Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI
Contact: Brad Wojciechowski (608) 266-2112
August 31, 2023

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

AGENDA

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

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of June 15, 2023 (5-8)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements, and Recognition

E. 11:00 A.M. Preliminary Hearing on Statement of Scope – SS 044-23 on Phar 8, Relating to Controlled Substances Requirements (9-12)
1) Review Public Hearing Comments

F. 11:00 A.M. Public Hearing for Clearinghouse Rule 23-031 on Phar 18, Relating to Licensure of Third Party Logistics Providers (13-24)
1) Review Public Hearing Comments and Respond to Clearinghouse Report

G. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates
   a. Kleppin, Susan – 7/1/2025
   b. O'Hagan, Tiffany – 7/1/2024
   c. Peterangelo, Anthony – 7/1/2027
   d. Walsh, Michael – 7/1/2024
   e. Weitekamp, John – 7/1/2026
   f. Wilson, Christa – 7/1/2025

H. Administrative Rule Matters – Discussion and Consideration (28-389)
1) Final Rule Draft: Phar 7 and 10, Relating to Required Disclosures to Consumers
2) Possible Rule Project: Phar 7 Comprehensive Review
3) Pending or Possible Rulemaking Projects

I. Appearance: Achieving DSCSA Compatibility and Pulse System – Discussion and Consideration (39)

1) NABP Associate Executive Director, Government Affairs and Innovation Josh Bolin, and Justin Macy

J. Remote Dispensing application on LicensE – Discussion and Consideration

K. Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies – Discussion and Consideration (40-56)

L. DSPS Pharmacy Inspection Process – Discussion and Consideration (57)

1) DSPS Pharmacy Inspection meeting
2) Inspections and Guidance relating to Controlled Substances

M. Credentialing Matters – Discussion and Consideration (58-59)

N. Legislative and Policy Matters – Discussion and Consideration (60-62)

1) Correspondence to Legislature regarding 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160 - Discussion and Consideration

O. Speaking Engagements, Travel, or Public Relation Requests, and Reports

P. Pilot Program Matters – Discussion and Consideration

Q. 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) Public Health Emergencies
13) Pilot Program Matters
14) Variances
15) Liaison Reports
16) Board Liaison Training and Appointment of Mentors
17) Informational Items
18) Division of Legal Services and Compliance (DLSC) Matters
19) Presentations of Petitions for Summary Suspension
20) Petitions for Designation of Hearing Examiner
21) Presentation of Stipulations, Final Decisions and Orders
22) Presentation of Proposed Final Decisions and Orders
23) Presentation of Interim Orders
24) Pilot Program Matters
25) Petitions for Re-Hearing
26) Petitions for Assessments
27) Petitions to Vacate Orders
28) Requests for Disciplinary Proceeding Presentations

29) Motions
30) Petitions
31) Appearances from Requests Received or Renewed
32) Speaking Engagements, Travel, or Public Relation Requests, and Reports

R. 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.).

S. Credentialing Matters

1) Application Reviews (63-250)

a. Allivet – Out of State Pharmacy Applicant (63-183)
b. Boyd A. Barwin – Pharmacist Technician Applicant (184-204)
c. Megan M. Currie – Pharmacist Technician Applicant (205-222)
d. David B. Hauge – Pharmacist Applicant (223-230)
e. International Rehabilitative Sciences Inc – Out of State Pharmacy Applicant (231-250)

T. Deliberation on Division of Legal Services and Compliance Matters

1) Administrative Warning (251-259)

a. 22 PHM 116 – W. (251-252)
b. 22 PHM 118, 23 PHM 067 – Z.H. (253-254)
c. 23 PHM 045 – C.C.A.T.P. (255-257)
d. 23 PHM 056 – C.A.S (258-259)

2) Case Closings (260-338)

a. 21 PHM 163 – K.S. (260-263)
b. 22 PHM 031 – B.D. (264-267)
c. 22 PHM 076 – W.P. (268-275)
d. 22 PHM 078 – W. (276-281)
e. 22 PHM 136 – W. (281-285)
f. 22 PHM 143 – M.P., S.E.B. (286-291)
g. 22 PHM 165 – S.S.H.P. (292-297)
h. 23 PHM 023 – W. (298-302)
i. 23 PHM 029 – C.R.S.L. (303-305)
j. 23 PHM 042 – W.R.P., M.D. (306-311)
k. 23 PHM 056 – W. (312-317)
l. 23 PHM 076 – K.A.J. (318-324)
m. 23 PHM 077 – N.T. (325-331)
n.)23 PHM 078 – M.L.T. (332-338)

3) Proposed Stipulation and Final Decision and Orders (339-367)

a. 21 PHM 151 – CVS Pharmacy #10550 (339-344)
b. 21 PHM 151 – Jeffrey F. Legore, R.Ph. (345-350)
c. 22 PHM 050 – Jerome Drugs, Inc. (351-361)
d. 22 PHM 165 – Jeremy J. Allen, PharmD, R.Ph. (362-367)

4) Monitoring

a. Alice Hinnawi, R.Ph. – Requesting Full Licensure (368-379)

U. 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

V. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

ADJOURNMENT

NEXT MEETING: OCTOBER 26, 2023

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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 virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
PHARMACY EXAMINING BOARD
MEETING MINUTES
JUNE 15, 2023

PRESENT: Susan Kleppin, Tiffany O'Hagan, John Weitekamp, Michael Walsh, Christa Wilson

EXCUSED: Anthony Peterangelo

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; and other Department staff

CALL TO ORDER

John Weitekamp, Chairperson, called the meeting to order at 11:03 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF APRIL 27, 2023

MOTION: Michael Walsh moved, seconded by Christa Wilson, to approve the Minutes of April 27, 2023 as published. Motion carried unanimously.

11:00 A.M. PUBLIC HEARING FOR CLEARINGHOUSE RULE 23-015 ON PHAR 7 AND 10, RELATING TO REQUIRED DISCLOSURES TO CONSUMERS

Review Public Hearing Comments and Respond to Clearinghouse Report

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to designate the Chairperson to work with DSPS staff on drafting the final rule and legislative report for Clearinghouse Rule 23-015 (Phar 7 and 10), relating to Consumer Disclosures. Motion carried unanimously.

LEGISLATIVE AND POLICY MATTERS

2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160

MOTION: Michael Walsh moved, seconded by Christa Wilson, to designate the Chairperson to draft and submit a letter to the legislature on behalf of the Board expressing the Board's support of the jurisprudence exam requirement for pharmacists and the Board's concerns with 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160 and to designate the Chairperson to testify on behalf of the Board at any public hearings for 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Preliminary Rule Draft: Phar 1, 5, 6, 7, and 8, Relating to Remote Dispensing

MOTION: Christa Wilson moved, seconded by Michael Walsh, to approve the preliminary rule draft of Phar 1, 5, 6, 7, and 8, relating to Remote Dispensing, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

AURORA PHARMACY PATIENT CONSULTATION SIGN

MOTION: Christa Wilson moved, seconded by Michael Walsh, to designate Susan Kleppin to serve as the liaison for review of Phar 7.08(8) approval requests. Motion carried unanimously.

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

Consideration of Attendance: NABP's DSCSA Interoperability Summit – August 2-3, 2023 – Chicago, IL

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to designate Brad Wojciechowski, as the Board's delegate, and John Weitekamp as the Board's alternate delegate, to attend the NABP's DSCSA Interoperability Summit on August 2-3, 2023 in Chicago, IL. Motion carried unanimously.

CLOSED SESSION

MOTION: Michael Walsh moved, seconded by Susan Kleppin, to convene to Closed Session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85(1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). John Weitekamp, Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Susan Kleppin-yes; Tiffany O'Hagan-yes; Michael Walsh-yes; John Weitekamp-yes; and Christa Wilson-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:56 p.m.

CREDENTIALING MATTERS

Creative Compounds Inc – Out of State Pharmacy Applicant

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to approve the Out of State Pharmacy application of Creative Compounds Inc, once all requirements are met. Motion carried unanimously.

Joshua Grutza – Pharmacist Applicant

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to request applicant complete a fitness to practice evaluation and to provide additional information regarding his compliance with probation and any additional information requested by the credentialing liaison. Upon receipt and review of the requested information, the credentialing liaison may act upon the application. Motion carried unanimously.

Shane Urness – Pharmacy Tech Applicant

MOTION: Michael Walsh moved, seconded by Tiffany O'Hagan, to approve the Pharmacy Tech application of Shane Urness, once all requirements are met. Motion carried unanimously.

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

Administrative Warnings

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to issue an Administrative Warning in the following DLSC Cases:

a. 22 PHM 056 – P.M.I.
b. 22 PHM 168 – W.
c. 23 PHM 026 – N.L.A.

Motion carried unanimously.

Case Closings

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

1. 22 PHM 060 – F.L. – No Violation
2. 22 PHM 135 – T.M. – No Violation
3. 22 PHM 152 – C.V.S. – No Violation
4. 22 PHM 160 – E.S.I. – No Violation
5. 22 PHM 189 – C.V.S. – Insufficient Evidence
6. 22 PHM 191 – C.S.P. – No Violation
7. 22 PHM 196 – O.R.X. – Insufficient Evidence
8. 22 PHM 197 – P. – Prosecutorial Discretion (P2)
9. 23 PHM 008 – C.V.S. – Insufficient Evidence
10. 23 PHM 026 – W. – No Violation

Motion carried unanimously.

RECONVENE TO OPEN SESSION

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to reconvene into Open Session. Motion carried unanimously.

The Board reconvened into Open Session at 2:06 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Susan Kleppin moved, seconded by Michael Walsh, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

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

ADJOURNMENT

MOTION: Susan Kleppin moved, seconded by Tiffany O'Hagan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 2:08 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:
Nilajah Hardin **Administrative Rules Coordinator**	**08/18/23** 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?
08/31/23	☒ Yes ☐ No	**11:00 A.M. Preliminary Hearing on Statement of Scope – SS 044-23 on Phar 8, Relating to Controlled Substances Requirements** **1. Review Preliminary Hearing Comments**

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	**N/A**

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

The Board will hold a Preliminary Hearing on this scope statement as directed by the Joint Committee for Review of Administrative Rules.

11) Authorization

Nilajah D. Hardin 08/18/23

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:	Sen.Nass
To:	Hereth, Daniel - DSPS; DSPS; DSPS Admin Rules
Cc:	Tierney, Michael - DSPS; Sen.Nass - LEGIS; Rep.Neylon - LEGIS; Grosz, Scott A - LEGIS; Kauffman, Jill - LEGIS; Duchek, Mike - LEGIS
Subject:	JCRAR Directive to Hold Preliminary Hearing on Scope Statement SS 044-23
Date:	Thursday, July 20, 2023 1:22:24 PM

July 20, 2023

John Weitekamp, Chairperson
Pharmacy Examining Board
Department of Safety & Professional Services
P.O. Box 8366
Madison, WI 53708-8366

RE: SS 044-23 – Controlled Substances Requirements

Dear Chairperson Weitekamp:

As co-chairperson of the Joint Committee for Review of Administrative Rules (JCRAR) and pursuant to s. 227.136 (1), Stats., I write to direct the Pharmacy Examining Board to hold a preliminary public hearing and comment period on Scope Statement SS 044-23, which was published in the Wisconsin Administrative Register on July 10, 2023.

Additionally, pursuant to s. 227.135 (2), Stats., please note that a scope statement may not be approved by the Secretary, the Department of Safety & Professional Services (DSPS), or any of the agencies under DSPS until after the preliminary public hearing and comment period is held by the agency, and accordingly, no activity may be conducted in connection with the drafting of a proposed rule until after such hearing and approval have occurred.

Please confirm receipt of this letter directing a preliminary hearing and comment period on the above scope statement.

Sincerely,

Steve Nass

Senator Steve Nass
Co-Chair, JCRAR

Cc: Dan Hereth, Secretary-designee, DSPS

STATEMENT OF SCOPE

PHARMACY EXAMINING BOARD

Rule No.: Phar 8

Relating to: Controlled Substances Requirements

Rule Type: Both Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only):
Clearinghouse Rule 21-071 went into effect on October 1, 2022. This rule repealed and recreated all of Wisconsin Administrative Code Chapter Phar 8. Upon receiving feedback and completing an additional review, the Pharmacy Examining Board has determined that additional changes are needed to Phar 8 to address areas where requirements are no longer in effect or do not match federal regulations. Emergency rules are needed to ensure that these requirements can be updated to protect patient safety and allow effective regulation of the profession until permanent rules can be promulgated.

2. Detailed description of the objective of the proposed rule:
Wisconsin Administrative Code Chapter Phar 8 was recently repealed and recreated. As a result of this change, the Board has found additional areas of Phar 8 that may need to be revised to align with current Pharmacy practices and federal regulations.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
Wisconsin Administrative Code Phar 8 includes requirements for controlled substance prescribing, record keeping, partial dispensing, and compliance with federal laws and regulations, among other requirements. The proposed rules would add to the existing requirements to address issues such as controlled substances prescribing, partial dispensing, and reporting and to create consistency between the code, current pharmacy practices and federal regulations.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
15.08 (5) (b) The Board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.

