)**

M. Newsletter Planning – Discussion and Consideration (52-54)

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

1) Travel Report: 2019 NABP/AACP District IV Meeting – October 16-18, 2019 – Indianapolis, IN – Franklin LaDien
2) Travel Report: NABP Interactive Member Forum – January 28-29 – Mount Prospect, IL – Cathy Winters
3) Pharmacy Society of Wisconsin Legislative Day, February 12, Madison, WI **(55-56)**

O. 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) Liaison Reports
14) Board Liaison Training and Appointment of Mentors
15) Informational Items
16) Division of Legal Services and Compliance (DLSC) Matters
17) Presentations of Petitions for Summary Suspension
18) Petitions for Designation of Hearing Examiner
19) Presentation of Stipulations, Final Decisions and Orders
20) Presentation of Proposed Final Decisions and Orders

21) Presentation of Interim Orders
22) Pilot Program Matters
23) Petitions for Re-Hearing
24) Petitions for Assessments
25) Petitions to Vacate Orders
26) Requests for Disciplinary Proceeding Presentations
27) Motions
28) Petitions
29) Appearances from Requests Received or Renewed
30) Speaking Engagements, Travel, or Public Relation Requests, and Reports

P. 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.).

Q. Credentialing Matters

1) Application Reviews

a. Intercept Pharmaceuticals, Inc. **(57-90)**

R. Deliberation on Division of Legal Services and Compliance Matters

1) Case Closings

a. 18 PHM 108 – A.J.W. **(91-94)**
b. 19 PHM 125 – W.P. **(95-98)**

S. Deliberation on Proposed Final Decisions and Orders

1) Walter P. Matoska, R.Ph., Respondent (DHA Case No. SPS-19-0050/DLSC Case No. 18 PHM 001) **(99-113)**

T. 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

U. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

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

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

ADJOURNMENT

NEXT MEETING: MARCH 5, 2020

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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. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
MEETING MINUTES
JANUARY 3, 2019

PRESENT: Franklin LaDien, Anthony Peterangelo, Philip Trapskin, Michael Walsh, John Weitekamp, Cathy Winters

EXCUSED: Shana Weiss

STAFF: Debra Sybell, Executive Director; Jameson Whitney, Legal Counsel; Sharon Henes, Administrative Rules Coordinator; Megan Glaeser, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv; and other Department staff

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 8:52 a.m. A quorum was confirmed with six (6) board members present.

ADOPTION OF AGENDA

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

APPROVAL OF MINUTES

Amendments to the Minutes:

- Page 3 of the Minutes: Correct the time Shana Weiss disconnected to show as "5:20 p.m."

MOTION: Cathy Winters moved, seconded by Michael Walsh, to adopt the Minutes of December 17, 2019 as amended. Motion carried unanimously.

ADMINISTRATIVE RULES MATTERS

Phar 7: CR 19-145, Relating to the Practice of Pharmacy

MOTION: John Weitekamp moved, seconded by Franklin LaDien, to approve the final rule draft text for Clearinghouse Rule CR 19-145, relating to the practice of pharmacy. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Michael Walsh, to authorize Cathy Winters to provide initial review and the Chairperson to provide final approval of the Legislative Report and Final Rule Order for Clearinghouse Rule CR 19-145, relating to the practice of pharmacy, for submission to the Governor's Office and Legislature. Motion carried unanimously.

MOTION: Philip Trapskin moved, seconded by Cathy Winters, to recognize Sharon Henes, and other members of Department staff, for the work executed in the promulgation of this rule. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 6:36 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:
Brice McCluskey, Operations Program Associate	1/21/2020
	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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/30/2020	☐ 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, we ask that you let us know ASAP as quorum is required for our Boards, Sections and Councils to meet pursuant to Open Meetings Law. DSPS Boards-Open Meetings Resources
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. DSPS Boards-Open Meetings Resources
3. Agenda Deadlines – Please let your executive Director know if you have items to be considered on an upcoming agenda no less than 8 business days prior to a meeting when possible. DSPS Boards-Reference Materials-Meeting Timeline
4. Travel Voucher and Per Diem Submissions – Please submit all Per Diem and Reimbursement Claims to DSPS within 30 days of date an expense is incurred. DSPS Boards-Travel and Reimbursement-Travel and Reimbursement Overview
5. Lodging Accommodations/Hotel Cancellation Policy – Lodging accommodations are provided to members who must leave home before 6:00 a.m. to attend a meeting. If you cannot attend a meeting it is the board member's responsibility to cancel their reservation within the stated cancellation timeframe. If a meeting is changed to a teleconference or cancelled or rescheduled, DSPS staff will make lodging cancellations or modifications as needed. DSPS Boards-Travel and Reimbursement-Travel and Reimbursement Overview
6. Inclement Weather Policy – In the event of inclement weather the agency may change a meeting from an in-person meeting to a teleconference.

11) Authorization

Brice McCluskey — *1/21/2020*

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:
Brice McCluskey, Operations Program Associate	1/21/2020
	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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/30/2020	☒ 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 of its Officers for 2020
2) The Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate
3) The Board should review and then consider continuation or modification of previously delegated authorities or any additional delegations that may be deemed necessary

11) Authorization

Brice McCluskey — *1/21/2020*

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

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PHARMACY EXAMINING BOARD

2019 ELECTION RESULTS, LIAIASON APPOINTMENTS, AND DELEGATION OF AUTHORITIES

2019 ELECTION RESULTS	
Chairperson	Philip Trapskin
Vice Chairperson	Franklin LaDien
Secretary	Cathy Winters

Appointment of Liaisons and Alternates

2019 LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Thaddeus Schumacher, Philip Trapskin, John Weitekamp
Office of Education and Examinations Liaison(s)	John Weitekamp *Alternate:* Cathy Winters
Monitoring Liaison(s)	Franklin LaDien *Alternate:* Cathy Winters
Professional Assistance Procedure (PAP) Liaison(s)	Franklin LaDien *Alternate:* John Weitekamp
Legislative Liaison(s)	Thaddeus Schumacher, Philip Trapskin, John Weitekamp
Travel Liaison	Chairperson *Alternate:* Vice Chairperson
Pilot Program Liaison(s)	Philip Trapskin, Cathy Winters
Digest Liaison(s)	Philip Trapskin
Appointed to Controlled Substances Board as per Wis. Stats. §15.405(5g)	John Weitekamp
PHARM Rep to SCAODA	John Weitekamp *Alternate:* Franklin LaDien
2019 SCREENING PANEL APPOINTMENTS	

January – December 2019	Franklin LaDien, Thaddeus Schumacher, John Weitekamp *Alternate:* Cathy Winters
2019 COMMITTEE MEMBER APPOINTMENTS	
Pharmacy Rules Committee	Thaddeus Schumacher, Philip Trapskin, John Weitekamp *Alternate:* Franklin LaDien

Delegation of Authorities

Document Signature Delegations

MOTION: Philip Trapskin moved, seconded by Franklin LaDien, 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: Philip Trapskin moved, seconded by Franklin LaDien, 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: Thaddeus Schumacher 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.

Monitoring Delegations

MOTION: Thaddeus Schumacher moved, seconded by Cathy Winters, to adopt the "Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor" as presented. Motion carried unanimously.

Credentialing Authority Delegations

Delegation of Authority to Credentialing Liaison (Generic)

MOTION: Thaddeus Schumacher moved, seconded by Cathy Winters, 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: Thaddeus Schumacher moved, seconded by John Weitekamp, 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: Thaddeus Schumacher moved, seconded by John Weitekamp, 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: Thaddeus Schumacher moved, seconded by John Weitekamp, 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.

MOTION: Thaddeus Schumacher moved, seconded by John Weitekamp, 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.

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

MOTION: Thaddeus Schumacher moved, seconded by John Weitekamp, to delegate authority to the Office of Education and Examination Liaison(s) to address all issues related to education, continuing education, and examinations. Motion carried unanimously.

Pilot Program Delegation

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

Rules Committee Delegation

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

Legislative Liaison Delegation

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

Voluntary Surrenders

MOTION: Cathy Winters moved, seconded by Thaddeus Schumacher, 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.

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

MOTION: Thaddeus Schumacher moved, seconded by Cathy Winters, 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: Thaddeus Schumacher 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.

Travel Delegation

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

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:
Ashley Ayres Monitoring and Intake Supervisor Division of Legal Services and Compliance	December 31, 2019 **Items will be considered late if submitted after 4:30 p.m. and less than:** ▪ **10 work days before the meeting for Medical Board** ▪ **14 work days before the meeting for all others**

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
January 30, 2020	☒ **Yes** ☐ **No**	Appointment of Monitoring Liaison and Delegated 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** ☐ **Both**	☐ **Yes (Fill out Board Appearance Request)** ☒ **No**	

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

1. Appoint primary and alternate liaisons for Monitoring, and for the Professional Assistance Procedure (PAP).

2. Adopt or reject the Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor document as presented in today's agenda packet, including reconsideration of Delegated Authority #10 & #11 (Pharmacy Examining Board only).

3. Delegate authority to Board Counsel to sign Monitoring orders on behalf of the Board/Section, after the Board/Section has taken action on Monitoring agenda items.