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

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

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

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

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

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

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

6. List with description of all entities that may be affected by the proposed rule:
Licensed Pharmacies, Pharmacists, Manufacturers, and Distributors

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
The practice of pharmacy is not regulated by the federal government and Wisconsin has its own controlled substances schedules. However, the federal government does regulate federally controlled substances and the vast majority of Wisconsin controlled substances are also federally controlled substances. Title 21 CFR Chapter II governs federally scheduled controlled substances, including: registration of manufacturers, distributors and dispensers of controlled substances; prescriptions; orders for schedule I and II controlled substances; requirements for electronic orders and prescriptions; and disposal.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):
None to minimal. It is not likely to have a significant economic impact on small businesses.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, (608) 267-7139

Approved for publication:

Authorized Signature

5/8/2023

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

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:
Nilajah Hardin **Administrative Rules Coordinator**	**08/18/23** 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?
08/31/23	☒ Yes ☐ No	**11:00 A.M. Public Hearing for Clearinghouse Rule 23-031 on Phar 18, Relating to Licensure of Third Party Logistics Providers** 1. **Review Public Hearing Comments and Respond to Clearinghouse Report**

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	**N/A**

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

The Board will hold a public hearing on this rule as required by the rulemaking process.

11) Authorization

Nilajah D. Hardin — 08/18/23

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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STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

An order of the Pharmacy Examining Board to create Phar 18, relating to licensure of third-party logistics providers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.075 (4), Stats.

Statutory authority: ss. 15.08 (5) (b), 450.02 (3) (a), 450.02 (3) (d), and 450.075 (4), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. states that "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."

Section 450.02 (3) (a), Stats. Authorizes the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. provides that the board "may promulgate rules necessary for the administration and enforcement of this chapter and Ch. 961."

Section 450.075 (4), Stats. says: "The board shall promulgate rules implementing this section. The rules shall ensure compliance with the federal drug supply chain security act, 21 USC 360eee, et seq. The board may not promulgate rules that impose requirements more strict than the federal drug supply chain security act or any regulations passed under the federal drug supply chain security act. The board may not promulgate rules that require a license under this section."

Related statute or rule: Wisconsin Administrative Code Chapter Phar 18

Plain language analysis: The object of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 25.

Summary of, and comparison with, existing or proposed federal regulation:
21 U.S. Code s. 360eee includes national standards for third-party logistics providers. These standards include guidelines for a federal licensure program issued by the Secretary of the U.S. Department of Health and Human Services. This section also includes clarifications for those states that have a licensure program. Third-party logistics providers must either be licensed at the state level, if such a licensure program exists, or federally. On February 4, 2022, the U.S. Food and Drug Administration announced a proposed rule in National Standards for Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. This rule has not been finalized yet.

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: No comments were received.

Comparison with rules in adjacent states:
Illinois: The Illinois Department of Financial and Professional Regulation is responsible for the licensure and regulation of wholesale distribution in Illinois, with input from the Illinois Board of Pharmacy. The Illinois Wholesale Distribution Act contains requirements for licensure of resident and non-resident third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a designated representative responsible for operations at each site [225 Illinois Complied Statutes ch. 120 s. 25.5].

Iowa: The Iowa Board of Pharmacy is responsible for the licensure and regulation of Pharmacy practice in Iowa. The Iowa Pharmacy Practice Act rules are contained the Iowa Administrative Code and include requirements for licensure of third-party logistics providers. In addition to obtaining licensure, each third-party logistics provider must also submit the information of a facility manager responsible for operations at each site [657 Iowa Administrative Code ch. 43].

Michigan: The Michigan Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice in Michigan. Act 368 Article 15 Part 177 of the Michigan Compiled Laws includes the regulations for wholesale distribution in Michigan, among several other occupations. Wholesale distributor-brokers serve the same function as third-party logistics providers. In Michigan, wholesale distributor-brokers are required to be licensed and must designate a facility manager or pharmacist-in-charge to be responsible for each site [Michigan Compiled Laws s. 333.17748].

Minnesota: The Minnesota Board of Pharmacy is responsible for the licensure and regulation of pharmacy practice and wholesale distribution in Minnesota. Chapter 151 of the Minnesota Statutes, or the Pharmacy Practice and Wholesale Distribution Act, also includes licensure requirements for third-party logistics providers. In Minnesota, the facility manager or designated representative responsible for each third-party logistic provider license cannot have any felony convictions relating to wholesale distribution and

must be fingerprinted as authorized by the Minnesota Board. [Minnesota Statutes s. 151.471].

Summary of factual data and analytical methodologies: The Board reviewed the statutory changes from 2021 Wisconsin Act 25 and added to the Wisconsin Administrative Code accordingly.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis: The proposed rules were posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, 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 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on August 31, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Phar 18 is created to read:

CHAPTER PHAR 18
THIRD-PARTY LOGISTICS PROVIDERS

Phar 18.01 Authority. The rules in this chapter are adopted pursuant to the authority delegated by ss. 15.08 (5) (b), 450.02 (3), and 450.075 (4), Stats.

Phar 18.02 Definitions. In this chapter:

(1) "Designated representative" means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.

(2) "Facility" has the meaning given in s. 450.01 (11m), Stats.

(3) "Out-of-state third-party logistics provider" has the meaning given s. 450.01 (13w), Stats.

(4) "Third-party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

Phar 18.03 Licensure, Renewal, and Reinstatement.

(1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-of-state third-party logistics provider of any drug or device may apply to obtain a license from the board.

(2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:

(a) The applicant shall submit all of the following:

1. A completed application form.
   Note: Application forms are available from the department of safety and professional services' website at http://dsps.wi.gov.
2. The fee specified in s. 440.05, Stats.
3. All of the following information relating to a designated representative:
   a. Name, address, and telephone number
   b. Date and place of birth
   c. A photograph of the person taken within the 12-month period immediately preceding the date of the application
   d. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
      i. Place of residence
      ii. Occupations, positions of employment, and offices held
      iii. The name and addresses for each business, corporation or entity listed in subs. ii.
      iv. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
      v. Whether the person has been enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction

vi. A description of any involvement with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and list of any lawsuits in which such a business was names as a party.

e. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld, or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the person shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

f. Verification that the requirements in Phar 18.05 (1) have been met.

4. A statement that each facility used by the applicant for third-party logistics provider services has been inspected in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each such inspection.

(b) Subject to ss. 111.321, 111.322, and 111.335, Stats., the applicant does not have an arrest or conviction record.

(c) Where operations are conducted at more than one facility, a person acting as a third-party logistics provider or out-of-state logistics provider may apply for a license for each such facility.

(3) RENEWAL. **(a)** Each license shall be renewed biennially. The renewal date and fee are specified by s. 440.08 (2), Stats.

(b) Every even-numbered year, each license shall complete a renewal application and return it with the required fee prior to July 1 of that year.

Note: Instructions for renewal applications can be found on the department of safety and professional services' website at http://dsps.wi.gov.

(4) REINSTATEMENT. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

(a) Evidence of completion of the requirements in Phar 18.03 (2) if the license has not been active within 5 years.

(b) Evidence of completion of disciplinary requirements, if applicable.

(c) Evidence of rehabilitation or change in circumstances warranting reinstatement.

Phar 18.04 Inspections. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

Phar 18.05 Responsible Persons. (1) DESIGNATED REPRESENTATIVE. The individual acting as the designated representative for a third-party logistics provider or an out-of-state third-party logistics provider shall meet all of the following requirements:

(a) Be at least 21 years old

(b) Has been employed full-time for at least three years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and recordkeeping related to, prescription drugs.

(c) Is employed full-time in a managerial position

(d) Is physically present at the third-party logistics provider's or out-of-state third-party logistics provider's facility during regular business hours This subsection does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

(e) Is actively involved in and aware of the daily operation of the third-party logistics provider or the out-of-state third-party logistics provider.

(f) Is a designated representative for only one applicant at any given time. This subsection does not apply if more than one third-party logistics provider or out-of-state third-party logistics provider is located at the facility and the third-party logistics provider or out-of-state third-party logistics providers located at the facility are members of an affiliated group.

(g) Have not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

(h) Has not been convicted of a felony

(i) Submits to the department 2 fingerprint cards, each bearing a complete set of the person's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for purposes of verifying the identity of the person and obtaining the person's criminal arrest and conviction record.

(2) OFFICERS, DIRECTORS AND MANAGERS. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall maintain a list of officers, directors, and managers, including a description of their duties and a summary of their qualifications.

Phar 18.06 Facility and Storage Requirements. All facilities licensed as third-party logistics providers or out-of-state third-party logistics providers shall ensure the following:

(1) Maintain access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

(2) Have written policies and procedures for all of the following:

(a) Address receipt, security, storage, inventory, shipment, and distribution of a product;

(b) Identify, record, and report confirmed losses or thefts;

(c) Correct errors and inaccuracies in inventories;

(d) Provide support for manufacturer recalls;

(e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

(g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

(h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

Phar 18.07 Security Requirements. All facilities shall require the following:

(1) Access from outside the premises is kept to a minimum and is well controlled;

(2) The outside perimeter of the premises is well lighted;

(3) Entry into areas where prescription drugs are held is limited to authorized personnel;

(4) An alarm system is maintained to detect entry after hours; and

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Phar 18.08 Compliance. A licensee who fails to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

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

(END OF TEXT OF RULE)

LCRC
FORM 2

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **23-031**

AN ORDER to create Phar 18, relating to licensure of third-party logistics providers.

Submitted by **PHARMACY EXAMINING BOARD**

06-20-2023 RECEIVED BY LEGISLATIVE COUNCIL.
07-12-2023 REPORT SENT TO AGENCY.

SG:KAM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☑ NO ☐

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☑ NO ☐

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 23-031

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

1. Statutory Authority

a. Relative to its statutory authority under s. 450.075 (4), Stats., the agency correctly identifies the optional nature of licensure contemplated under the proposed rule in s. Phar 18.03 (1). However, it may assist the reader to further explain the nature of licensure in the agency's plain language analysis of the proposed rule. Similarly, and as noted in comment 5. e., below, the agency should review the proposed rule text that follows s. Phar 18.03 (1) for consistency with the optional nature of licensure under the proposed rule. For example, the statement that a license "shall be renewed biennially" in s. Phar 18.03 (3) (a) does not reflect the permissive nature of licensure.

b. In s. Phar 18.04, should the agency identify that the statutory requirements regarding inspections under s. 450.075 (6), Stats., apply regardless of whether a provider is licensed under ch. Phar 18?

c. Should the agency identify the unique, ongoing applicability requirements of s. 450.075 (7) (b), Stats., in the rule analysis or proposed rule text, or both?

2. Form, Style and Placement in Administrative Code

a. The text of s. Phar 18.03 (2) (a) should be revised to avoid further division beyond subdivision paragraphs. Subdivision paragraphs may not be further divided. [s. 1.10 (1) (b) 6., Manual.] In making such revisions, and throughout the proposed rule, the agency should ensure all rule provisions end in proper punctuation.

b. Introductory text (e.g., "is/have/has/submits") in s. Phar 18.05 (1) (a) to (i) should be revised for consistency in order to maintain parallel structure in the list and with s. Phar 18.05 (1) (intro.). [s. 1.05 (1) (e), Manual.]

c. Throughout ss. Phar 18.06 and 18.07, review the end of each rule provision for consistency with s. 1.11 (3), Manual.

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

a. In s. Phar 18.03 (2) (a) 3. d. vi., replace "was names" with "was named" for verb tense agreement.

b. In s. Phar 18.04, add an oxford comma to the phrase "authored federal, state and local law enforcement officials". [s. 1.06 (1) (b), Manual.]

c. In s. Phar 18.05 (1) (d), insert a period after "hours" and before "This subsection".

d. In s. Phar 18.06 (1) (intro.), the phrase "ensure the following" should be removed for clarity. Similarly, in s. Phar 18.06 (2), remove "for all of the following", and insert "to".

e. As implied by ss. Phar 18.03 (3) and (4), 18.04, and 18.08, and other provisions in the proposed rule, it may aid clarity for the agency to explain, in its plain language analysis or notes to the proposed rule text, or both, how the concepts of disciplinary action and non-compliance with license requirements interact with the permissive nature of licensure under the proposed rule.

6. Potential Conflicts With, and Comparability to, Related Federal Regulations

In the agency's plain language analysis, it indicates that federal rules have not yet been finalized. Does the agency intend to update s. Phar 18.08 to specifically identify the federal regulations for which compliance is required under state licensure? Similarly, can the agency more specifically identify which state laws and regulations must be complied with in order to avoid disciplinary action under s. Phar 18.08? At this point in the rulemaking process, can the agency confirm that the substantive requirements of the proposed rule, such as those in ss. Phar 18.06 and 18.07, are no more strict than requirements under federal law, as required by s. 450.075 (4), Stats.?

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:
Nilajah Hardin **Administrative Rules Coordinator**	**08/18/23** 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?
08/31/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Final Rule Draft: Phar 7 and 10, Relating to Required Disclosures to Consumers** 2. **Possible Rule Project: Phar 7 Comprehensive Review** 3. **Pending or Possible Rulemaking Projects**

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	**N/A**

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

Attachments:
1. Phar 7 and 10 Final Rule Draft
2. Phar 7 and 10 Legislative Report
3. Phar 7 and 10 Clearinghouse Report
4. Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 08/18/23

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
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
PHARMACY EXAMINING BOARD	**:**	**CR 23-015**

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The objective of the proposed rule is to revise Wisconsin Administrative Code chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9. Section Phar 7.15 was created to outline the new consumer disclosure requirements created in 2021 Wisconsin Act 9. Additional requirements were also added to Phar 10.03 regarding unprofessional conduct of a licensee.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Pharmacy Examining Board held a public hearing on June 15, 2023. No public comments were received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment: #5.b. "In SECTION 1 of the proposed rule, the proposed text restates the statutes interpreted with minimal additional detail (the statute requires updates of pharmacy lists at least monthly while the rule requires updates monthly, for example). Consider whether the proposed rule is necessary, or alternatively, whether the proposed rule should be revised in order to add additional detail. For example, it could be clarified to include how, under s. Phar 7.15 (2), generic drug product equivalents are determined to be "most commonly" prescribed."

Response: The Board accepts this comment and acknowledges that although minimal additional detail has been provided in Phar 7.15, it nonetheless provides clarification to licensees on which lists need to be posted for consumers and which list of most commonly prescribed drugs needs to be available in each pharmacy, as well as where to find them. The Board believes the wording provides additional clarification for the public.

Comment: #5.c. "In SECTION 2 of the proposed rule, it is unnecessary to refer to compliance with a "valid" rule. Rhetorically, why would a person be required to comply with an invalid rule? Additionally, and related to comment b., above, are the provisions created by SECTION 2 merely duplicative of s. 450.10 (1) (a) 2., Stats.?"

> **Response**: The Board accepts this comment and has removed the word "valid" from Section 2. As to the duplicative nature of the section, the Board considers these disclosures important to the safety of the public such that it should be considered unprofessional conduct if a licensee does not comply with them.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-015)

PROPOSED ORDER

An order of the Pharmacy Examining Board to **create** Phar 7.15, 10.03 (20), and 10.03 (21), relating to required disclosures to consumers.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 15.08 (5) (b), 450.13 (5m), 450.135 (8m), Stats.

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

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "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."

Section 450.02 (3) (a), Stats. allows the board to "promulgate rules relating to the manufacture of drugs and the distribution and dispensing of prescription drugs."

Section 450.02 (3) (d), Stats. says that the board "may promulgate rules necessary for the administration and enforcement of this chapter and ch. 961."

Section 450.02 (3) (e), Stats. provides that the board "may promulgate rules establishing minimum standards for the practice of pharmacy."

Related statute or rule: 2021 Wisconsin Act 9

Plain language analysis: The objective of the proposed rule is to revise Wisconsin ~~the Pharmacy a~~Administrative ~~c~~Code~~, including but not necessarily limited to~~ chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9. Section Phar 7.15 was created to outline the new consumer disclosure requirements created in 2021 Wisconsin Act 9. Additional requirements were also added to Phar 10.03 regarding unprofessional conduct of a licensee,

Commented [NH1]: Clearinghouse Comment 5a

~~The Pharmacy Examining Board is required under Act 9 to create and maintain a list of the 100 most commonly prescribed generic drug product equivalents, including the generic and brand name of the drug, which shall be made available to each pharmacy on an annual basis either directly or on the board's website.~~

~~Act 9 created several new requirements for pharmacies as well. A pharmacy must make available to the public information on how to access the list of 100 most commonly prescribed generic drug product equivalents maintained by the Pharmacy Examining Board. Pharmacies also must make available to the public information on how to access the FDA's list of all currently approved interchangeable biological products. Finally, a pharmacy must maintain disclosures to the public in a conspicuous place near where drugs are dispensed regarding the ability of a pharmacist to substitute a less expensive drug or interchangeable biological product.~~

Summary of, and comparison with, existing or proposed federal regulation: Federal Regulations part: 21 CFR Subchapter D covers regulations for the FDA on Drugs for Human Use.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation (IDFPR) under the State Board of Pharmacy, regulates pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Illinois Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Iowa: Iowa pharmacists are regulated by the Board of Pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Iowa Board of Pharmacists is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Michigan: The Michigan Department of Licensing and Regulatory Affairs (MDLRA) regulates pharmacists under the authority of the Michigan Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Michigan Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Minnesota: In Minnesota, pharmacists are regulated by the Minnesota Department of Health, with input from the Minnesota Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Minnesota Board of Pharmacy is not

responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Summary of factual data and analytical methodologies:
The proposed rules were developed by reviewing the current federal food and drug-approved interchangeable biological products; technical information provided by the American Pharmacists Association (APhA), and 2021Wisconsin Act 9, relating to pharmacy benefit managers, prescription drug benefits, and granting rule-making authority.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule was posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens. No comments were received.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:
These 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 Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, at 11:00 a.m. June 15, 2023, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.15 is created to read:

Commented [NH2]: Clearinghouse Comment 2a, 2b, and 5b

Phar 7.15 Consumer Disclosures.

(1) Each pharmacy shall post in a prominent place and maintain the consumer disclosures required in ss. 450.13 (5m) and 450.135 (8m), Stats.

(2) ~~The Board shall maintain a~~ A link to the 100 most commonly prescribed generic drug product equivalents as determined by the Board, shall be maintained on the Department website as required in s. 450.13 (5m) (b), Stats.

Note: Copies of the required consumer disclosures are located on the Department of Safety and Professional Service's website: https://dsps.wi.gov

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall maintain and make available to the public a list of the drugs from the list in sub. ~~Phar 7.15~~ (2) that are available for purchase at that pharmacy. The list shall be updated monthly, with all of the following information included:

(a) brand name.
(b) generic equivalent drugs and biological products.
(c) interchangeable biological products.
(d) retail price.

(4) The list required under sub.~~Phar 7.15~~ (3) may differ depending on whether the drugs on the list from Phar sub. ~~7.15~~ (2) are available for purchase at a specific pharmacy.

SECTION 2. Phar 10.03 (20) and (21) are created to read:

Commented [NH3]: Clearinghouse Comment 5b

Phar 10.03 (20) Violating or attempting to violate any provision or term of ch. 450, Stats., or of any ~~valid~~ rule of the board.

Phar 10.03 (21) Failure to comply with ss 450.13 (5m) or 450.135 (8m), Stats.

SECTION 3. 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)

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

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

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
April 19, 2023

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
Phar 7 and 10

4. Subject
Consumer Disclosures

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

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

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 ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ 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

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
The objective of the proposed rule is to implement the statutory changes from 2021 Wisconsin Act 9

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.
The rule will was posted for 14 days on the Department of Safety and Professional Services' website to solicit comments on the potenetial economic impact. No comments 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)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $1,200 in one-time costs to implement the rule. The estimated costs may not be absorbed in the agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefits to implementing this rule are clear and specific rules for licensees regarding required disclosures to consumers. The alternative to implementing the rule is to continue to relay on the statute for guidance on required consumer disclosures in pharmacies.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are better pharmacy practice due to posting and maintenance of consumer disclosures as required by rule and statute in Wisconsin.

17. Compare With Approaches Being Used by Federal Government
Federal Regulations part: 21 CFR Subchapter D covers regulations for the FDA on Drugs for Human Use.

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

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

Illinois: The Illinois Department of Financial and Professional Regulation (IDFPR) under the State Board of Pharmacy, regulates pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Illinois Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Iowa: Iowa pharmacists are regulated by the Board of Pharmacists. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Iowa Board of Pharmacists is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Michigan: The Michigan Department of Licensing and Regulatory Affairs (MDLRA) regulates pharmacists under the authority of the Michigan Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Michigan Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

Minnesota: In Minnesota, pharmacists are regulated by the Minnesota Department of Health, with input from the Minnesota Board of Pharmacy. All consumer disclosures relating to prescription medication and pharmacy benefits management are regulated by the State Department of Insurance. Currently, the Minnesota Board of Pharmacy is not responsible, nor regularly provides consumer disclosures regarding generic or prescription medication.

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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)

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

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

LCRC
FORM 2

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **23-015**

AN ORDER to create Phar 7.15 and 10.03 (20) and (21), relating to consumer disclosures.

Submitted by **PHARMACY EXAMINING BOARD**

04-19-2023 RECEIVED BY LEGISLATIVE COUNCIL.
05-11-2023 REPORT SENT TO AGENCY.

SG:KAM

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Anne Sappenfield
Legislative Council Director

CLEARINGHOUSE RULE 23-015

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. In SECTION 1 of the proposed rule, cross-references should follow the style prescribed in s. 1.15 (2) (c), Manual. For example, "Phar 7.15 (3)" should be written "sub. (3)".

b. In SECTION 1 of the proposed rule, in s. Phar 7.15 (3), a period should follow the text in pars. (a) to (d).

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

a. The plain language analysis draws heavily from the scope statement underlying the proposed rule. However, the general nature of these documents are different, and the speculative language present at the time the scope statement was issued should be made more specific in the plain language analysis. For example, by the time a proposed rule is submitted for Clearinghouse review, the scope of the treatments in the proposed rule is known, not "including but not necessarily limited to" particular code chapters, as indicated in the scope statement. As such, the plain language analysis should be revised to more specifically describe the contents of the proposed rule.

b. In SECTION 1 of the proposed rule, the proposed text restates the statutes interpreted with minimal additional detail (the statute requires updates of pharmacy lists at least monthly while the rule requires updates monthly, for example). Consider whether the proposed rule is necessary, or alternatively, whether the proposed rule should be revised in order to add additional detail. For example, it could be clarified to include how, under s. Phar 7.15 (2), generic drug product equivalents are determined to be "most commonly" prescribed.

c. In SECTION 2 of the proposed rule, it is unnecessary to refer to compliance with a "valid" rule. Rhetorically, why would a person be required to comply with an invalid rule? Additionally, and related to comment b., above, are the provisions created by SECTION 2 merely duplicative of s. 450.10 (1) (a) 2., Stats.?

Pharmacy Examining Board
Rule Projects (updated 08/18/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet (EmR 2303)	052-22	12/27/2024	Phar 1, 5, 7, 10, and 19	Registration of Pharmacy Technicians	Permanent Preliminary Rule Draft in Progress; Emergency Rule Effective 02/03/23-05/01/24	Board Approval of Permanent Preliminary Rule Draft for Posting for EIA Comment and Submission to Clearinghouse for Review
Not Assigned Yet (EmR 2213)	053-22	12/27/2024	Phar 1, 5, 6, 7 and 8	Remote Dispensing	Permanent Rule Pending Fiscal Estimate; Emergency Rule Effective 11/01/22-05/01/24	Submission to the Clearinghouse for Review; Public Hearing Anticipated for 10/26/23 Meeting
21-074	079-20	12/22/2022	Phar 5, 6, 7, 11, 12	Name and Address Change, Floor Design, Procedures for Disciplinary Proceedings, Superseded References, and Technical Correction	Rule Effective 07/01/23	N/A
23-015	102-21	05/01/2024	Phar 7 and 10	Consumer Disclosures	Final Rule Draft and Legislative Report Reviewed at 08/31/23 Meeting	Submission of Final Rule to Governor's Office and Legislature
Not Assigned Yet	044-23	01/10/2026	Phar 8	Controlled Substances Requirements	Preliminary Hearing on Statement of Scope Held at 08/31/23 Meeting	Scope Approval for Implementation
Not Assigned Yet	007-23	07/23/2025	Phar 15	Compounding Pharmaceuticals	Drafting	Board Review and Approval of Preliminary Rule Draft
23-031	097-21	04/18/2024	Phar 18	Third Party Logistics Providers	Public Hearing held at 08/31/23 Meeting	Drafting Final Rule and Legislative Report

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director on behalf of Josh Bolin and Justin Macy		**2) Date when request submitted:** 8/7/2023 **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: 8/31/2023	**5) Attachments:** ☐ Yes ☐ No	**6) How should the item be titled on the agenda page?** Appearance – NABP Associate Executive Director, Government Affairs and Innovation Josh Bolin, and Justin Macy 1) Achieving DSCSA Compatibility and Pulse System
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☒ Yes Josh Bolin, and Justin Macy - NABP ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>
10) Describe the issue and action that should be addressed: <Click Here to Add Description>		
11) Authorization  **8/7/2023** **Signature of person making this request** — **Date** **Supervisor (Only required for post agenda deadline items)** — **Date** **Executive Director signature (Indicates approval for post agenda deadline items)** — **Date**		

Directions for including supporting documents:
1. This form should be saved with any other documents submitted to the Agenda Items folders.
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: Whitney DeVoe, Board Counsel		2) Date when request submitted: 08/18/23 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: 08/31/2023	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Discussion of Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies	
7) Place item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No	9) Name of Case Advisor(s), if applicable: N/A	
10) Describe the issue and action that should be addressed: Discussion of Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies			
11) Authorization			
Whitney DeVoe Signature of person making this request			08/18/23 Date
Supervisor (Only required for post agenda deadline items)			Date
Executive Director signature (Indicates approval for post agenda deadline items)			Date

Directions for including supporting documents:

1. This form should be saved with any other documents submitted to the Agenda Items folders.
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.