   Current practice is for Department Monitors to draft Monitoring orders after Board meetings, send them to Board Counsel for review, and then send them to the Executive Director for subsequent review and signature. With the new proposed process, Department Monitors would only send their orders to Board Counsel for review and signature, eliminating the need for a second review by the Executive Director.

11) Authorization

Ashley Ayres — December 31, 2019

Signature of person making this request **Date**

Supervisor (if required) **Date**

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

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

Revised 10/12

Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors 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/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 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 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.

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

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

10. *(Except Pharmacy)* 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. *(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.

    a. Year 1: 49 screens (including 1 hair test, if required by original order)
    b. Year 2: 36 screens (plus 1 hair test, if required by original order)
    c. 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

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

13. *(Except Nursing)* – Board Monitoring 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 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 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 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.

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:
Brice McCluskey, Operations Program Associate	1/21/2020
	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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/30/2020	☐ Yes ☒ No	2020 Meeting Dates

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 review the finalized 2020 meeting dates. Any conflicts should be identified so to ensure quorum.

1/3/2020 (Phar 7)
1/30/2020
3/5/2020
6/4/2020
7/23/2020
9/24/2020
10/22/2020
12/3/2020

11) Authorization

Brice McCluskey	*1/21/2020*
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:
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2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Revised 12/2016

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes Administrative Rules Coordinator	16 January 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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
30 January 2020	☐ Yes ☐ No	Public Hearing on Clearinghouse Rule 19-165 relating to storage a. Review and respond to Clearinghouse Report and Public Hearing comments Public Hearing on Clearinghouse Rule 19-164 relating to pharmacy internships a. Review and respond to Clearinghouse Report and Public Hearing comments

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	

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

Hold Public Hearings at 9:00 a.m.

Discuss any public hearing comments. Review, discuss and respond to any Clearinghouse comments.

11) Authorization

Sharon Henes *1/16/20*

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

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Revised 12/2016

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 6.07 (2) and 6.075 (1) (b); to amend Phar 6.07 (3), 6.075 (2) and 6.075 (4); and to repeal and recreate Phar 6.07 (1) relating to storage.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.09 (4), Stats.

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

Explanation of agency authority:

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

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

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

The Board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

Related statute or rule: N/A

Plain language analysis:

Section 1 and 2 repeals the specific requirement that a pharmacy have a refrigerator, sufficient shelf, drawer or cabinet space for prescription labels, prescription containers and adequate stock

of prescription drugs, chemicals and pharmacy equipment. This is replaced with the storage of drugs shall be secure, neat, clean and orderly.

Section 3 clarifies that all controlled substances are to be stored securely or dispersed in a way which obstructs theft or diversion.

Section 4 repeals the definition of "dry place" as it is no longer being used.

Section 5 amends the manner in which drugs are to be stored. Drugs are to be stored at appropriate conditions including, temperature and humidity, to prevent drug adulteration. It also adds the pharmacy's humidity will be monitored at least once during each business days and when the pharmacy is closed.

Summary of, and comparison with, existing or proposed federal regulation: None

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

Iowa: Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.

Michigan: Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

Minnesota: Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board reviewed the storage requirements in light of health care evolving and recognizing that there are different types of pharmacies which may not require the specific items required in the current rule.

In addition, stakeholders raised concerns regarding the implementation of CR 16-073 and the Pharmacy Examining Board made clarifications to the temperature and humidity provisions as a result of the concerns raised.

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

This rule was posted for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do 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:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 30, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 6.07 (1) is repealed and recreated to read:

Phar 6.07 (1) The storage of drugs shall be secure, neat, clean and orderly.

SECTION 2. Phar 6.07 (2) is repealed.

SECTION 3. Phar 6.07 (3) is amended to read:

Phar 6.07 (3) ~~Controlled~~ All controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispensed throughout the inventory of non-controlled substances in a manner that obstructs theft or diversion.

SECTION 4. Repeal Phar 6.075 (1) (b) is repealed.

SECTION 5. Phar 6.075 (2) and (4) are amended to read:

Phar 6.075 (2) STORAGE. Drugs shall be stored at appropriate ~~temperature and under appropriate~~ conditions, including ~~in a dry place~~ temperature and humidity, ~~according~~ to ~~the manufacturer recommendation or an official pharmaceutical compendium~~ prevent drug adulteration.

Phar 6.075 (4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy and the humidity of the pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature and the humidity over the course of the time a pharmacy is closed shall be obtained.

SECTION 7. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
26 December 2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 6

4. Subject
Storage

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☒ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0.00

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☐ No

11. Policy Problem Addressed by the Rule
With health care evolving, there are different types of pharmacies and some may not require the specific items in the current rule. In addition, stakeholders raised concerns they had in implementing CR 16-073 (specifically maintaining temperature and humidity provisions).

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
This rule was posted for economic comments and none were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
There is no economic or fiscal impact on specific businesses, business sectors, public utility rate payers, lcoal governmental units and the State's economy as a whole.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is having a rule which works for the changes in health care and allows for different types of pharmacies. In addition, it is a benefit for all to have a rule which allows for achieveable humidity and temperature requirements in pharmacies.

16. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule is have a rule which works for everyone.

17. Compare With Approaches Being Used by Federal Government
None

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Illinois requires all pharmacies and equipment in the pharmacy to be maintained in a clean condition and in good repair. Illinois does require a sink to be required in all pharmacies that maintain drug inventory. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.
Iowa: Iowa requires effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program.
Michigan: Michigan requires all prescription drugs to be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings. Michigan requires a pharmacy to have necessary drawers, shelves, storage cabinets, prescription files, a sink with hot and cold running water and a refrigerator of reasonable capacity. In Michigan, controlled substances are required to be stored in a securely locked, substantially constructed cabinet, room, or cart or they may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.
Minnesota: Minnesota requires a refrigerator and a sink with hot and cold running water. The refrigerator designated for drug storage shall have a manual, electromechanical, or electronic temperature recording equipment, devices, or logs to document proper storage of legend drugs every business day.

19. Contact Name	20. Contact Phone Number
Sharon Henes	(608) 261-2377

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 17.02 (1), (3), (5), (6), (7) and (8), 17.03, 17.04, 17.05, 17.06 and 17.07; to amend Phar 2.02 (1) (d) 1., and 3. and Phar 17.02 (4); and to create Phar 17.035 relating to pharmacy internships.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.03 (2) (b), Stats.

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

Explanation of agency authority:

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

The board may promulgate rules necessary for the administration of chs. 450 and 961. [s. 450.02 (3) (d), Stats.]

The board may promulgate rules establishing minimum standards for the practice of pharmacy. [s. 450.02 (3) (e), Stats.]

Related statute or rule: Ch. Phar 2

Plain language analysis:

This rule simplifies and brings into statutory compliance ch. Phar 17.

SECTION 1 removes references which are rendered obsolete by the proposed rule revisions to Phar 17.

SECTION 2 amends the statutory citations to correctly reflect the statutory authority.

SECTIONS 3 and 5 repeal unnecessary definitions due to the simplification of the rules.

SECTION 4 amends the definition for "intern" to mean a person who is completing an internship. It does not include a person who is allowed an exemption to practice pharmacy without a license under direct supervision (a person who has successfully completed two years of pharmacy school or a pharmacist from another state while waiting for the Wisconsin license application to be processed).

SECTIONS 6 and 8 repeal the different types (academic, foreign graduate, practical experience, and student non-academic).

SECTION 7 creates general requirements for an internship. The intern may only perform duties under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep track of the hours and locations worked by the intern. This documentation will be signed by the intern and the pharmacist and disclosed to the Board upon request.

Summary of, and comparison with, existing or proposed federal regulation:

There are no federal regulations relating to pharmacist interns.

Comparison with rules in adjacent states:

Illinois: Illinois requires approved pharmacy programs to contain a minimum of 400 hours of direct contact hours in clerkship and externship experience including supervised training in inpatient environments providing for interdisciplinary experiences with other health professionals and distributive aspects of pharmacy practice.

Iowa: In Iowa an intern is a person who is enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board is registered for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. A licensed pharmacist must be on duty and responsible for intern during all periods of training and tasks usually restricted to a pharmacist may be delegated to interns at the discretion of the supervising pharmacist.

Michigan: Michigan requires an intern to obtain an intern license Before training an intern, a licensed pharmacist must obtain board approval. The preceptor is responsible for the overall internship program at the pharmacy.

Minnesota: Minnesota requires a person to register with the board before beginning an internship. Pharmacists intending to act as preceptors for interns must also register with the board. An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Immediate and direct supervision by a licensed pharmacist is not required when the intern performs tasks that do not involve dispensing and compounding. However, all drug therapy and related

recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board did a comprehensive review of chapter Phar 17 to ensure the chapter is statutorily compliant and current with professional standards and practices.

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

This rule was posted for economic comments and none were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do 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 Dan.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on January 30, 2020 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 2.02 (1) (d) 1., and 3. are amended to read:

Phar 2.02 (1) (d) 1. A statement from the dean of the school of pharmacy or the academic records office of the respective educational institution certifying the number of hours that the applicant has successfully completed in a practical experience program ~~described in ch. Phar 17~~.