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.66 Virginia [Amended]

■ 2. Section 73.66 is amended as follows:

* * * * *

R–6602A Fort Pickett, VA [Removed]

R–6602B Fort Pickett, VA [Removed]

R–6602C Fort Pickett, VA [Removed]

R–6602A Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long. 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°59′51″ N, long. 77°50′33″ W; to lat. 36°57′59″ N, long. 77°52′13″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. Surface to but not including 4,000 feet MSL.

Time of designation. Continuous May 1 to Sept. 15. Other times by NOTAM 24 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

R–6602B Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. 4,000 feet MSL to but not including 11,000 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

R–6602C Fort Barfoot, VA [New]

Boundaries. Beginning at lat. 37°05′38″ N, long. 77°51′53″ W; to lat. 37°04′26″ N, long. 77°51′44″ W; thence along State Highway No. 40; to lat. 37°03′56″ N, long. 77°51′04″ W; to lat. 37°02′44″ N, long. 77°50′37″ W; to lat. 37°01′06″ N, long. 77°50′42″ W; to lat. 36°57′55″ N, long. 77°53′18″ W; to lat. 36°58′13″ N, long. 77°57′41″ W; to lat. 37°01′51″ N, long. 77°58′39″ W; to lat. 37°01′51″ N, long. 77°55′57″ W; to lat. 37°04′22″ N, long. 77°55′57″ W; to lat. 37°05′38″ N, long. 77°54′41″ W; to the point of beginning.

Designated altitudes. 11,000 feet MSL to but not including 18,000 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA Washington ARTCC.

Using agency. Virginia National Guard, Commander, Fort Barfoot, VA.

* * * * *

Issued in Washington, DC, on July 21, 2023.

Karen L. Chiodini,

Acting Manager, Airspace Rules and Regulations.

[FR Doc. 2023–15863 Filed 7–26–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–637]

RIN 1117–AB64

Transfer of Electronic Prescriptions for Schedules II–V Controlled Substances Between Pharmacies for Initial Filling

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic controlled substance prescriptions between DEA-registered retail pharmacies.

DATES: This rule is effective August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Executive Summary

On November 19, 2021, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPRM) proposing to permit the transfer of electronic prescriptions for controlled substances (EPCS) in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only.[1] In this rulemaking, DEA is finalizing the regulatory text proposed in the NPRM with modifications to address concerns brought forth by commenters.

The final rule amends DEA regulations to explicitly state that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule requires that: the transfer must be communicated directly between two licensed pharmacists; the prescription must remain in its electronic form; and the contents of the prescription required by 21 CFR part 1306 must be unaltered during the transmission. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

In addition, the final rule describes the information that must be recorded to document transfer of EPCS between pharmacies for initial dispensing. It also clarifies that, in lieu of manual data entry, the transferring and/or receiving pharmacy's prescription processing software may, if capable, capture the required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. The transferring and/or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate. The electronic records documenting EPCS transfers must be maintained by both pharmacies for two years from the date of the transfer. The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

[1] 86 FR 64881.

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General the authority to promulgate and enforce any rules, regulations, and procedures that he may deem necessary and appropriate for the efficient executions of his functions under subchapter I (Control and Enforcement) of the CSA.[2] The Attorney General has delegated this authority to the Administrator of the DEA.[3]

Purpose

DEA is revising its regulations to state that, upon request from the patient, a registered retail pharmacy may transfer an electronic controlled substance prescription in schedules II–V to another registered retail pharmacy for initial filling. This final rule specifies the procedures that retail pharmacies must follow and the information that must be documented when transferring EPCS. DEA believes that allowing the electronic transfer of controlled substance prescriptions will decrease the potential for duplicate prescriptions and thus reduce the opportunity for diversion or misuse.

Background

The CSA and its implementing regulations specify the requirements for issuing and filling prescriptions for controlled substances. DEA regulations permit a pharmacist to dispense a controlled substance prescription in schedule II only pursuant to a written prescription (including an electronic prescription), except in limited emergency situations, when dispensing pursuant to an oral prescription is permitted.[4] No prescription for a controlled substance in schedule II may be refilled.[5] DEA regulations permit a pharmacist to dispense a controlled substance in schedules III, IV, and V pursuant to a signed paper prescription, a facsimile of a signed paper prescription, an electronic prescription, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.[6] Prescriptions for controlled substances in schedules III and IV may not be filled or refilled more than six months after the date of issuance or be refilled more than five times.[7]

The CSA does not address the transfer of paper or electronic prescriptions for controlled substances in any schedule between pharmacies for initial filling. DEA regulations address the transfer of controlled substance prescriptions (schedules III–V) between pharmacies for refill dispensing, but not for initial dispensing.[8]

Unlike paper prescriptions which are issued directly to the patient, electronic prescriptions are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file.[9] If a paper prescription is presented at a pharmacy that is unable to fill it, the paper prescription could be returned to the patient, and the patient could then take the prescription to another pharmacy. However, because the pharmacy receives an electronic prescription as an electronic data file and not a physical paper prescription, it cannot give the prescription to the patient to take to another pharmacy. In this scenario, the pharmacy can only inform the patient that the prescription cannot be filled. The patient could then call the prescribing practitioner to request that a new prescription be sent to a different pharmacy.

DEA realizes that this scenario creates the potential for duplication of prescriptions, if the practitioner transmits a new prescription to a different pharmacy and does not cancel or void the original prescription that was sent to the first pharmacy. It also recognizes that this scenario creates additional burden for patients, who have to get back in touch with the prescribing practitioner to request a new prescription. As more practitioners are issuing controlled substance prescriptions electronically (as discussed below), there is an increasing need to address how a pharmacy should handle an electronic controlled substance prescription that it receives but cannot fill.

DEA's March 2010 interim final rule (IFR), *Electronic Prescriptions for Controlled Substances,* provides practitioners with the option of issuing, and pharmacies with the option of receiving, dispensing, and archiving EPCS in schedules II–V.[10] In a request for information (RFI) published in August 2020, the Centers for Medicare and Medicaid Services (CMS) reported that it has seen a steady increase in the volume of controlled substance prescriptions submitted electronically since DEA published the EPCS IFR.[11] Additionally, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") mandates electronic prescribing of schedules II–V controlled substances (with some exceptions) covered under Medicare Part D, beginning January 1, 2021.[12] Further, Surescripts, a health information network and electronic prescribing intermediary, stated in its 2021 National Progress Report that as of January 2022, 35 States require, or will soon require, electronic prescribing of opioids, all controlled substances, or all prescriptions.[13] In the same report, Surescripts also reported that the rate of electronic prescribing of controlled substances increased from 38 percent in 2019 to 58 percent in 2020 and to 73 percent in 2021. Thus, procedures for transferring EPCS between pharmacies for initial dispensing are needed urgently. In this final rule, DEA is amending its regulations to allow, upon request of the patient, the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial filling on a one-time basis.

Summary of the Notice of Proposed Rulemaking

DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** on November 19, 2021.[14] The NPRM proposed to permit the transfer of EPCS in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only. The NPRM also proposed the procedures that would need to be followed and the information to be documented when transferring EPCS for initial filling. The proposed rule focused only on the transfer of EPCS for initial dispensing. The NPRM did not propose changes to 21 CFR 1306.25, which permits the transfer of paper, oral, or electronic prescriptions in schedules III, IV, and V for refill dispensing, or the existing requirements for prescriptions (paper or electronic) in 21 CFR part 1306, Prescriptions, and 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions. DEA invited comments

[2] 21 U.S.C. 871(b).

[3] 28 CFR 0.100(b).

[4] 21 CFR 1306.11(a) and (d).

[5] 21 U.S.C. 829(a) and 21 CFR 1306.12(a).

[6] 21 CFR 1306.21(a).

[7] 21 CFR 1306.22(a).

[8] 21 CFR 1306.25.

[9] An electronic prescription is defined as "a prescription generated on an electronic application and transmitted as an electronic data file." 21 CFR 1300.03.

[10] 75 FR 16236 (Mar. 31, 2010). DEA subsequently reopened the comment period in 2020 to solicit public comment on certain issues. 85 FR 22018 (Apr. 21, 2020).

[11] *Medicare Program: Electronic Prescribing of Controlled Substances; RFI,* 85 FR 47151 (August 4, 2020).

[12] Public Law 115–271, sec. 2003(a)(b) (Oct. 24, 2018). This requirement is codified at 42 U.S.C. 1395w–104(e)(7).

[13] Surescripts, National Progress Report 2021 (*https://surescripts.com/docs/default-source/national-progress-reports/2021-national-progress-report.pdf?sfvrsn=71fcbe15_12*) (accessed June 2, 2022).

[14] 86 FR 64881.

from the public to be submitted on or before January 18, 2022.

Discussion of Public Comments

DEA received 183 comments in response to the NPRM.[15] The commenters included practitioner and professional organizations, pharmacy organizations, pharmacists' associations, State boards of pharmacy, a home delivery pharmacy, a health service organization, a health system, a health information technology developer, a standards developer, and members of the general public. DEA thanks all commenters for their input during the rulemaking process.

The majority of commenters expressed support for the rule. In fact, 89 comments were general statements of support, with no discussion of the proposed regulatory changes. Thirty-seven commenters shared personal accounts of occasions when they or a family member had an electronic prescription sent to the wrong pharmacy or a pharmacy that could not fill the prescription. While most commenters supported the rule in its entirety, some supported the rule's general purpose but were opposed to certain provisions and proposed changes to those particular provisions. Other commenters raised issues of concern, without proposing changes, or sought clarification. Only one commenter opposed the entire rule. Five comments were outside the scope of the rule. These comments, along with DEA's responses, are discussed below.

Patients' Consent for EPCS Transfers

Comments. Two commenters expressed concern that the proposed rule appears to allow the pharmacy to decide when and where a prescription is transferred instead of the patient. One commenter stated that patients should be allowed to request transfers of their prescriptions. Another commenter stated that the rule should require the transferring pharmacy to do the following: (1) Inform the patient of the need to transfer the prescription and the name and location of the pharmacy where the prescription will be transferred, and (2) obtain and document the patient's consent to transfer the prescription to the specified pharmacy location.

DEA Response. To prevent treatment delays, reduce patient burden, and minimize opportunities for diversion, DEA is allowing the transfer of EPCS between pharmacies for initial filling upon the patients' request. If a patient is notified by a pharmacy that the pharmacy is unable to fill an EPCS, the patient may ask to have the prescription transferred to another pharmacy, chosen by the patient, that is able to fill the prescription. For additional clarity, DEA is adding "upon request from the patient" to 21 CFR 1306.08(e) in this final rule. However, DEA believes requiring a pharmacy to obtain and document a patient's consent to transfer a prescription would be unnecessarily burdensome.

Initial Dispensing Only

Comments. Two commenters expressed concern that the NPRM proposed allowing the transfer of EPCS between pharmacies for initial dispensing only, and did not address the transfer of EPCS for refill dispensing.

DEA Response. DEA currently permits the transfer of prescription information for refill dispensing of prescriptions for schedule III, IV, and V controlled substances on a one-time basis, if allowed under existing State or other applicable law.[16] DEA notes that prescriptions for controlled substances in schedule II may not be refilled. The existing requirements for transferring EPCS for refill dispensing remain unchanged by this final rule.

EPCS Transferred as Electronic Data Files

Comments. Seventeen commenters mentioned the proposed provision in 21 CFR 1306.08(f)(1), which requires that the prescription be transferred from one pharmacy to another pharmacy in its electronic form. Two commenters supported this provision; one stated that they would no longer support the rule if this provision is removed. Eleven commenters expressed concern that most pharmacies' applications and prescription management software do not have the technology needed to transfer prescriptions electronically. Two commenters noted that pharmacies within the same chain may be able to transfer controlled substance prescriptions electronically because they share a common database but independent community pharmacies are not integrated in this way. Thus, one commenter stated that independent pharmacies would be disproportionately burdened by the rule, and the other commenter stated that the rule appears to be written in favor of keeping a prescription within a chain pharmacy network. One commenter noted that although this functionality became available when the National Council for Prescription Drug Programs (NCPDP) released the SCRIPT Standard Version 2017071, the technology standard that facilitates electronic prescribing, many pharmacy vendors have not implemented the functionality. However, another commenter stated that the SCRIPT Standard Version 2017071 does not facilitate the electronic transfer of controlled substance prescription information at this time and noted that an updated version of the standard that would facilitate this transfer has been approved by NCPDP. The commenter also stated that implementation of the updated version of the standard will likely be a multi-year process. NCPDP confirmed in its comment that the recently approved changes to the standard include support for the one-time transfer of EPCS between pharmacies.

Two commenters stated that DEA should allow the electronic transfer of controlled substance prescriptions for initial filling as one option, but should not mandate electronic transfer as the only option for transferring EPCS. Six commenters suggested that the final rule should allow the transfer of EPCS between pharmacies through pharmacist-to-pharmacist communication by phone or via facsimile. One commenter, noting that pharmacists have been transferring prescriptions successfully for a long time, stated that pharmacists should be trusted and allowed to transfer EPCS by oral communication between the two pharmacists, or by transmitting via facsimile a printed copy of the prescription, annotated with all the required documentation to indicate that the prescription was transferred.

DEA Response. DEA disagrees with the commenter's suggestion that the rule is written in favor of keeping a prescription within a chain pharmacy network and does not believe independent pharmacies will be disproportionately burdened by this rule. DEA has always required, since it began allowing controlled substances to be prescribed electronically, that all records related to such prescriptions must be retained electronically.[17] The final rule permits the transfer of EPCS between pharmacies for initial filling upon request from the patient.[18] Thus, the patient decides if, and to which pharmacy, a prescription is transferred. In addition, NCPDP confirmed in its comment that the new SCRIPT Standard Version 2017071, which is available to both independent and chain

[15] A total of 183 comments were received; however, five commenters submitted duplicate comments.

[16] *See* 21 CFR 1306.25.

[17] See 75 FR 16235 at 16243 and 21 CFR 1311.305(a).

[18] New 21 CFR 1306.08(e).

pharmacies, enables the transfer of prescriptions between pharmacies. DEA acknowledges that some pharmacies may need to coordinate with their pharmacy technology vendors to have certain SCRIPT transactions, including the transaction used to transfer prescriptions between pharmacies, incorporated into their pharmacy applications. The cost associated with this incorporation, if any, is not set by DEA and is beyond the scope of DEA's authority. Further, in 2018, CMS adopted SCRIPT 2017071 as the official electronic prescribing standard for prescriptions covered under Medicare Part D.[19] Consequently, pharmacies that wish to transfer EPCS covered under a Medicare Part D drug plan are already required to have and use the SCRIPT 2017071 transaction that facilitates the transfer of prescriptions between pharmacies.[20] Hence, the final rule continues to require that once a controlled substance prescription is created electronically, it must remain in its electronic format and all records related to the prescription must be retained electronically.

Transfer of EPCS for Initial Filling on a One-Time Basis Only

Comments. Six commenters mentioned the provision that permits the transfer of EPCS between pharmacies for initial dispensing on a "one-time basis only." Two commenters opposed the one-time only limitation. The commenters stated that DEA should at a minimum, allow pharmacies that share a real-time online database, if not all pharmacies, to transfer EPCS for initial dispensing more than once, if needed. One of the commenters also noted that DEA permits pharmacies that share a real-time, online database to transfer prescriptions for schedule III–V controlled substances for refill dispensing up to the maximum number of refills permitted by law and the prescriber's authorization. Four commenters asked DEA to clarify the applicability of the one-time only limitation in specific scenarios. For example, two commenters noted that a prescription could be transferred from one pharmacy that cannot fill it to another pharmacy that is also unable to fill the prescription. One of the commenters stated that as written, the rule would not allow the prescription to be transferred again and thus the patient would be burdened with having to contact the prescribing practitioner to request a new prescription, which is the specific scenario the rule seeks to prevent. Two commenters asked about the transfer of EPCS issued with authorized refills. The commenters asked whether the refills would be transferred with the prescription or remain at the pharmacy that received the prescription from the prescribing practitioner. Another commenter asked if the one-time only transfer allowed for initial dispensing is in addition to the transfer allowed for refill dispensing under 21 CFR 1306.25. One commenter asked if the one-time only limit prohibits the transfer of subsequent controlled substance prescriptions issued to the same pharmacy that transferred the previous prescription to an alternate pharmacy for initial dispensing.

DEA Response. DEA believes the one-time transfer allowance is sufficient to accommodate most situations in which a transfer would be needed for initial dispensing. In an article discussing the adoption of the SCRIPT Standard Version 2017071, Surescripts notes that the receiving pharmacy has to initiate the prescription transfer, when a transfer is requested.[21] In the interest of patient care, as well as good business practice, DEA believes a pharmacy would not request the transfer of a prescription that it cannot fill. As such, the scenario described by the commenters in which a prescription is transferred from one pharmacy to another pharmacy that is also unable to fill the prescription should occur rarely, if ever. Nonetheless, DEA recommends that the patient confirms the ability of the receiving pharmacy to fill the prescription before requesting the transfer.

DEA wishes to clarify that the one-time basis stipulation for transferring EPCS for initial filling is per prescription. In other words, each prescription transmitted from a practitioner to a retail pharmacy may be transferred one time, upon request from the patient, regardless of whether any previous EPCS were transferred. If the prescription being transferred includes authorized refills, the refills are transferred with the prescription to the pharmacy receiving the transfer. This final rule adds additional text to 21 CFR 1306.08(e) to provide this clarification. As proposed in the NPRM, this final rule permits the transfer of EPCS between pharmacies for initial dispensing on a one-time basis only. This is consistent with the current regulations at 21 CFR 1306.25 for the transfer of prescription information between pharmacies for refill dispensing of schedule III–V EPCS on a one-time basis only.[22] DEA notes that 21 CFR 1306.25 remains unchanged by this final rule.

Comments. One commenter asked that DEA clarify in the final rule that a pharmacy that receives transfers of EPCS will not be held responsible for filling a transferred prescription that may have been transferred multiple times.

DEA Response. Pharmacists continue to have a corresponding responsibility to ensure they are filling valid controlled substance prescriptions; nothing in DEA's regulations on EPCS alters a pharmacy's responsibilities to ensure the validity of a controlled substance prescription.[23] Therefore, DEA does not believe any further clarifications are needed in this final rule.

Transfers Communicated Between Two Licensed Pharmacists

Comments. One commenter suggested that DEA allow the transfer of EPCS to be communicated between pharmacy personnel (*e.g.,* pharmacy technicians, pharmacist interns, etc.), as permitted by State laws, instead of requiring the communication to be between two licensed pharmacists.

DEA Response. Existing DEA regulations ". . . include any other person (*e.g.,* pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State" in the definition of a pharmacist.[24] As such, DEA does not believe any further clarification is needed, as the existing regulations include the allowance requested by the commenter. However, DEA emphasizes that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of DEA regulations.[25]

Pharmacy Software that Automatically Populates Prescription Data

Comments. Five commenters asked that DEA allow the transferring and receiving pharmacies' prescription processing software, if capable, to

[19] *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program,* 83 FR 16440 (April 16, 2018).

[20] 42 CFR 423.160(b)(2)(iv).

[21] Swartz, L. and Whittemore, K. A giant leap: The industry adopts a new version of the national e-prescribing standard. November 2019. *https://surescripts.com/docs/default-source/intelligence-in-action/ncpa-surescripts_script_2017071_pharmacist_ce_article_11-2019.pdf* (accessed April 14, 2023).

[22] 21 CFR 1306.25(a).

[23] 21 CFR 1306.04(a) and 1311.100(f).

[24] 21 CFR 1300.01(b).

[25] 21 CFR 1306.04(a).

capture the required information from the electronic prescription and automatically populate the corresponding data fields to document prescription transfers on behalf of the pharmacists.

DEA Response. In light of the comments received on this issue, DEA is revising this final rule to permit a transferring or receiving pharmacy's prescription processing software, if capable, to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. However, the transferring or receiving pharmacist must ensure that the populated information is complete and accurate. This provision is added in a new paragraph (f)(6) in 21 CFR 1306.08.

Schedule II Controlled Substances Prescriptions

Comments. One commenter stated that, when a practitioner issues multiple prescriptions for schedule II controlled substances pursuant to 21 CFR 1306.12, the rule should allow one or all of those prescriptions to be transferred for initial dispensing, if requested by the patient.

DEA Response. Although issued at the same time, each prescription for schedule II controlled substances issued pursuant to 21 CFR 1306.12 is a separate prescription. Therefore, if issued electronically, any of these prescriptions may be transferred between pharmacies on a one-time basis for initial dispensing under the conditions set forth in this final rule.

Partial Fills

Comments. Two commenters noted that the proposed rule does not address partial fills of EPCS. The commenters requested clarification regarding the ability of a pharmacy to partially fill a controlled substance prescription and then transfer the remainder to another pharmacy for dispensing of the remaining portion. One of the commenters specifically asked about partial filling of schedule II controlled substance prescriptions while the other commenter asked about all controlled substance prescriptions.

DEA Response. Current DEA regulations permit partial filling of prescriptions for controlled substances in schedules III–V.[26] Existing regulations also permit partial filling of a prescription for a schedule II controlled substance if the pharmacy is unable to supply the full quantity.[27] In this case, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; no additional quantity may be supplied after the 72-hour period without a new prescription.[28] In addition, DEA published a final rule [29] on July 21, 2023, which amends 21 CFR 1306.13 to allow a pharmacist to partially fill a prescription for a schedule II controlled substance at the request of the prescribing practitioner or the patient, if permissible under State law.[30] This rule becomes effective on August 21, 2023.

Regarding the transfer of prescriptions for controlled substances, existing regulations permit the transfer of schedules III–V controlled substance prescriptions for refill dispensing only.[31] Further, under this final rule, the regulations will permit the transfer of EPCS in schedules II–V between DEA-registered retail pharmacies for initial dispensing upon request from the patient. At this time, however, no DEA regulation permits a partially-filled controlled substance prescription to be transferred from one DEA-registered pharmacy to another for dispensing of the remaining portion of the prescription. DEA did not propose any revisions related to the partial filling of controlled substances prescriptions in the proposed rule; thus, such a change would be outside the scope of this final rule. Nonetheless, DEA believes these regulations provide adequate options for patients to obtain their medication without significant treatment disruptions or delays when pharmacies are unable to fill controlled substances prescriptions received electronically. DEA does not believe further revisions to these regulations are warranted at this time.

Economic Impact Analysis

Comments. Four commenters mentioned the economic impact analysis that was included in the NPRM. One commenter, while supporting the proposed rule, stated that the analysis focused only on monetary benefits and did not include unquantifiable benefits such as the reduced stress and improved productivity patients will experience as a result of the rule. A practitioner organization agreed with DEA's conclusion that the rule will result in net cost savings overall. However, the commenter noted that the analysis assumed that a practitioner's administrative staff would handle calls from patients requesting new prescriptions, but some practitioners do not employ administrative staff and must handle the calls themselves. Thus, the commenter stated that the actual net cost savings of the rule will be higher than DEA's estimate.

One pharmacists' association supports DEA's proposal to allow the transfer of EPCS between pharmacies for initial filling from a patient care perspective, but expressed concern about the economic impact of the proposed rule on pharmacies. The association noted that although DEA estimates the rule will result in overall health system cost savings of $22 million annually, pharmacies will actually incur significant costs of $91,625,000 annually, as estimated by DEA.[32] The association also noted that while DEA acknowledges that pharmacies will incur additional expenses, including modifying software configurations, updating business processes, and training personnel, these costs were not included in DEA's analysis. Another commenter agreed that the analysis did not include costs for software upgrades and further noted that the analysis underestimated the time required to process prescription transfers. The commenter stated that processing a prescription transfer can take 15 minutes or more, depending on how busy the pharmacies are at the time of the request. Moreover, the commenter stated that the economic impact analysis did not include additional time and expenses incurred by patients who may need to travel farther to pick up medication from the pharmacy receiving the transfer.

DEA Response. DEA agrees that, in addition to saving time, as indicated in the analysis below, this rule is likely to benefit patients in many other ways, including reducing stress, as noted by the commenter. In addition to minimizing opportunities for diversion, DEA's chief reasons for this rulemaking are to provide patients with the option of transferring EPCS for initial filling to prevent treatment delays and reduce patient burden. However, this final rule does not require a patient to request a transfer. DEA emphasizes that the patient decides if, and to which pharmacy, a prescription is transferred. Thus, this rule does not impose any additional travel burden on patients.

[26] 21 CFR 1306.23.

[27] 21 CFR 1306.13.

[28] 21 CFR 1306.13(a).

[29] *Partial Filling of Prescriptions for Schedule II Controlled Substances*, 88 FR 46983 (July 21, 2023).

[30] 21 CFR 1306.13(b).

[31] 21 CFR 1306.25.

[32] The analysis has been updated since the NPRM using the most recent data available. The updated estimated overall health system cost savings is $29 million and the cost to pharmacies is $50,005,000. See the Executive Order 12866 and Regulatory Flexibility Act sections below under Regulatory Analyses for the detailed analysis.

DEA also agrees the cost savings per transfer would be higher for prescribing practitioners who do not have administrative staff and would have to handle calls from patients requesting new prescriptions themselves under current regulations. According to Surescripts' "2021 National Progress Report," the rate of electronic prescribing of controlled substances was 73 percent in 2021.[33] DEA believes it is reasonable to assume that, on average, EPCS utilization will skew toward practitioners with larger infrastructure and administrative staff, while recognizing that there are some small and independent offices without administrative staff that may experience greater cost savings than estimated. This is because, under this final rule, the prescribing practitioners at those small and independent offices (versus administrative staff at larger practices), would no longer have to handle calls from patients requesting new prescriptions be sent to alternate pharmacies for initial dispensing.