3. Verification of practical experience acquired by the applicant in another state ~~as described in ch. Phar 17~~, which is approved and verified by the board or by the agency which is the equivalent of the board in the state in which the practical experience was acquired.

SECTION 2. Phar 17.01 is amended to read:

Phar 17.01 **Authority.** The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), and ~~450.03 (1) (g) and (2) (b)~~ 450.02 (3) (d) and (e), Stats.

SECTION 3. Phar 17.02 (1) and (3) are repealed.

SECTION 4. Phar 17.02 (4) is amended to read:

Phar 17.02 (4) "Intern" means a person ~~engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g), Stats~~ completing an internship in order to meet the requirement under s. 450.03 (2) (b), Stats. It does not include a person practicing pharmacy pursuant to s. 450.02 (1) (f) or (g), Stats.

SECTION 5. Phar 17.02 (5), (6), (7) and (8) are repealed.

SECTION 6. Phar 17.03 is repealed.

SECTION 7. Phar 17.035 is created to read:

Phar 17.035 Internship. (1) The intern shall be limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist.
(2) The supervising pharmacist shall keep a written record of the hours and location worked by an intern under the pharmacist's supervision, signed by the intern and the supervising pharmacist. The written record shall be disclosed to the board upon request.

SECTION 8. Phar 17.04, 17.05, 17.06 and 17.07 are repealed.

SECTION 9. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
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MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
Phar 17

3. Subject
Pharmacy Internship

4. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected
20.165(1)(g)

6. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☒ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
The Pharmacy Examining Board did a comprehensive review of chapter Phar 17 to ensure the chapter is statutorily compliant and current with professional standards and practices.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.
This rule was posted for economic impact comments and none were received.

11. Identify the local governmental units that participated in the development of this EIA.
None

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
There is no economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to implementing the rule is providing updated references and terminology and reflecting current pharmacy practice. If the rule is not implemented, it will continue to provide outdated references and terminology and reflect practices that are no longer current.

14. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule is updated references and terminology and reflecting current pharmacy practice.

15. Compare With Approaches Being Used by Federal Government
There are no federal regulations relating to pharmacist interns.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Illinois requires approved pharmacy programs to contain a minimum of 400 hours of direct contact hours in clerkship and externship experience including supervised training in inpatient environments providing for interdisciplinary experiences with other health professionals and distributive aspects of pharmacy practice.

Iowa: In Iowa an intern is a person who is enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board is registered for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. A licensed pharmacist must be on duty and responsible for intern during all periods of training and tasks usually restricted to a pharmacist may be delegated to interns at the discretion of the supervising pharmacist.

Michigan: Michigan requires an intern to obtain an intern license before training an intern, a licensed pharmacist must obtain board approval. The preceptor is responsible for the overall internship program at the pharmacy.

Minnesota: Minnesota requires a person to register with the board before beginning an internship. Pharmacists intending to act as preceptors for interns must also register with the board. An intern performing tasks associated with dispensing or compounding shall be immediately and directly supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. Immediate and direct supervision by a licensed pharmacist is not required when the intern performs tasks that do not involve dispensing and compounding. However, all drug therapy and related recommendations that an intern proposes to make to other health professionals and patients must be reviewed and approved by a licensed pharmacist before they are made.

17. Contact Name	18. Contact Phone Number
Sharon Henes, Administrative Rules Coordinator	(608) 261- 2377

This document can be made available in alternate formats to individuals with disabilities upon request.

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE RULE 19-164

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

4. Adequacy of References to Related Statutes, Rules and Forms

In s. Phar 17.02 (4), the new language references "a person practicing pharmacy pursuant to s. 450.02 (1) (f) or (g), Stats.", but s. 450.02 (1) (f) and (g), Stats., does not exist. It appears the board may have intended to cite "s. 450.03 (1) (f) or (g), Stats.". The citation should be reviewed and corrected as appropriate.

5. Clarity, Grammar, Punctuation and Use of Plain Language

In the board's plain language analysis for the proposed rule, the description of the changes made in SECTIONS 6 and 8 of the rule should clarify that different types of "internships" are repealed. Additionally, the description of the changes made in SECTIONS 6 and 8 should mention the repeal of postgraduate internships.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes Administrative Rules Coordinator	17 January 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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
30 January 2020	☒ Yes ☐ No	Administrative Rule Matters 1. Review of 21 CFR 1305 (New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances) 2. Pending or Possible Rulemaking Projects

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

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

11) Authorization

Sharon Henes *1/17/20*

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.

[Federal Register Volume 84, Number 189 (Monday, September 30, 2019)]
[Rules and Regulations]
[Pages 51368-51377]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2019-21021]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1305

[Docket No. DEA-453]

RIN 1117-AB44

New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to implement a new single-sheet format for DEA Form 222, used by DEA registrants to order schedules I and II controlled substances. The rule provides for a two-year transition period, during which the existing triplicate version of the forms may continue to be used. The rule also includes a number of minor procedural changes.

DATES: This rule is effective October 30, 2019.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8209.

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; maintenance and submission of records and reports; and for the efficient execution of his statutory functions. **21 U.S.C. 821**, **827**, **871**(b). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. **21 U.S.C. 958**(f). The Attorney General has delegated this authority to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA originally published a notice of proposed rulemaking (NPRM) on this matter in the Federal Register on November 27, 2007. 72 FR 66118. On February 21, 2019, the DEA issued another NPRM, 84 FR 5395, superseding the 2007 NPRM. The DEA now finalizes the 2019 NPRM, with a number of minor changes.

Discussion of Comments

DEA received twelve comments on the 2019 NPRM, copies of which are available online at www.regulations.gov. The commenters included individuals, pharmaceutical distributors, retail pharmacies, pharmaceutical companies, and associations representing retail pharmacies and pharmacists. The DEA thanks all commenters for their thoughtful questions and suggestions, and appreciates their input during the rulemaking process.

Two comments were general statements of support for the rule, with no discussion of the proposed regulatory changes. Another comment stated that adopting "the single-sheet form would make sense only if security measures are in place," but supported the rule, saying that "all-important concerns have been addressed," and noting that the rule would result in a net cost savings. Of the remaining comments, most sought clarification of certain provisions in the proposed rule or recommended additional changes. Several comments expressed support for various provisions in the proposed rule. Only one comment explicitly opposed the rule. The substantive comments received, along with DEA's responses, will be discussed below.

Power of Attorney Issues

Comment: Multiple commenters raised issues relating to the proposed changes to the power of attorney (POA) provisions in **21 CFR 1305.05**(d). The comments focused on which persons would be authorized to sign a POA, and how POAs may be signed.

Under the current rules, **Sec. 1305.05**(d) requires that a POA be signed by four people: The person who signed the registrant's most recent application for DEA registration or reregistration, the person to whom the POA is being granted, and two witnesses. The proposed amendment to Sec. 1305.05(d) would require that this first signature be made not by the person who in fact signed the most recent application for DEA registration or reregistration, but instead by any person directly authorized to sign such an application under **Sec. 1301.13**(j): By the registrant, if an individual; by a partner of the registrant, if a partnership; or by an officer of the registrant, if a corporation, corporate division, association, trust or other entity. Multiple commenters recognized, and supported, that this amendment would allow a broader range of individuals to sign POAs, but expressed concerns that it would not include one type of person currently authorized to sign. Under the existing rules, if, e.g., an officer of a corporation executes a POA under Sec. 1301.13(j) to authorize a non-officer to sign applications for registration and reregistration on behalf of the corporation, and that individual has signed the most recent application, then that individual may also sign a POA under Sec. 1305.05, despite not being an officer of the corporation. Under the proposed change to Sec. 1305.05(d), this person would no longer be authorized to sign a POA. Multiple commenters suggested the DEA update the final rule to continue to allow persons in this situation to sign POAs in addition to permitting those individuals with expanded authority to sign a POA identified in the proposed Sec. 1305.05(d).

Response: Given the significance of Form 222 signature authority, and the potential for diversion when that authority is abused, the DEA deems it appropriate to require an officer, a partner, or the registrant him- or herself to sign POAs under **Sec. 1305.05**. The DEA appreciates that this change may require some registrants to update their business processes to ensure POAs are signed by the appropriate persons, but POAs are effective until revoked, and registrants would only need to execute a single POA under the new rule to authorize the person who signed the most recent application for registration.

Comment: A few of the commenters, who raised concerns about the expanded authority for signing a POA, also requested changes to **Sec. 1305.05**(d) to allow POAs to be signed electronically as an alternative to a written signature on a hard-copy form. Commenters stated electronic signatures are a secure and traceable method of signing documents, and are already commonly accepted in commercial transactions. Commenters also stated that electronic signature systems are able to accommodate witness signatures, but that given the security features of electronic signatures, witness signatures are not needed when a document is signed electronically.