In regards to the estimated additional costs that pharmacies will incur, DEA notes that, although the rule allows EPCS to be transferred at the request of a patient, it does not require a pharmacy to transfer EPCS if it is unable to do so (*e.g.,* due to system limitations). In the economic analysis, DEA estimated that there will be additional costs to the transferring and receiving pharmacies. However, a pharmacy is expected to participate in transfers of EPCS based on its own analysis of benefits and costs. While only costs were quantified, benefits to pharmacies may include customer retention, increased customer traffic, increased customer loyalty, good will, etc., leading to increased sales over time. DEA estimates each transfer of EPCS will cost $2.92 and $4.38 for the transferring and receiving pharmacies, respectively.[34] Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per EPCS transfer for a pharmacy. The average cost is $3.65 per transfer.[35] Applying this total to the estimated maximum number of transfers of 13.7 million per year results in a maximum total net cost, to all pharmacies combined, of $50,005,000 annually.[36] As noted above, this $50 million estimate does not reflect the costs that are mandated by this rule, as this rule by its terms does not require pharmacies either to transfer EPCS or receive EPCS, but it does reflect the estimated cost of doing business for pharmacies that choose to transfer EPCS or receive EPCS under this rule.

In the Regulatory Flexibility Act analysis below, DEA compared the estimated cost of this rule to the annual revenues of the smallest of small pharmacy firms, those with less than $100,000 in annual revenue. The estimated cost of this rule is $9 annually for the 666 smallest of small pharmacies.[37] The average cost per firm of $9 equates to 0.01745 percent of average receipt per firm of $51,565.[38] DEA anticipates this rule will not have a significant economic impact for the smallest of small pharmacies; and therefore, this rule will also not have a significant economic impact for larger pharmacies. Additionally, as noted in the analysis, DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal. As discussed above, these costs are not being mandated by this rule, but would be voluntarily borne by the various pharmacies in order to improve or expand their abilities for transferring EPCS.

Other Comments

Comments. One commenter recommended that EPCS transmitted to one pharmacy and dispensed at another pharmacy should not be considered transferred prescriptions if the pharmacy that received the prescription and the pharmacy that dispensed the prescription are both owned by the same entity and share the same integrated information technology (IT) system.

DEA Response. The CSA and DEA regulations require each registrant to maintain complete and accurate records of controlled substances.[39] Each pharmacy, not the entity who owns the pharmacy, is a DEA registrant and is therefore, subject to DEA's recordkeeping requirements. Consequently, a prescription that is received at one pharmacy and dispensed at a different pharmacy is a transferred prescription because the transaction is occurring between two different DEA registrants, even if they are owned by the same entity and share an integrated IT system.

Comments. One commenter recommended that DEA require a pharmacy transferring EPCS to verify that the pharmacy receiving the transferred prescription will be able to dispense the prescription's full quantity prior to transferring the prescription to that receiving pharmacy.

DEA Response. This rule provides for transfers of EPCS at the request of the patient. Although DEA suggests that the transferring pharmacy or the patient verify, prior to the transfer, that the receiving pharmacy is able to fill the transferred prescription, DEA is not requiring pharmacies to do so.

Comments. One commenter stated that the prescribing practitioner should receive an automatic notification when a controlled substance prescription that they issued is transferred.

DEA Response. DEA does not believe that it is necessary to require pharmacies to notify practitioners when an electronic controlled substance prescription that they issued is transferred. DEA believes this would be unnecessarily burdensome to pharmacies.

Comments. One commenter asked that DEA expand exceptions to the definition of "online pharmacy" to clarify that using the internet to transfer prescription information between pharmacies does not render a pharmacy an "online pharmacy."

DEA Response. DEA does not believe further clarification is necessary. The definition of an online pharmacy contains ten exceptions, which include a DEA-registered pharmacy whose dispensing of controlled substances via the internet consists solely of filling prescriptions that were electronically prescribed in a manner otherwise consistent with DEA regulations and the CSA.[40]

Comments. One commenter recommended that DEA work with State prescription drug monitoring programs (PDMPs) to require pharmacies receiving transferred EPCS to report the transfers to the PDMP. The commenter stated that prescribers should be able to easily identify transferred prescriptions when searching a PDMP database.

DEA Response. PDMP reporting is beyond the scope of this rule and DEA's authority, as PDMPs are regulated by the States.

Comments. One commenter suggested that DEA should preempt any State requirements for transferring EPCS that exceed the requirements established by DEA.

[33] The numbers have been updated since the NPRM with 2021 data. See the Executive Order 12866 section below under Regulatory Analyses for the detailed analysis.

[34] Id.

[35] The numbers have been updated since the NPRM with 2021 data. See the Regulatory Flexibility Act section below under Regulatory Analyses for the detailed analysis.

[36] Id.

[37] Id.

[38] Id.

[39] 21 U.S.C. 827 and 21 CFR 1304.21(a).

[40] *See* 21 CFR 1300.04(h)(9).

DEA Response. DEA generally will not preempt any State laws or regulations related to dispensing controlled substances,[41] including the transfer of EPCS between pharmacies for initial dispensing.

Comments. One commenter recommended that DEA revise the language in the proposed 21 CFR 1306.08(g), which states that EPCS transfers for initial dispensing are permissible only if allowable under existing State or other applicable law. The commenter stated that, as currently written, a State would have to enact a law to expressly allow this activity. The commenter recommended replacing "only if allowable under existing State or other applicable law" with "unless prohibited by existing State or other applicable law."

DEA Response. DEA understands the commenter's concern. However, DEA is not amending this language at this time. The regulations for the transfer of EPCS between pharmacies for initial dispensing were written to parallel those for the transfer of prescription information for refill dispensing, as well as those for prescriptions in general. DEA notes that the phrase, "only if allowable under existing State or other applicable law," is included in several provisions in 21 CFR part 1306.[42]

Comments. One commenter recommended that DEA use the term "forward" instead of "transfer" when referring to the transfer of prescription information for initial dispensing. The commenter was concerned that the transfer of prescription information for initial dispensing would be confused with the transfer of prescription information for refill dispensing outlined in 21 CFR 1306.25. The commenter noted that while schedule II controlled substance prescriptions cannot be transferred for refill dispensing because refills are not permitted, this rule, if promulgated, will allow the transfer of schedule II controlled substance prescriptions between pharmacies for initial dispensing.

DEA Response. DEA understands the commenter's concern and preference for differentiating between prescriptions transferred for initial dispensing and those transferred for refill dispensing. However, DEA uses "transfer" to refer to the exchange of prescription information between pharmacies for both initial and refill dispensing. Therefore, this final rule continues to use the term "transfer."

[41] *See* 21 U.S.C. 903.

[42] *See* 21 CFR 1306.12(b)(1)(iv) and (v) and 1306.25(e).

Out of Scope

Five comments were outside the scope of this rule. Three commenters asked DEA to also allow controlled substance prescriptions prescribed orally and via facsimile to be transferred between pharmacies for initial dispensing. This is beyond the scope of this rule which only addresses the one-time transfer of EPCS between pharmacies for initial dispensing. One commenter disagreed with health insurance entities requiring prior authorization for medications currently being prescribed and those prescribed to treat chronic illnesses. The commenter also stated that after patients have been prescribed medications to treat chronic illnesses for an extended period of time, the prescriptions should be allowed to be refilled without requiring patients to revisit the prescribing practitioner or requiring the practitioner to issue new prescriptions. Additionally, the commenter stated that practitioners should be allowed to prescribe stimulants for less than a 30-day supply. One commenter wanted medications used to treat attention-deficit/hyperactivity disorder removed from the controlled substances lists. These comments are beyond the scope of this rulemaking and therefore are not addressed.

Summary of Changes From the NPRM

DEA is finalizing the proposed regulatory text with modifications to address concerns brought forth by commenters. The final rule adds "upon request from the patient," to the proposed text in 21 CFR 1306.08(e) to clarify that prescription transfers must be requested by the patient. Further, a new sentence is also added to 21 CFR 1306.08(e) to clarify that, when a prescription for a schedule III, IV, or V controlled substance issued with authorized refills is transferred, the authorized refills are transferred with the original prescription.

Additionally, a new paragraph is added to 21 CFR 1306.08(f) to state that a transferring or receiving pharmacy's prescription processing software, if capable, is permitted to capture the information required from the electronic prescription and automatically populate the corresponding data fields to document the transfer of prescriptions between pharmacies. The new paragraph also states that the transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

Summary of the Final Rule

DEA is amending its regulations to allow, upon request from the patient, the transfer of EPCS between registered retail pharmacies for initial filling on a one-time basis only. The final rule explicitly states that an electronic prescription for a controlled substance in schedule II–V may be transferred between retail pharmacies for initial filling on a one-time basis only, upon request from the patient, and clarifies that any authorized refills included on a prescription for a schedule III, IV, or V controlled substance are transferred with the original prescription. The final rule specifies the following requirements that must be met when EPCS are transferred between pharmacies for initial dispensing. The prescription must be transferred in its electronic form and may not be converted to another form (*e.g.,* paper, facsimile) for transmission. The information required to be on a controlled substance prescription pursuant to 21 CFR part 1306 must be unaltered during the transmission. The transfer must be communicated between two licensed pharmacists. The final rule also stipulates that the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

The final rule describes the documentation requirements for pharmacies transferring EPCS for initial filling. A pharmacist transferring an electronic controlled substance prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also update the prescription record with the following information: the name, address, and DEA registration number of the pharmacy to which the prescription was transferred; the name of the pharmacist receiving the transfer; the name of the transferring pharmacist; and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the aforementioned required information from the electronic prescription and automatically populate the corresponding data fields to document the transfer. However, the transferring or receiving pharmacist, as applicable, must ensure that the

populated information is complete and accurate. The final rule requires the electronic records documenting EPCS transfers to be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the prescription and the pharmacy receiving and filling the prescription.[43] The existing requirements for all prescriptions, as outlined in 21 CFR part 1306, Prescriptions, and the requirements for prescribing and pharmacy applications, as outlined in 21 CFR part 1311, Requirements for Electronic Orders and Prescriptions, remain unchanged in this final rule.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 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). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. The Office of Management and Budget (OMB) has determined that this rule is not a "significant regulatory action" under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedule II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies. As described below, DEA estimates the annual cost savings of this rule is $29 million.[44]

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (*e.g.*, facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, the final rule requires that the electronic records documenting the transfer be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

As DEA regulations previously did not permit the transfer of schedule II–V EPCS from one retail pharmacy to another retail pharmacy for initial filling, DEA anticipates the ability to transfer EPCS under this final rule will affect the following parties: the first (transferring) pharmacy, patient, prescriber, and second (receiving) pharmacy. To quantify the economic impact of this rule, DEA estimated the average cost and cost savings for each transfer and applied this cost or cost savings to the estimated number of transfers.[45] DEA notes, however, that nothing in this rule mandates that pharmacies must transfer EPCS, or must receive EPCS; so, the economic analysis addresses the estimated costs and cost savings in instances where the transferring and receiving pharmacies agree to engage in such transfers under the terms of this rule.

Estimated Cost or Cost Savings per Transfer

To estimate the unit cost or cost savings, DEA compared the anticipated activities for each of the affected parties when a pharmacy receives EPCS it cannot fill under current practices (prior to the final rule) versus the final rule. The term "current" is used in the analysis to mean prior to the implementation of this final rule. The anticipated activities for each of the affected parties under current practices are described below. DEA understands there may be many operational variations; however, DEA believes the scenarios described below are good representations for the purposes of estimating costs.

The anticipated activities for each of the affected parties under current practice are described below.

1. The first (transferring) pharmacy contacts the patient to inform the patient that it is unable to fill the prescription.
2. The first pharmacy notes action taken, as needed.
3. The patient receives the call from the first pharmacy notifying the patient that it is unable to fill the prescription.
4. The patient contacts the prescriber and requests a new prescription.
5. The prescriber's secretary or administrative personnel receives the phone call from the patient.
6. The prescriber cancels the EPCS at the first pharmacy and issues a new EPCS at an alternate (receiving) pharmacy.
7. The alternate pharmacy receives and fills the EPCS.
8. The patient receives the filled prescription from the alternate pharmacy.

By contrast, the anticipated activities for each of the affected parties under the final rule and the economic impact are described below.

1. The first (transferring) pharmacy contacts the patient to inform them that it is unable to fill the prescription. DEA assumes the duration of the call to the patient is the same under the current and final rule scenarios, and therefore, there is no impact on the transferring pharmacy.
2. The patient receives a call from the transferring pharmacy notifying the patient that it is unable to fill the prescription; the patient requests that the prescription be transferred to an alternate (receiving) pharmacy. DEA assumes the duration of the call from the transferring pharmacy is the same under current and final rule scenarios. Therefore, there is no impact to the patient.
3. The patient (nor the transferring or receiving pharmacy) does not need to contact the prescriber to request a new prescription under the final rule. Therefore, there are cost savings for the patient from not contacting the prescriber.
4. The prescriber does not receive a call from the patient. Therefore, there are cost savings for the prescriber.