Response: Electronic signatures are a widely accepted form of signature both in the government and the private sector, and the DEA agrees that allowing electronic signatures on POAs under **Sec. 1305.05** is a reasonable way of giving registrants more flexibility in the execution process. However, the requirement to have two witness signatures on a POA is essential to preventing diversion, and the DEA does not believe that electronic signatures are an adequate substitute for that requirement because they do not offer the necessary safeguards against diversion. Requiring two additional

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parties to confirm the validity of a POA significantly reduces the risk of a fraudulent POA being used to divert controlled substances, or otherwise disrupt the closed system of distribution. Therefore, the witness requirement will be kept in place, but witnesses may sign a POA electronically, if the electronic signature technology used has this capability. This final rule adds **Sec. 1305.05**(f) to explicitly allow electronic signatures for POAs, but does not make any changes to the witness signature requirement. This final rule also includes some non-substantive changes to that section to improve clarity.

Anonymous Comment

Comment: An anonymous commenter stated that the proposed rule conflicts with the requirements of **21 U.S.C. 828**(d)(1) as it requires purchasers to make a copy of a submitted order form "on a form provided by the [A]ttorney [G]eneral." The commenter stated that DEA should petition Congress to change section 828 before the DEA changes the triplicate form to a single-sheet form. This commenter also stated that, with the DEA no longer providing forms to be used to create copies, the rule would impose costs on registrants, not reduce their costs.

Response: The DEA does not interpret the provisions of **21 U.S.C. 828**(d)(1) to preclude the single-sheet framework proposed in the NPRM. The language of section 828(d)(1) is broad enough to allow for regulations permitting registrants to create a photocopy of a Form 222, or indeed to create an electronic copy and not retain any paper form at all. Section 828(d)(1) only states that the Attorney General (delegated to the Administrator of the DEA) must issue order forms pursuant to 21 U.S.C. 828(a) and (c)(2). Section 828(c)(2) requires distributors of controlled substances in schedule I or II to use a form issued by the Administrator and "make or cause to be made a duplicate thereof" on such form. The DEA interprets section 828(d)(1) to mean that the distributor must make a copy; it does not mean that the issued form itself must be a form with carbon copies. Therefore, the DEA does not interpret the proposed rule's change to the Form 222 to necessitate any changes to section 828.

Regarding the economic impact of the rule, while it does impose certain costs on affected registrants, the DEA estimates it will result in a net cost savings for purchasers, dispensing suppliers, and non-dispensing suppliers of between $312 and $336 per entity per year.\1\

\1\ More information about the economic impact of this rule can be found in the Regulatory Flexibility Act section, below.

Comment by Healthcare Distribution Alliance (HDA)

Comment: HDA noted that **Sec. 1305.13**(a) as amended in the proposed rule is not explicit as to when the purchaser must make a copy of the Form 222. HDA stated that they believe the DEA's intent was for the purchaser to make a copy before submitting the form to a supplier, and that they support the provision under that reading.

Response: HDA is correct that under the proposed rule, a purchaser would be required to make a copy of the original Form 222 before submitting it to a supplier. Since the supplier would retain the original for its records, the purchaser would not have an opportunity to create a copy after submitting the original to the supplier. The regulatory text in **Sec. 1305.13**(a) has been updated in this final rule to make this requirement explicit.

Comment: HDA also recommended updating **Sec. 1305.13**(b) to not require suppliers that are required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) to create a copy of the original Form 222. As drafted in the proposed rule, Sec. 1305.13(b) required suppliers to "record on the original and a copy their DEA registration number" and other information, regardless of whether the supplier needed to submit a copy of the form to the DEA. By removing "and a copy" from this section, only suppliers who do not report to ARCOS would be required to create a copy of the original, per proposed Sec. 1305.13(d).

Response: The DEA agrees that removing "and a copy" from **Sec. 1305.13**(b) would help clarify that ARCOS-reporting suppliers are not required to make a copy of the original Form 222. This final rule updates Sec. 1305.13(b) accordingly.

Comment: Relatedly, HDA commented that while the proposed rule specified that purchasers would be permitted to make an electronic copy of a Form 222 to keep for their records, the proposed rule did not explicitly state whether suppliers could retain the original Form 222 in an electronic form, instead of the paper original itself. HDA suggested the DEA clarify this issue, and allow suppliers to retain the original Form 222 in an electronic form.

Response: The proposed rule was clear that under the proposed changes to **Sec. 1305.13**, suppliers would be required to retain the original of a Form 222, and could not fulfill their recordkeeping responsibilities by retaining a copy, whether paper or electronic. HDA's comment suggests allowing suppliers to retain the original Form 222 "in an electronic form," but this amounts to nothing more than creating an electronic copy. The original form is on paper, and so the only way to retain the original is to retain that same paper form. The new single-sheet Form 222 is designed with multiple security features that would not be preserved in a copy, paper or electronic. Retaining the original forms and making them available for inspection is necessary in order to maintain the closed system of distribution and to prevent diversion. Since the DEA is not changing the requirement that suppliers must retain the original Form 222 for their records, and may not retain a copy, whether paper or electronic, no changes have been made to this provision in this final rule.

Comment: HDA's comment also included a suggestion to increase the number of order lines on the form, provided that this could be done without reducing legibility or requiring the form to be larger than 8.5" x 11", and recommended the DEA coordinate with the Food and Drug Administration (FDA) to ensure the single-sheet Form 222 can accommodate any changes to the National Drug Code (NDC) format currently being considered.

Response: The new form will include 20 order lines, double the previous number, and will fit on a standard 8.5" x 11" sheet. The DEA is aware of the pending changes to the NDC format, and, although no changes are being made to the NDC field on the new Form 222, the DEA will be monitoring the FDA's rulemaking on the matter,

and will update the Form 222 as necessary in the future. Based on the current state of that rulemaking, any changes to the NDC format would only require minor modifications to the single-sheet Form 222.

Comment: Finally, HDA offered a number of comments related to the electronic Controlled Substances Ordering System (CSOS).

Response: While the DEA appreciates these comments, changes to CSOS are outside the scope of this rulemaking.

Comment by CVS Health

Comment: CVS Health commented that the DEA should further explain the procedure in **21 CFR 1305.11**(c) for signing and dating an electronic requisition for new Form 222, and clarify that signing and dating is not

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required for electronic requisition requests, but that registrants instead must comply with DEA requirements for using the DEA secured network connection.

Response: CVS Health is correct that registrants are not required to sign or date electronic requisition requests made through a DEA secured network connection. Nor are registrants required to provide their address on such requests. **Section 1305.11**(c) has been updated in this final rule to reflect this.

Comment: CVS Health further suggested that, in the regulatory text of the final rule, the DEA explicitly state that purchasers are permitted to retain their copies of Forms 222 as electronic scanned images.

Response: The DEA agrees an explicit statement authorizing purchasers to retain electronic copies of Forms 222 would improve clarity, and **Sec. 1305.13**(a) has been updated in this final rule to include such a statement.

Comment: CVS Health also asked how purchasers should record the number of containers and date received from the supplier, if the purchaser has retained an electronic copy of the order form, noting that printing out the electronic copy, filling it out with the receipt information, and rescanning it is a somewhat inefficient process. CVS Health suggested adding a provision to the final rule allowing purchasers to create an electronic file with the receipt information and "electronically link" this file to the electronic copy of the Form 222, provided that the information is readily retrievable upon request.

Response: The DEA appreciates that some registrants' records systems may process order forms in this way, or in a way that poses a similar inefficiency. However, creating a separate file for order receipt data would significantly complicate the inspection process. With double the number of records for DEA investigators to review during an inspection, this would add additional complexity, and consequently time and expense, to the enforcement process, and risk increasing diversion. Therefore, although requiring the order receipt data to be entered onto the copy of the Form 222 may, in some cases, require purchasers to take additional steps when processing the order, the DEA deems this necessary to prevent diversion and protect the public health and safety.

Comment: Finally, CVS Health recommended updating **Sec. 1305.17**(c) to clarify that the requirement to maintain Forms 222 separately from all other records does not apply when a purchaser stores its copy of a form electronically.

Response: Given the nature of electronic records systems, the DEA agrees that electronic copies of Forms 222 do not need to be stored on a different server or electronic system from a registrant's other records. The requirement to store Forms 222 separately from all other records may be met, for electronic copies, by storing them in such a way that they can be readily retrieved separately from all other records. Purchasers must be able, during an inspection or upon other DEA requests, to readily retrieve their electronic copies of Forms 222, with any related statements or other documents, and without any other records. **Section 1305.17**(e) has been added in this final rule to make this requirement clear.

Comment by Costco

Comment: As discussed above, Costco requested changes to **Sec. 1305.05**(d) to allow POAs to be signed electronically, and to not require witness signatures when a POA is signed electronically.

Response: As discussed above, this final rule adds a provision allowing a POA under **Sec. 1305.05** to be signed electronically, but retains the requirement that such POAs be signed by two witnesses.

Comment by National Association of Chain Drug Stores (NACDS)

Comment: NACDS' comment discussed the POA provisions of the proposed rule, but also requested that the final rule allow pharmacies to continue to requisition Forms 222 using Form 222a. NACDS indicated this would be helpful in situations where pharmacies need more forms than allotted or when there is a need beyond the normal demand. NACDS stated that this method of requisition would be in addition to those specified in the proposed rule.