[43] 21 CFR 1304.06(g).

[44] This analysis has been updated since the NPRM with the latest available data.

[45] DEA expects minor system and implementation expenses, which consist of modifying software configurations, updating business processes, and minimal personnel training. DEA estimates the cost of these changes is minimal.

5. The prescriber does not need to issue a new EPCS. Therefore, there are cost savings for the prescriber.

6. The transferring pharmacy transfers the prescription (including contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer). Transferring the prescription will take longer than simply informing the patient that the prescription cannot be filled. Therefore, there is an additional cost to the transferring pharmacy to transfer a prescription.

7. The alternate (receiving) pharmacy receives the transfer and fills the transferred EPCS (including being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer). DEA anticipates there will be additional costs related to being contacted by the transferring pharmacy and exchanging information. Therefore, there is an additional cost to the receiving pharmacy to transfer a prescription, but the receiving pharmacy also obtains full reimbursement for the cost of filling the prescription.

8. The patient receives the filled prescription from the alternate (receiving) pharmacy. DEA assumes the burden is the same under the current and final rule scenarios, and therefore, there is no impact on the patient. Note that there may be a burden for the patient in needing to travel to a different pharmacy, but that is a cost that arises in every case where the patient must go to a different pharmacy than expected because the first pharmacy is unable to fill the prescription. There is no difference under this rule in the patient's burden in traveling to a different pharmacy, whether the EPCS is transferred under this rule, or the prescriber sends a new EPCS to the second pharmacy, or the patient takes a paper prescription to the second pharmacy.

Table 1 summarizes the activity scenarios under current practices (prior to the final rule) and final rule and the anticipated economic impact.

TABLE 1—PERSONS AND ACTIVITIES, CURRENT VS. FINAL RULE

Persons	Change in activity		Economic impact
	Current	Final Rule	
First or Transferring Pharmacy.	First pharmacy contacts patient to inform that they are unable to fill the prescription.	Transferring pharmacy contacts patient to inform that it is unable to fill the prescription.	Assume duration of call/contact is same ==> no impact.
	Note action taken (*i.e.*, void, cancel, etc.), as needed.	Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to transfer vs. noting action taken.
Patient	Receive call from pharmacy that it is unable to fill the prescription.	Receive call from pharmacy that it is unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy.	Assume duration of call/contact is same ==> no impact.
	Contact prescriber to request new prescription.	N/A	Cost savings from not having to contact prescriber.
	Receive filled prescription from second (receiving) pharmacy.	Receive filled prescription from receiving pharmacy.	Assume same burden ==> no impact.
Prescriber	Receive call from patient. (prescriber's secretary).	N/A	Cost savings.
	Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A	Cost savings.
Second (Receiving) Pharmacy.	Receive prescription and fill	Receive transfer and fill. "Transfer" includes: being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to receive and record transfer, but the receiving pharmacy gets full reimbursement for filling prescription.

Cost or cost savings is based on applying the loaded labor rate for each of the affected persons to the estimated time to conduct the activity. The Bureau of Labor Statistics (BLS) hourly wage data for various occupation codes was used to estimate the labor rates for each of the affected persons. Occupation codes 29–1051 Pharmacists, 00–0000 All Occupations, and 43–6013 Medical Secretaries and Administrative Assistants are used as best representations of first (transferring) and second (receiving) pharmacists, patient, and prescriber's secretary, respectively. DEA estimates the best representation for prescribers are the occupation codes 29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants for practitioner, nurse practitioner, and physician assistant prescribers, respectively. The occupation code 29–1215 Family Medicine Physicians was chosen to represent practitioners as DEA estimates that it best represents the typical prescribing practitioner.

DEA estimates the median hourly wages for the first (transferring) and second (receiving) pharmacist, patient, prescriber's secretary, and prescriber are $61.81, $22.00, $18.01, and $99.18, respectively.[46] [47] Additionally, BLS reports that average benefits for private industry is 29.5 percent of total compensation. The 29.5 percent of total compensation equates to 41.8 percent (29.5 percent/70.5 percent) load on

[46] BLS, May 2021 National Occupational Employment and Wage Estimates United States. *http://www.bls.gov/oes/current/oes_nat.htm.*

[47] The prescriber median hourly wage is a weighted average of the hourly wages of the occupation codes 29–1215 Family Medicine Physicians, 29–1171 Nurse Practitioners, and 29–1071 Physician Assistants, with the weights based on 1,368,536 Practitioner, 331,410 Nurse Practitioner, and 143,725 Physician Assistant active DEA registrations on 6/10/2022.

wages and salaries.[48] The load of 41.8 percent is added to each of the hourly rates to estimate the loaded hourly rates. The loaded hourly rates for the first (transferring) and second (receiving) pharmacy, patient, prescriber's secretary, and weighted average prescriber are $87.65, $31.20, $25.54, and $140.64, respectively. Table 2 summarizes the calculation for the loaded hourly wages for each of the affected persons.

TABLE 2—LOADED HOURLY WAGES

Affected persons	Occupation code	Occupation code description	Median hourly wage	Loaded hourly median wage
Patient	00–0000	All Occupations	$22.00	$31.20
Pharmacist	29–1051	Pharmacists	61.81	87.65
Medical secretary	43–6013	Medical Secretaries and Administrative Assistants.	18.01	25.54
Prescriber		Prescriber (Weighted Average)	99.18	140.64

The below sections describe the calculation conducted to quantify the economic impact associated with the changes in activities under the current and final rule scenarios described above.

1. Currently, the first pharmacy contacts the patient to inform the patient that the pharmacy is unable fill the prescription. DEA estimates that it takes three minutes for the first pharmacist to call the patient. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.05 (3/60) hours results in a cost of $4.38. Under the final rule, the first (transferring) pharmacist would also contact the patient regarding the inability to fill the prescription. DEA estimates that it would also take three minutes for the transferring pharmacist to call the patient under the final rule, resulting in the same cost of $4.38. Therefore, there is no economic impact to the transferring pharmacy associated with this activity under the final rule.

2. Currently, the first pharmacist notes in the electronic prescription record that the prescription was not filled. DEA estimates that it takes one minute for the first pharmacist to make the entry in the electronic prescription record. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.0167 (1/60) hours results in a cost of $1.46. Under the final rule, the transferring pharmacy may transfer the prescription, upon request from the patient, to the receiving pharmacy. Additionally, the transferring pharmacy must also contact the receiving pharmacy and exchange and document information such as the transferring pharmacy's name, address and DEA registration number, the name of the transferring pharmacist, and the name of the pharmacist receiving the transfer. DEA estimates that it takes three minutes for the transferring pharmacist to transfer the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 multiplied by 0.05 (3/60) hours results in a cost of $4.38. Therefore, the net cost to the transferring pharmacy under the final rule is $2.92 ($4.38–$1.46) per transfer.

3. Under current practices, the patient first receives a call from the pharmacist who informs him/her that his/her prescription cannot be filled. DEA estimates that the call between the pharmacist and the patient lasts three minutes. From Table 2, the estimated loaded hourly rate of a patient is $31.20. Multiplying the loaded hourly rate of $31.20 multiplied by 0.05 (3/60) hours results in a cost of $1.56 to the patient. Under the final rule, this activity does not change. With transfers of EPCS, the pharmacist must still contact the patient. Thus, under the final rule, the patient also receives a call from the pharmacist. Estimating three minutes for the call, there is still a cost of $1.56 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final rule.

4. Under current practices, the patient must contact the prescriber to request a new prescription. DEA estimates that it takes five minutes for the patient to contact the prescriber. From Table 2, the estimated loaded hourly rate of the patient is $31.20. Multiplying the loaded hourly rate of $31.20 by 0.083 (5/60) hours results in a cost of $2.60. Under the final rule, the patient no longer needs to contact the prescriber; the patient requests an electronic transfer of the prescription from the first (transferring) pharmacy to the second (receiving) pharmacy; thus, there is zero cost to the patient. Therefore, this activity under the final rule results in a cost savings to the patient of $2.60 per transfer.

5. Under current practices, the patient has to contact the prescriber asking for a new prescription. DEA estimates that it takes five minutes for the prescriber's medical secretary to receive the call from the patient. From Table 2, the estimated loaded hourly rate of a medical secretary is $25.54. Multiplying the loaded hourly rate of $25.54 by 0.083 (5/60) hours results in a cost of $2.13. Under the final rule, the patient no longer needs to contact the prescriber; thus, this interaction will not occur. Therefore, this activity under the final rule results in a cost savings to the prescriber of $2.13 per transfer.

6. Under current practices, after the medical secretary receives the call from the patient and the information is relayed to the prescriber, the prescriber issues a new prescription. DEA estimates the prescriber takes two minutes to cancel the first prescription and issue a new prescription. From Table 2, the estimated loaded hourly rate of a prescriber is $140.64. Multiplying the loaded hourly rate of $140.64 by 0.03 (2/60) hours results in a cost of $4.69. Under the final rule, the prescriber does not need to issue a new prescription; the original prescription is simply transferred to the receiving pharmacy. Therefore, this activity under the final rule results in a cost savings to the prescriber of $4.69 per transfer.

7. Under current practices, the second (receiving) pharmacy receives and fills the prescription. DEA estimates that it takes 15 minutes for the second (receiving) pharmacy to receive and fill the prescription. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.25 (15/60) hours results in a cost of $21.91. Under the final rule, DEA also estimates the receiving pharmacist still conducts this activity at the same loaded labor

[48] BLS, "Employer Costs for Employee Compensation—December 2021" (ECEC).

rate and time duration, resulting in a cost of $21.91. However, under the final rule, the receiving pharmacist must also receive and record transfer information from the transferring pharmacy. DEA estimates that it takes three minutes for the receiving pharmacy to receive and record transfer information. From Table 2, the estimated loaded hourly rate of a pharmacist is $87.65. Multiplying the loaded hourly rate of $87.65 by 0.05 (3/60) hours results in a cost of $4.38. Therefore, this activity under the final rule results in a cost to the receiving pharmacy of $4.38 per transfer, but the receiving pharmacy would get the full reimbursement for filling the prescription.

8. Under current practices, DEA assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to traveling to pick it up; thus, the patient only makes one trip to the second pharmacy where the prescription was transferred. DEA estimates that it takes 20 minutes for the patient to pick up the filled prescription. From Table 2, the estimated loaded hourly rate of a patient is $31.20. Multiplying the loaded hourly rate of $31.20 by 0.33 (20/60) hours results in a cost of $10.40. Under the final rule, DEA also assumes that the patient is informed that the first pharmacy is unable to fill the prescription prior to traveling to pick up the prescription; thus, the patient only makes one trip. Estimating 20 minutes for the patient to pick up the filled prescription, under the final rule, there is still a cost of $10.40 to the patient. Therefore, there is no economic impact to the patient associated with this activity under the final rule.

As shown by Table 3, the final rule results in a total cost of $8.76 and a total cost savings of $10.88 per transfer. This results in an overall net cost savings of $2.12 per transfer.

TABLE 3—COST/COST SAVINGS CALCULATION, CURRENT VS. FINAL RULE

Person/activity	Current		Final rule		Costs/(cost savings) ($)
	Estimated time (minutes)	Cost, current ($)	Estimated time (minutes)	Cost, final rule ($)	
Transferring pharmacist:					
1. Contact patient	3	4.38	3	4.38	
2.a. Void/transfer prescription	1	1.46			(1.46)
2.b. Transfer prescription			3	4.38	4.38
Patient:					
3. Receive call from pharmacist	3	1.56	3	1.56	
4. Contact prescriber	5	2.60			(2.60)
5. Received filled prescription	20	10.40	20	10.40	
Prescriber:					
6. Receive call from patient (secretary)	5	2.13			(2.13)
7. Issue new prescription (prescriber)	2	4.69			(4.69)
Receiving pharmacist:					
8.a. Receive prescription and fill	15	21.91	15	21.91	
8.b. Receive and record transfer info			3	4.38	4.38
Total Costs					8.76
Total Cost Savings					(10.88)
Net Cost Savings					(2.12)

Estimated Number of Transfers

As mentioned earlier, in order to calculate the total cost savings, DEA applied the $2.12 net cost savings per transaction, from above, to the estimated number of total transfers. DEA estimated the number of total transfers by estimating the number of EPCS for the analysis period, the first five years after the rule goes into effect, and applying an estimated percentage of EPCS that will be transferred.[49]

Surescripts' National Progress Reports for 2019, 2020, and 2021 form the basis for estimating the number of EPCS for the five-year analysis period.[50] The reports indicate that the rate of electronic prescribing for non-controlled substances (E–RX) was 76, 83, 86, 89, and 97 percent in 2017, 2018, 2019, 2020, and 2021, respectively.[51] Additionally, the reports indicate that the rate of EPCS is rising rapidly; the rate was 17, 26, 38, 58, and 73 percent in 2017, 2018, 2019, 2020, and 2021, respectively.[52] Furthermore, there were 65, 96.8, 134.2, 203.6, and 256.9 million EPCS filled in 2017, 2018, 2019, 2020, and 2021, respectively.[53] Dividing the total EPCS by the rate of EPCS, DEA estimates the total controlled substances prescriptions, electronic and non-electronic, were 382.4, 372.3, 353.2, 351.0, and 351.9 million in 2017, 2018, 2019, 2020, and 2021, respectively. Table 4 summarizes the data provided by the reports and the estimated total prescriptions for controlled substances for years 2017–2021.