Response: While the DEA appreciates the importance of offering registrants multiple options for requisitioning Forms 222, Form 222a has been out of use for some time. The requisition options in the proposed rule--through a DEA secured network connection, by contacting any Division Office, or by contacting the Registration Section through the customer service center--should be sufficiently broad to accommodate the vast majority of registrants, without requiring the time and expense of maintaining an outdated form.

Comment by Novartis

Comment: After briefly touching on the POA issues discussed above, Novartis' comment asked how many forms could be requisitioned per registration type, and whether there would be a particular data source (e.g., ARCOS) that would be used to determine that number based on business activity.

Response: Currently, registrants are asked to provide a written explanation of need if the number of Forms 222 requested in a given requisition request exceeds a particular number (not made public, for security reasons), unique to each business activity. The proposed rule did not include any changes to the default numbers for each business activity, or how a registrant's business activity is determined for these purposes. This final rule does not make any changes to these policies either, and under the new rules registrants may continue to requisition Forms 222 in the same numbers as under current practice. Registrants will still be asked to provide a written explanation when more than the default number of forms is requested.

Comment: Novartis also asked whether the proposed rule would include any change to how Forms 222 are ordered in bulk, and if so, what the new procedure would be.

Response: The proposed rule included no substantive changes to the bulk ordering process. The rule gave three ways to requisition order forms--through a DEA secured network connection, by contacting any Division Office, or by contacting the Registration Section through the customer service center--but registrants will provide the same information in the same format as under existing practice.

Comment: Novartis sought additional information on the details of the new form, specifically: Whether it would be printed on color paper or in color ink; if so, whether a black and white copy would satisfy the purchaser's recordkeeping requirements; what type of paper stock the form would be printed on; and whether a sample of the new form would be made available to registrants. Novartis stated that registrants using electronic ordering systems will need time to update their systems before adopting the new single-sheet form. Novartis stated it would take six to eight months to update its own system.

Response: The new Form 222 will be printed in color on white 8.5" x 11", 24 pound paper stock. A black and white copy of the form is sufficient to meet the purchaser's recordkeeping obligations. A sample of the new form can be obtained by request, using the contact information first provided above, and is included in the information collection request associated with this rulemaking, available on www.reginfo.gov under

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Office of Management and Budget (OMB) Control Number 1117-0010. With respect to registrants needing to update their electronic ordering systems to accommodate the new single-sheet format, the DEA appreciates that it will take time to implement the necessary changes; this is why the proposed rule included a two-year transition period. Registrants may continue to use existing stocks of triplicate Forms 222 while they update their ordering systems, to avoid any disruptions.

Comment by Kroger Health

Comment: As discussed above, Kroger Health suggested the DEA update **Sec. 1305.05**(d) to expand the range of people authorized to sign a POA. Kroger Health also suggested changes to Sec. 1305.05 to allow POAs to be signed electronically, and to not require witness signatures when a POA is signed electronically.

Response: As discussed above, this final rule retains the requirement that POAs under **Sec. 1305.05** be signed by an officer, a partner, or the registrant him- or herself, and does not expand this provision to include the person who signed the most recent application for registration. Additionally, this final rule adds a provision allowing a POA under Sec. 1305.05 to be signed electronically, but retains the requirement that such POAs be signed by two witnesses.

Comment by Janssen

Comment: As discussed above, Janssen suggested the DEA update **Sec. 1305.05**(d) to expand the range of people authorized to sign a POA.

Response: As discussed above, this final rule retains the requirement that POAs under **Sec. 1305.05** be signed by an officer, a partner, or the registrant him- or herself, and does not expand this provision to include the person who signed the most recent application for registration.

Comment by American Pharmacists Association (APhA)

Comment: APhA sought clarification whether the handling and recordkeeping for triplicate Forms 222 during the transition period would remain the same as under the current rules, or if any of the proposed changes would apply.

Response: In general, for triplicate forms used during the transition period, registrants should continue to use the same handling and recordkeeping procedures they use under the existing rules. The provisions in Sec. 1305.20 are the specific requirements applicable to the use of triplicate Forms 222 during the transition period, and are largely duplicative of the existing rules governing the use of triplicate forms. However, when Sec. 1305.20 is silent as to a particular requirement included in other sections of **part 1305**, those other sections are controlling. For example, the requirements for signing POAs in **Sec. 1305.05** are not superseded by any provision in Sec. 1305.20; therefore, the new rules for who may sign a POA, and how, are applicable to the use of triplicate Forms 222 during the transition period.

Comment: APhA recommended the DEA coordinate with the FDA to accommodate any changes to the NDC format.

Response: As previously discussed, the DEA is monitoring FDA's rulemaking on this matter, and will update the new single-sheet Form 222 as needed in the future.

Comment: APhA stated that the proposed rule would require purchasers to "make a copy (photocopy or scan)" of executed Forms 222 for their records, and would similarly allow "dispensing suppliers" to submit a copy of Form 222 to the DEA by fax or email. However, APhA noted that there were other methods of creating an electronic copies besides scanning. APhA encouraged the DEA to clarify that purchasers and suppliers would not be arbitrarily restricted in how they can create an electronic copy of Forms 222, and that capturing an image of a form using, e.g., a smartphone, would be deemed to meet the recordkeeping requirements of the rule.

Response: The DEA agrees registrants should be permitted to make an electronic copy of Forms 222 in any reasonable method, and the regulatory text in the proposed rule did not indicate otherwise. Photocopying and scanning were given in the preamble as two possible methods of creating a copy, but are not the only methods that would be allowed. The proposed changes to the regulatory text in **Sec. 1305.13**(a) did not restrict registrants to only photocopying or scanning, so no changes are needed in the final rule to give registrants the flexibility APhA suggested.

Also, as is discussed below, the DEA is removing fax as an option for submitting copies of Forms 222 to the DEA. The DEA believes the cost of providing this submission option would outweigh the marginal benefit to the few registrants who would submit copies by fax.

Comment: Finally, APhA stated it approves of the DEA's decision to allow purchasers to retain either the original of the single-sheet Form 222 or a "readily retrievable" copy of the form for their records. APhA stated this flexibility would be more efficient and reduce costs, and encouraged the DEA to keep this provision in the final rule.

Response: The terms of the proposed rule would not allow purchasers to retain the original of a Form 222 for their records, and the DEA is not updating these terms in this final rule to allow purchasers to do so. As the proposed amendments to **Sec. 1305.13**(a) clearly stated, the original of the single-sheet Form 222 must be submitted to the supplier. The purchaser must create a copy of the original form and retain the copy for its records. The purchaser does not have the option of retaining the original. The proposed amendments to Sec. 1305.13(d) clearly stated that suppliers must keep the original of the Form 222 on file. The preamble to the proposed rule also made clear that purchasers would make and retain a copy of the Form 222, and suppliers would retain the original.\2\ These requirements have not been changed in this final rule, and therefore no changes to the relevant regulatory text have been made.

\2\ 84 FR 5395 at 5397 (Feb. 21, 2019) ("[purchasers] would be required to complete and retain a copy of the form and send the original to their supplier for filling. The supplier would be required to record certain information related to the filling on the original and retain such original").

Changes in the Final Rule

This final rule makes a number of substantive changes to the provisions of the proposed rule, as well as some non-substantive corrections and style edits to improve clarity. Regulatory text referring to registrants as "he or she," "him or her," or in similar ways has been updated to reflect that purchasers may be corporate entities. The substantive changes to the regulatory text are listed below.

Section 1305.05

As discussed in the comment analysis section, above, **Sec. 1305.05**(f) has been added to permit electronic signatures on POAs executed under that section. The witness requirement remains in place, but witnesses are permitted to sign a POA electronically.

This final rule also includes some non-substantive changes to **Sec. 1305.05**(d) to improve clarity.

Section 1305.11

As discussed in the comment analysis section, above, **Sec. 1305.11**(c) has been updated to reflect that registrants are not required to sign or date Form 222 requisition requests, or to provide their address with such requests.

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Section 1305.13

As discussed in the comment analysis section, above, **Sec. 1305.13**(a) has been updated to make explicit that purchasers must make a copy of the original Form 222 for their records before forwarding the original to the supplier, and that purchasers may retain either paper or electronic copies of Forms 222 for their records.

As discussed in the comment responses, above, **Sec. 1305.13**(b) has been updated to not require ARCOS-reporting suppliers to create and fill out copies of Forms 222 in addition to the originals.

Section 1305.13(d) has been updated to remove fax as one of the options for submitting copies of completed Forms 222 to the DEA. On further review, the DEA believes the cost of providing this submission option would outweigh the marginal benefit to the few registrants who would submit copies by fax. Even if fax submission were permitted, the DEA believes that the vast majority of registrants would use the other options available--mail and email. Removing fax submissions as an option will simplify the processing of Form 222 copies for DEA, though excepted cost savings of this change are minimal.

Section 1305.17

As discussed in the comment responses, above, **Sec. 1305.17**(e) has been added in this final rule to clarify that the requirement to maintain copies of Forms 222 separately from all other records may be met, for electronic copies, by storing them in such a way that they are readily retrievable separately from all other records.

Additionally, newly added **Sec. 1305.17**(e) also includes a provision allowing electronic copies of Forms 222 to be stored at a location different from the registered location, provided such forms are readily retrievable at the registered location upon request. This will give purchasers more flexibility in utilizing electronic records systems while still ensuring the inspection process is not unduly hindered by complex recordkeeping arrangements.

Section 1305.18

Section 1305.18 has been updated to properly reflect the requirements of **Sec. 1301.52**(c), which directs registrants discontinuing business activities with respect to controlled substances to return all unexecuted Forms 222 to the Registration Section at DEA headquarters. **Section 1305.18** currently states that unused Forms 222 should be returned to the nearest DEA office. This final rule resolves this conflict by updating Sec. 1305.18 to require registrants to return all unused Forms 222 to the Registration Section. The current mailing address for the Registration Section may be found in **21 CFR 1321.01**.

Section 1305.20

Section 1305.20(h) has been updated to provide that unused triplicate Forms 222 should be returned to the Registration Section at DEA headquarters. This matches the new language in **Sec. 1305.18**, and resolves the conflict with **Sec. 1301.52**(c).

The introductory text to Sec. 1305.20 has been updated to make clear that even if registrants still have a supply of triplicate Forms 222 available after the two-year transition period, they must switch to using the new single-sheet Form 222 at that point.

Regulatory Analysis

The DEA conducted a regulatory analysis of the final rule to determine how its provisions will impact registrants and the DEA. The results of this analysis are outlined below.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule was developed in accordance with the principles of Executive Orders 12866, 13563 and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by OMB, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

1. The DEA expects that this regulatory action will not have an annual effect on the economy of $100 million or more in at least one year and therefore is not an economically significant regulatory action. DEA's analysis finds that this final rule will result in an annual cost-savings of $25.9 million; approximately $22.1 million to purchasers (persons executing DEA Form 222s) primarily due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use; approximately $0.2 million to non-dispensing suppliers (manufacturers and distributors) due to the elimination of the requirement that registrants mail copies of their completed order forms to their DEA field office; $2.9 million to dispensing suppliers due to having the option to scan and email completed order forms; and $0.8 million to the DEA from reduction in cost of forms production, postage, and equipment maintenance.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. This regulatory action is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This final rule is estimated to have a total cost savings of $25.9 million. Although this final rule is not a significant regulatory action under Executive Order 12866, this final rule is expected to be an Executive Order 13771 deregulatory action.

An economic analysis of this rule can be found in the rulemaking docket at https://www.regulations.gov.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

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Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of Executive Order 13132. The final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator hereby certifies that this final rule has been drafted, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)), and by approving it, certifies that this rule will not have a significant economic impact upon a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. The DEA is amending its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by the DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. The DEA is also

making a number of minor procedural changes, including, among other things, who can issue the power of attorney that is required for others to sign DEA Form 222. This final rule affects all parties (purchaser and suppliers) to transactions where a DEA Form 222 is used.

Based on its records, the DEA estimates that 71,481 entities are affected by this rule, which consists of 336 manufacturers, 378 distributors, 31,887 pharmacies, 7,980 hospitals and clinics and 30,900 practitioners. The DEA estimates that 65,984 (92.3%) of the total 71,481 affected entities are small entities (312 manufacturers, 364 distributors, 31,217 pharmacies, 3,716 hospitals and clinics and 30,375 practitioners). The estimated economic impact varies for purchasers and suppliers, and among the suppliers, dispensing suppliers and non-dispensing suppliers.

"Purchasers" are registrants (primarily pharmacies, practitioners, hospitals and clinics) who execute DEA Form 222 to order schedules I and II controlled substances. The use of the new single sheet form will require purchasers to make a copy (paper or electronic) prior to submission to a supplier at an estimated cost of $0.22 per form, or a total of $734,646 per year. However, some cost savings are expected due to efficiencies gained from the new form. Key advantages include: (1) Reduction in number of forms executed due to increased number of lines per form, (2) reduction in form failure due to upgraded high-quality secure paper (fewer incidences of tears, carbon not copying through, improper tear of perforated edges, etc.), and (3) increased efficiency in completing the form due to ability to use a computer printer to fill the form (in addition to the existing allowable methods of typewriter, pen, or indelible pencil). Purchasers, as a group, are anticipated to save $22,794,750, for a net savings of $22,060,104, or $312 per entity.

"Dispensing suppliers" are individual or institutional practitioners (e.g., physicians, pharmacies, hospitals, clinics, etc.) that are registered to dispense a controlled substance and may also distribute (without being registered to distribute) a quantity of such substance to another practitioner using a DEA Form 222. The final rule will allow the dispensing supplier to submit their copy of the order form to the DEA via email, as an alternative to submitting it by mail. Assuming dispensers will opt for the less costly scan and email method, based on an estimated 17,480 dispensing suppliers, the DEA estimates the dispensing suppliers, as a group, will save $2,861,977 per year or $164 per supplier.

"Non-dispensing suppliers" are persons registered with the DEA as manufacturers or distributors of controlled substances listed in schedules I or II. The final rule and new form will remove the requirement to ship their copies of the received order forms to their DEA field office at the end of each month. The DEA estimates, by removing this requirement, the non-dispensing suppliers, as a group will save $239,657 per year, or $336 per entity.

In summary, the final rule is estimated to save purchasers, dispensing suppliers, and non-dispensing suppliers, $312, $164, and $336 per entity per year, respectively. The DEA uses 3% of annual revenue as threshold for "significant economic impact." The annual revenue at which $312, $164, and $336 is 3% equates to $10,400, $5,467, and $11,200, respectively. The DEA estimates the annual revenues of purchasers, dispensing suppliers, and non-dispensing suppliers are greater than $10,400, $5,467, and $11,200, respectively, resulting in an economic impact of less than 3% of annual revenue.

Therefore, the DEA's evaluation of economic impact by size category indicates that the rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), the DEA has identified the following collections of information related to this final rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at http://www.reginfo.gov/public/do/PRAMain.

A. Collections of Information Associated With the Final Rule

Title: U.S. Official Order Forms for Schedules I & II Controlled Substances (Accountable Forms), Order Form Requisition.

OMB Control Number: 1117-0010.

Form Number: DEA-222.

The DEA Form 222 provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the distribution of schedules I and II controlled substances within the closed system of distribution. The DEA is amending its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. Currently, the DEA Form 222 is a triplicate form with interleaved carbon paper.

The new single-sheet format is expected to lower labor burden due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the

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use of a printer, and general ease of use. Additionally, this rule removes the requirement for ARCOS-reporting suppliers to mail completed order forms to the DEA field offices. Finally, this rule will also allow suppliers that do not report to ARCOS (generally dispensers who distribute) to submit completed order forms to DEA headquarters via mail or email.

DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition to using the new single-sheet form. When a registrant's supply of triplicate forms is depleted, the DEA will issue the registrant the new single-sheet forms. This rule includes a "sunset date"--a date after which use of the triplicate forms will not be allowed--of October 30, 2021.

This rule does not impact those who use the electronic equivalent order form. Since the proposed rule, the DEA has adjusted its methodology to estimate the amount of online responses relative to paper responses to account for the additional ordering lines included on the new paper form. As a result, the estimated number of online responses has decreased, but the average burden per response has increased, so the total annual hour burden estimate remains the same. The DEA now estimates the following number of respondents and burden associated with this collection of information (which includes DEA Form 222 and the electronic equivalent):

- Number of respondents: 125,435.
- Frequency of response: 42.7 per respondent per year (average).
- Number of responses: 5,350,000 (3,300,000 paper DEA Form 222; 2,050,000 electronic equivalent).
- Burden per response: $0.1925.
- Total annual hour burden: 1,030,000.

Since this rule eliminates the requirement that suppliers mail completed DEA Forms 222 to their local DEA field offices, the cost burden associated with that requirement is also eliminated. However, this rule requires purchasers to make copies of the new single-sheet Form 222 before submitting the original to the supplier; the DEA estimates this printing/copying will have a cost burden of $130,350.

If you need a copy of the information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

Any additional comments on this collection of information may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to OMB Control Number 1117-0010.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. Accordingly, this final rule is not subject to the reporting requirements under the CRA.

List of Subjects in 21 CFR Part 1305

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set forth above, the DEA amends 21 CFR part 1305 as follows:

PART 1305--ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

- 1. The authority citation for **part 1305** continues to read as follows:

  Authority: 21 U.S.C. 821, **828**, **871**(b), unless otherwise noted.

- 2. Amend **Sec. 1305.05** by revising paragraph (d) and adding paragraph (f) to read as follows:

Sec. 1305.05 Power of attorney.

* * * * *

(d) A power of attorney must be executed by:

(1) The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;

(2) The person to whom the power of attorney is being granted; and

(3) Two witnesses.

* * * * *

(f) A power of attorney executed under this section may be signed electronically, by any or all of the persons required to sign.

- 3. Revise **Sec. 1305.11** to read as follows:

Sec. 1305.11 Procedure for obtaining DEA Forms 222.

(a) DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 that will be furnished upon a requisition for order forms unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person with an active registration that is authorized to order schedule I and II controlled substances is entitled to obtain a DEA Form 222, which will be supplied at any time after the DEA registration is granted. Any person holding a registration authorizing the person to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting any Division Office or the Registration Section of the Administration through the customer service center.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired.

(d) DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local Division Office or the Registration Section of the Administration to modify the registration.

- 4. Amend **Sec. 1305.12** by revising paragraph (a) to read as follows:

Sec. 1305.12 Procedure for executing DEA Forms 222.

(a) A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil.

* * * * *

- 5. Amend **Sec. 1305.13** by revising paragraphs (a), (b), (d), and (e) to read as follows:

Sec. 1305.13 Procedure for filling DEA Forms 222.

(a) A purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. The copy retained by the purchaser may be in paper or electronic form.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order

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cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

* * * * *

(d) The supplier must retain the original DEA Form 222 for the supplier's files in accordance with **Sec. 1305.17**(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under **Sec. 1304.33(**c) (such as a practitioner) must

make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

* * * * *

- 6. Amend **Sec. 1305.14** by revising the first two sentences of paragraph (a) and paragraph (b) to read as follows:

Sec. 1305.14 Procedure for endorsing DEA Forms 222.

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in **Sec. 1305.13**, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided in Part 3 on the original DEA Form 222) the DEA number of the second supplier, and must be signed and dated by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. * * *

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

- 7. Amend **Sec. 1305.15** by revising paragraphs (b) and (d) to read as follows:

Sec. 1305.15 Unaccepted and defective DEA Forms 222.

* * * * *

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason (*e.g.,* illegible or altered).

* * * * *

(d) When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with **Sec. 1305.17**. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

- 8. Amend **Sec. 1305.16** by revising paragraphs (a) and (d) to read as follows:

Sec. 1305.16 Lost and stolen DEA Forms 222.

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, the purchaser must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return the original DEA Form 222 to the purchaser, who must attach it to the statement.

* * * * *

(d) If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance.

* * * * *

- 9. Amend **Sec. 1305.17** by revising paragraphs (a), (b), and (c) and adding paragraph (e) to read as follows:

Sec. 1305.17 Preservation of DEA Forms 222.

(a) The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain the original of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under **Sec. 1305.12**(e)), at the registered location printed on the DEA Form 222.

* * * * *

(e) Electronic copies of DEA Forms 222 will be deemed to be maintained separately from all other records of the registrant, for the purposes of this section, if such copies are readily retrievable separately from all other records. Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location.

- 10. Revise **Sec. 1305.18** to read as follows:

Sec. 1305.18 Return of unused DEA Forms 222.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under **Sec. 1301.36** of this chapter for all Schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section.

- 11. Amend **Sec. 1305.19** by revising paragraph (a) to read as follows:

Sec. 1305.19 Cancellation and voiding of DEA Forms 222.

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

* * * * *

- 12. Add Sec. 1305.20 to read as follows:

Sec. 1305.20 Transition provisions allowing continued use of existing stocks of triplicate DEA Forms 222.

Registrants may continue to use existing stocks of the triplicate DEA Form 222 until October 30, 2021. In any case, as soon as a registrant's supply of triplicate DEA Forms 222 is exhausted, the registrant must use the new single-sheet DEA Form 222. The provisions of this part are applicable to the use of triplicate forms, except for the specific rules as provided in this section.

(a) *Procedure for obtaining triplicate DEA Forms 222.* The DEA will no longer issue triplicate forms. Triplicate DEA

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Forms 222 will not be accepted after October 30, 2021.

(b) *Procedure for executing triplicate DEA Forms 222.* (1) A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the triplicate DEA Form 222. Triplicate DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(2) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. Triplicate DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(3) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(4) Each triplicate DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a DEA Form 222 under **Sec. 1305.05**. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(5) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

(c) *Procedure for filling triplicate DEA Forms 222.* (1) A purchaser must submit Copy 1 and Copy 2 of the triplicate DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(2) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the triplicate DEA Form 222. No triplicate DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (c)(6) of this section.

(3) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the triplicate DEA Form 222, except as specified in paragraph (c)(6) of this section.

(4) The supplier must retain Copy 1 of the triplicate DEA Form 222 for his or her files in accordance with paragraph (g)(3) of this section and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(5) The purchaser must record on Copy 3 of the triplicate DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(6) DEA triplicate Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the triplicate DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

(d) *Procedure for endorsing triplicate DEA Forms 222.* (1) A triplicate DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in paragraph (c) of this section, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the triplicate DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the triplicate DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute triplicate DEA Forms 222 on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with paragraphs (c)(2) through (4) of this section, including shipping all substances directly to the purchaser.

(2) Distributions made on endorsed triplicate DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

(e) *Unaccepted and defective triplicate DEA Forms 222.* (1) A triplicate DEA Form 222 must not be filled if either of the following apply:

(i) The order is not complete, legible, or properly prepared, executed, or endorsed.

(ii) The order shows any alteration, erasure, or change of any description.

(2) If a triplicate DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g. illegible or altered).

(3) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(4) When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with paragraph (g) of this section. A defective triplicate DEA Form 222 may not be corrected; it must be replaced by a new triplicate DEA Form 222 for the order to be filled.

(f) *Lost and stolen triplicate DEA Forms 222.* (1) If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, the purchaser must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first triplicate DEA Form 222 were not received through loss of that triplicate DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the triplicate DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second triplicate DEA Form 222 sent to the supplier. If the first triplicate DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. However, if the registrant no longer can use triplicate forms, then the registrant shall proceed by issuing a new single-sheet form in accordance with **Sec. 1305.16**.

(2) Whenever any used or unused triplicate DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the

Divisional Office responsible for the area in which the registrant is located,

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stating the serial number of each form stolen or lost.

(3) If the theft or loss includes any original triplicate DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the triplicate DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(4) If an entire book of triplicate DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the triplicate DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(5) If any unused triplicate DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

(g) *Preservation of triplicate DEA Forms 222.* (1) The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(2) The supplier must retain Copy 1 of each triplicate DEA Form 222 that it has filled.

(3) Triplicate DEA Forms 222 must be maintained separately from all other records of the registrant. Triplicate DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents (not including unexecuted triplicate DEA Forms 222, which may be kept elsewhere under paragraph (b)(5) of this section), at the registered location printed on the triplicate DEA Form 222.

(4) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain triplicate DEA Forms 222 for these substances separately from all other DEA triplicate Forms 222 and records required to be maintained by the registrant.

(h) *Return of unused triplicate DEA Forms 222.* If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under **Sec. 1301.36** of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the Registration Section.

(i) *Cancellation and voiding of triplicate DEA Forms 222.* (1) A purchaser may cancel part or all of an order on a triplicate DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

(2) A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (i)(1) of this section.

Dated: September 23, 2019.

Uttam Dhillon,
Acting Administrator.

[FR Doc. 2019-21021 Filed 9-27-19; 8:45 am]

BILLING CODE 4410-09-P

PHARMACY RULES LIST

Current Rule Projects

In Process

Phar 8 (Scope) – Review and draft (New scope expires February 12, 2022)
- Projects specifically identified which fall under this chapter
- Partial fill of controlled substances
- Security of controlled substances

Phar 15 (Compounding) – Drafting (Scope expires March 9, 2022)
Phar 6 (Storage) – Public Hearing (Scope expires Feb. 6, 2021)
Phar 7 (Practice of Pharmacy) – Legislative Review (Scope expires Feb 4, 2020)
Phar 17 (Intern) – Public Hearing (Scope Expires March 18, 2020)
Phar 7 (Delegate – Check - Delegate) – Effective 3/1/20
Phar 7 (Pharmacist Tech Ratio) – Effective 3/1/20
Phar 7 (Automated Final Check) – Effective 3/1/20

Identified Future Rule Projects

Items in 2017 Act 108 Report submitted to JCRAR 3/22/19
- Phar 5.02
- Phar 11.01
- Phar 12.04
- Phar 6.04

Rules resulting from 2019-2020 Legislative Session
Required rules pursuant to 450.073 (3), Wis. Stats. (Electronic track and trace)
Compliance with Drug Supply Chain Security Act
- Wholesale and Distributor Requirements
- Product Tracing Requirements

Phar 12 Update (including security requirements)
Phar 13 Clean-Up
Out of state pharmacies
Phar 2 – Foreign educated applicants

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 Philip Trapskin	10/16/19 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?
1/30/2020 ~~10/23/2019~~	☒ Yes ☐ No	Education and Examination Matters 1. MPJE Item Review and Related Matters

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:

The Board is being asked to consider developing a process to identify state law changes governing the practice of pharmacy to inform possible changes to the exam.

11) Authorization

Kimberly Wood — *10/16/2019*

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.

From:	Janso, Lisa
To:	Sybell, Debra - DSPS
Subject:	RE: Quick Question
Date:	Monday, September 30, 2019 6:16:48 PM
Attachments:	image001.png image002.png image003.png image004.png image005.png image006.png MEMO - EO - MPJE 2019 Workshop Announcement.pdf MEMO - EO - 2019 MPJE State Item Pool Review Notification.pdf

Hi Deb,

Our pleasure! We hope you find the Forum to be beneficial as well.

The meetings usually occur in March and September of each year. In March, we hold an MPJE Item Development Workshop (tentatively scheduled for March 11-13, 2020). In September, we hold the MPJE State-Specific Review and Pre-test Item Selection (tentatively scheduled for September 10-11). I have attached the corresponding memos from this year to provide more information on these meetings. We usually send the memos to the states a couple months in advance of the meetings.

Feel free to let us know if you have any additional questions.

Best regards,
Lisa

Lisa Janso, MS
Executive Committee Manager
847/391-4462

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | ljanso@nabp.pharmacy

From: Sybell, Debra - DSPS <debra.sybell@wisconsin.gov>
Sent: Monday, September 30, 2019 5:41 PM
To: Janso, Lisa <ljanso@nabp.pharmacy>
Subject: Quick Question

Hi Lisa,

Thanks for all of the information shared at the meeting today and the discussion. I appreciated it!

- Explore when workgroup meetings will occur for MPJE Question Writing and Review.

On another matter, can you provide me with the dates for the next set of workgroup meetings for the MPJE Question Writing and Review? I would like to make the Pharmacy Examining Board members aware of this so they can set aside time on their calendars to participate if available.

Thanks!

Best,

Deb

Deb Sybell
Executive Director
Division of Policy Development
Wisconsin Department of Safety and Professional Services
Debra.Sybell@wisconsin.gov
(608) 267-7223

NABP
National Association of Boards of Pharmacy
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Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: EXECUTIVE OFFICERS – MPJE PARTICIPATING STATES, MPJE Item Writers, MPJE Review Committee

FROM: Maureen Garrity, Competency Assessment Director

DATE: January 3, 2019

RE: MPJE Item Development Workshop – March 13-15, 2019

The National Association of Boards of Pharmacy® (NABP®) will host the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Item Development Workshop on March 13-15, 2019, at NABP Headquarters in Mount Prospect, IL. The item development process is a collaborative effort, and NABP encourages all MPJE participating states to attend this important workshop.

The tentative meeting schedule is (all times are CDT):

Wednesday, March 13: Arrive in Chicago, IL, by 3 PM and check in at the Hilton Northbrook Hotel desk

- Shuttle to NABP Headquarters in Mt Prospect, IL
- Item authoring training session: 3:30 - 4:45 PM (Group dinner to follow)

Thursday, March 14: 8:30 AM - 4 PM Item writing (Dinner on your own)

Friday, March 15: 8:30 AM - 3 PM Item writing

NABP will reimburse approved expenses (travel, food, and lodging) for up to two participants from each state to attend the workshop. However, NABP may need to limit the attendance from any jurisdiction to one participant in the event of space limitations. If your state board is unable to send a representative, the writing assignment will need to be completed remotely. Full details including content areas to be targeted and logistics will be provided at a later date to the designated item writers who will write remotely.

Please provide contact information on the response form for the individuals who will attend the workshop on site, or for those who will complete the state assignment remotely. The NABP Meeting Services department will forward travel and hotel information approximately six weeks prior to the meeting once NABP has secured the names of the attendees.

If you have any questions or comments, please contact Anne Woolridge, competency assessment supervising coordinator, at awoolridge@nabp.pharmacy or 847/391-4534, or Maureen Garrity at mgarrity@nabp.pharmacy or 847/391-4596.

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F) 847/375-1114

TO: EXECUTIVE OFFICERS – MPJE Jurisdictions

FROM: Maureen Garrity, Competency Assessment Director

DATE: June 6, 2019

RE: 2019 MPJE State-Specific Review and Pre-test Item Selection

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The National Association of Boards of Pharmacy® (NABP®) will host the Multistate Pharmacy Jurisprudence Examination® (MPJE®) State-Specific Review on September 12-13, 2019. The purpose of the review is to ensure that the most current and valid items are available for testing in each of the jurisdictions. In addition to the review, new items must be selected for pre-testing in each jurisdiction. Both the review and selection of new items are integral to the validity and the sustainability of the examination program.

The tentative meeting schedule is (all times are CDT):

Thursday, September 12:	8:30 AM - 4:30 PM (Group dinner to follow)
Friday, September 13:	8:30 AM - 4 PM

NABP will reimburse approved expenses (travel, food, and lodging) for up to two participants from each jurisdiction to attend the review. However, NABP may need to limit the attendance from any jurisdiction to one participant if overall responses exceed space and resource limitations.

If your jurisdiction chooses to conduct the review and new item selection remotely, the item pools will be available on a password-protected, secure website. We encourage your designated remote reviewers to schedule specific days and times to complete the review, just as if they were traveling to the NABP office. NABP will send complete details to the designated remote reviewers in mid-August.

Please provide contact information on the response form for the individual(s) you designate to attend the workshop or who will remotely complete the assignment. Please email the form directly to MPJE@nabp.pharmacy by July 12, 2019. The NABP Meeting Services department will forward travel and hotel information to designees approximately six weeks prior to the meeting. Detailed instructions will be sent to those individuals designated as reviewers prior to the start of the remote review window.

If you have any questions or concerns, feel free to contact Maureen Garrity at mgarrity@nabp.pharmacy or Anne Woolridge at awoolridge@nabp.pharmacy.

Attachment: 2019 MPJE State-Specific Review Participant Form

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

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.	9/13/19 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?
~~9/25/19~~ ~~12/17/19~~ 1/30/2020	☒ Yes ☐ No	Newsletter Planning – Discussion and Consideration

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

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

Review and discuss the example email newsletter format.

11) Authorization

Kimberly Wood *9/13/19*

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.

Wood, Kimberly - DSPS

From: Wisconsin Department of Safety and Professional Services <WIDSPS@public.govdelivery.com>
Sent: Friday, August 23, 2019 11:15 AM
To: Wood, Kimberly - DSPS; Cathy Winters
Subject: Wisconsin Pharmacy Examining Board Update : TEST

Having trouble viewing this email? View it as a Web page.

WISCONSIN
DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

DATE: Month D, YYYY

Wisconsin Pharmacy Examining Board Updates

You are receiving this update as a licensee of the Wisconsin Pharmacy Examining Board.

Important Information Regarding Recent Changes to Administrative Rules

- Effective November 1, 2017, Phar 6 has been updated pursuant to 2017 Wisconsin Act 18:
  - Phar 6 - Pharmacy Licenses and Equipment
  - 2017 Wisconsin Act 18
- Effective November 1, 2017, Phar 14 has been updated:
  - Phar 14 - Home Medical Oxygen Providers
- Effective September 1, 2017, Phar 7.10 has been updated:
  - Phar 7.10 - Administration of drug products and devices other than vaccines
- On October 1, 2016 the following Pharmacy Chapters were updated:
  - Rules:
    - Phar 1
    - Phar 2
    - Phar 4
    - Phar 5
    - Phar 8
  - Orders
    - Phar 1, 8 Relating to Definitions and Controlled Substances
    - Phar 1, 2 and 4 Relating to Application and Examination
    - Phar 5 Relating to Renewal and Reinstatement

- Phar 8 Relating to Identification Card Required for Certain Controlled Substances

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Department Updates

Click here to subscribe to email updates on a number of topics from the department.

Pending Rule Changes

Keep current with any pending rule changes affecting your profession by visiting the DSPS website to view the Pending Rules listing.

CONTACT US

Email: dsps@wisconsin.gov | **Phone:** (608) 266-2112 | **Office Hours:** 7:45 a.m.- 4:30 p.m.

The mission of the Department of Safety and Professional Services is to promote economic growth and stability while protecting the citizens of Wisconsin as designated by statute.

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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.	1/8/2020
	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:

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/30/2020	☒ Yes ☐ No	Speaking Engagements, Travel, or Public Relation Requests 1) Pharmacy Society of Wisconsin Legislative Day – February 12, 2020 – Madison, WI

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 consider authorization of a member(s) to speak at the PSW Legislative Day on February 12, 2020 in Madison, WI.

11) Authorization

Kimberly Wood *1/8/2020*

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.
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Pharmacy Society of Wisconsin

December 20, 2019

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

RE: Speaking Invitation: PSW Legislative Day – February 12, 2020

Dear Dr. Trapskin,

The Pharmacy Society of Wisconsin (PSW) is hosting its annual Legislative Day on Wednesday, February 12, 2020 in Madison, Wisconsin. We anticipate an attendance of over 300 pharmacists, pharmacy technicians, and pharmacy students. The agenda will include a discussion of several pharmacy-related legislative and regulatory priorities.

On behalf of the Board of Directors and staff of the Pharmacy Society of Wisconsin, I would like to invite you and other members of the Pharmacy Examining Board to attend our Legislative Day and address our members. They would appreciate hearing a regulatory update from Pharmacy Examining Board members. I have sent an invitation to Andrea Magermans of the ePDMP requesting a presentation after the PEB provides a regulatory update.

The details of the day are as follows:

Date: Wednesday, February 12, 2020
Location: Monona Terrace Convention Center, 1 John Nolen Drive, Madison, WI
Requested Speaking Time: 11 a.m. to 12 p.m.

Please let me know at your convenience if you will be able to join us, and please do no not hesitate to contact me at dwomack@pswi.org or 608-827-9200 with any questions. Thank you for your consideration of this request.

Sincerely,

Danielle Womack

Danielle M. Womack, MPH
Vice President, Public Affairs
Pharmacy Society of Wisconsin

701 Heartland Trail
Madison, WI 53717
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