[49] Due to the rapidly evolving industry and regulatory conditions, the analysis period is five years.

[50] Surescripts, "2019 National Progress Report" for 2017 data, "2020 National Progress Report" for 2018–2020 data, and "2021 National Progress Report" for 2018–2021 data.

[51] Ibid.

[52] Ibid.

[53] Ibid.

TABLE 4—ESTIMATED TOTAL PRESCRIPTIONS FOR CONTROLLED SUBSTANCES
[2017–2021]

	2017	2018	2019	2020	2021
Non-Controlled Substances:					
Rate of E–Rx (%)	76	83	86	89	97
Controlled Substances:					
Total Rx, E and non-E (millions of Rx)	382.4	372.3	353.2	351.0	351.9
Rate of EPCS (%)	17	26	38	58	73
Total EPCS (millions of Rx)	65.0	96.8	134.2	203.6	256.9

As shown in Table 4, the estimated total prescriptions for controlled substances decreased from 382.4 million in 2017 to 351.9 million in 2021. For the purposes of this analysis, DEA estimates the total number of controlled substances prescriptions will stay constant at 351.9 million per year for the five-year analysis period.

Also, from Table 4, the rate of electronic prescribing for non-controlled substances is higher than that of controlled substances. However, DEA estimates the rate of electronic prescribing for controlled substances will match that of non-controlled substances in year one due to a CMS December 2020 rule, which requires electronic prescribing for all controlled substances (with some exceptions) covered under Medicare Part D.[54] The 2021 rate of electronic prescriptions for non-controlled substances was 97 percent. While it is possible that this rate could continue to increase in the future, DEA has no basis to estimate how much higher the rate would go. As the rate of increase has been slowing over the past several years, DEA conservatively estimates that the rate of electronic prescribing for non-controlled substances has peaked at 97 percent and the rate of electronic prescribing for controlled substances will be 97 percent for the analysis period. Multiplying the estimated total number of controlled substance prescriptions, 351.9 million per year, by the estimated rate of EPCS of 97 percent, the estimated total EPCS is 341.3 million per year for the analysis period, the first five years after the rule goes into effect.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.[55] Applying the four percent transfer rate to the total EPCS prescriptions, DEA estimates the number of transfers is 13.7 million per year for each of the first five years.

Total Cost Savings

In order to calculate the total cost savings, DEA applied the $2.12 net cost savings per transaction to the estimated 13.7 million transfers, resulting in a total annual net cost savings of $29.0 million over the five-year analysis period. The net present value (NPV) of the cost savings is $132.8 million at three percent discount rate and $118.9 million at seven percent discount rate. The annualized cost savings from year one to year five is $29.0 million at three percent and seven percent. Table 5 summarizes the NPV and annualized cost savings calculation.

TABLE 5—NPV AND ANNUALIZED COST SAVINGS

	3 Percent	7 Percent
NPV of Cost Savings	$132.8	$118.9
Annualized Cost Savings	29.0	29.0

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 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 tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. 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 these small entities.

The RFA requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. DEA has analyzed the economic impact of each provision of this final rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

DEA is amending its regulations to allow the transfer of electronic prescriptions for schedules II–V controlled substances between registered retail pharmacies for initial dispensing, upon request from the patient, on a one-time basis only. This amendment specifies the procedure that must be followed and the information that must be documented when transferring EPCS between DEA-registered retail pharmacies.

The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (*e.g.*, facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record

[54] 85 FR 84472 (Dec. 28, 2020).

[55] Conference call between CMS and DEA, January 2021. CMS's estimate is a "high" estimate and "four percent" is considered the maximum percent of electronic prescriptions that are transfers.

the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist receiving the transfer. Finally, the final rule requires that the electronic records documenting the transfer be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

DEA anticipates this final rule will affect pharmacies, offices of physicians, and hospitals, as the majority of prescribers are employed by offices of physicians or hospitals. Table 6 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by this final rule. There may be other small entities under Small Business Administration size standards in other NAICS code industries affected by this final rule. However, DEA believes the list in Table 6 is a good general representation of affected small entities and their industries as defined by NAICS.

TABLE 6—AFFECTED INDUSTRIAL SECTORS

Business activity	NAICS code	NAICS Code description
Pharmacy	446110	Pharmacies and Drug Stores.
Prescriber	621111	Offices of Physicians (except Mental Health Specialists).
	622110	General Medical and Surgical Hospitals.

CMS estimates that as much as four percent of electronic prescriptions for non-controlled substances in 2019 were transfers.[56] DEA assumes, for the purposes of this analysis, that such transfers of EPCS are distributed proportionally across all prescribers and pharmacies. Therefore, DEA estimates a substantial number of small entities in the affected industries will be affected by this final rule.

In order to determine whether the final rule will result in a significant impact on the affected small entities, the following steps were taken:

1. Estimate the cost or cost savings per transfer.
2. Estimate the total cost or cost savings of transfers.
3. Allocate the total cost or cost savings across all affected entities in proportion to their revenue to estimate the cost or cost savings per entity.
4. Compare the cost or cost savings to the annual revenue for the smallest of small entities. If the impact is not significant for the smallest of small entities, then the impact is not significant for the larger small entities.

Table 3 summarizes the cost or cost savings on a per-transfer basis. The net cost to the transferring pharmacy is $2.92 (the cost of transferring the prescription, $4.38 (2.b.), minus the cost of updating the prescription record to note that the prescription was not filled, $1.46 (2.a.)). The cost to the receiving pharmacy is $4.38 (8.b.) per transfer. Each transfer affects two different pharmacies, the transferring and receiving pharmacies. Since pharmacies are likely to transfer and receive, an average was taken to determine the typical cost per transfer for a pharmacy. The average cost is $3.65 (($2.92 + $4.38)/2) per transfer. Also, from Table 3, the total cost savings to a prescriber (office of physician or hospital) is $6.82, the sum of the cost savings from not receiving a call from the patient $2.13 (6.) and the cost savings from not issuing a new prescription $4.69 (7.).

To calculate the total cost to pharmacies and total cost savings to prescribers, the unit cost and cost savings are multiplied by the estimated total annual transfers. From above, the estimated number of transfers is 13.7 million per year. Multiplying the average net cost of $3.65 per transfer for pharmacies by 13.7 million transfers, the estimated total cost of transfers to all pharmacies is $50,005,000 per year. Multiplying the cost saving of $6.82 per transfer for prescribers (office of physician or hospital) by 13.7 million transfers, the estimated total cost saving to all prescribers is $93,434,000 per year.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. SUSB data includes the number of firms at various size ranges. For the purposes of this analysis, the term "firm" as defined in the SUSB is used interchangeably with "entity" as defined in the RFA. Based on SUSB data, there are 19,234, 161,286, and 2,560 firms in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[57] Furthermore, the total receipts for all firms, including all size ranges, are $282 billion, $474 billion, and $997 billion (rounded) for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively.[58] Table 7 summarizes the SUSB data and provides receipt values without rounding.

TABLE 7—NUMBER OF FIRMS AND TOTAL RECEIPTS

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipts ($000)
446110	Pharmacies and Drug Stores	All size ranges	19,234	281,653,229
621111	Offices of Physicians (except Mental Health Specialists)	All size ranges	161,286	473,954,346
622110	General Medical and Surgical Hospitals	All size ranges	2,560	997,368,727

[56] Conference call between CMS and DEA, January 2021. CMS's estimate is a "high" estimate and "four percent" is considered the maximum percent of electronic prescriptions that are transfers.

[57] SUSB, 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size, U.S., 6-digit NAICS, *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html* (*https://www2.census.gov/programs-surveys/susb/tables/2017/us_6digitnaics_rcptsize_2017.xlsx*). (Accessed June 8, 2022.) 2017 data by enterprise receipt size is the latest available.

[58] Ibid.

SUSB data also includes the number of firms and receipts for various receipt-size ranges. The smallest size range is firms with annual revenue less than $100,000. The average receipt per firm was calculated based on the number of firms and for the receipts for the firms in the size range. For example, in the 446110—Pharmacies and Drug Stores industry sector, there are 666 firms with receipts under $100,000, and their combined receipts is $34,342,000. Dividing $34,342,000 by 666 results in an average receipt of $51,565 per firm. Performing the same calculation for all three industries, the average receipt per firm is $51,565, $50,554, and $259,478 for the smallest size category in 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 8 summarizes the calculation for the average receipt per firm.

TABLE 8—AVERAGE RECEIPT PER FIRM

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipts ($000)	Average receipt per firm ($)
446110	Pharmacies and Drug Stores	<100,000	666	34,342	51,565
621111	Offices of Physicians (except Mental Health Specialists)	<100,000	14,302	723,029	50,554
622110	General Medical and Surgical Hospitals	100,000–* 499,999	23	5,968	259,478

*"Receipts" not available for the smallest size range of "<100,000; therefore, used next size range of "100,000–499,000" for comparison.

To compare the average cost per firm with the average receipt per firm, DEA allocated the cost and cost savings proportionally by revenue, divided by the number of firms to calculate the average cost per firm, and compared the average cost per firm as a percent of receipt per firm. For example, the receipts for the 666 firms with receipts under $100,000 in 446110—Pharmacies and Drug Stores industry sector is $34,342,000. This is 0.0121930 percent of total receipt of $281,653,229,000 for all size ranges. Allocating 0.0121930 percent of total cost to pharmacies of $50,005,000 to the 666 firms, the average cost per firm is $9.[59] Dividing the average cost per firm of $9 by the average receipt per firm of $51,565, the average cost per firm is 0.01745 percent of average receipt per firm.

This calculation is repeated for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors. However, the economic impact for 621111—Offices of Physicians (except Mental Health Specialists) and 622110—General Medical and Surgical Hospitals industry sectors is a cost savings, rather than a cost. Although employment of prescribers is expected to be split between these two industries, to be conservative, the total cost savings (rather than estimating a split between the two industries) is compared to the average receipt per firm. In summary, the average cost or cost savings per firm as percent of receipt is 0.01745 percent, 0.01978 percent, and 0.00925 percent for 446110—Pharmacies and Drugs Stores, 621111—Offices of Physicians (except Mental Health Specialists), and 622110—General Medical and Surgical Hospitals industry sectors, respectively. Table 9 summarizes the calculation and results.

TABLE 9—COST OR COST SAVINGS PER FIRM AS PERCENTAGE OF RECEIPTS

NAICS Code	NAICS Code description	Receipt size ($)	Number of firms	Receipt as percent of total (percent)	Allocated cost to firms in size range ($)	Average cost per firm ($)	Average cost/ cost savings per firm as percent of receipt (percent)
446110	Pharmacies and Drug Stores	<100,000	666	0.012193	6,097	9	0.01745
621111	Offices of Physicians (except Mental Health Specialists).	<100,000	14,302	0.152552	142,536	10	*(0.01978)
622110	General Medical and Surgical Hospitals.	100,000–499,999	23	0.000598	559	24	*(0.00925)

*Cost savings.

In conclusion, the average cost or cost savings per firm as percent of receipt of 0.01745 percent, 0.01978 percent, and 0.00925 percent are not significant economic impacts. Therefore, DEA concludes this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this final rule will not result in any Federal mandate that may 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 annually for inflation) in any 1 year." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA), DEA has identified the following collection of information related to this rule and has submitted this collection request to the Office of Management and Budget (OMB) for review and approval.[60] This final rule establishes the recordkeeping requirements for pharmacies electronically transferring of schedules II–V EPCS for initial dispensing. 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

[59] ($50,005,000 x 0.0121930 percent)/666 = $9.

[60] 44 U.S.C. 3501 *et seq.*

obtained at *https://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Rule

Title: Recordkeeping Requirements for the electronic transfer of electronic prescriptions for schedules II–V controlled substances between pharmacies for initial filling.

OMB Control Number: 1117–0061.

DEA Form Number: N/A.

DEA is creating a new collection of information by requiring pharmacies to create and maintain certain records relating to the transfer of unfilled EPCS between pharmacies for initial filling. The rule requires the transferring pharmacy to note in the electronic prescription record that the prescription was transferred. The transferring pharmacy is also required to add to the prescription record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, as well as the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the rule requires the pharmacy receiving the transfer to record the name, address, and DEA registration number of the transferring pharmacy, the name of the transferring pharmacist, the name of the pharmacist receiving the transfer, and the date of the transfer. In addition, the rule required the records to be maintained by both pharmacies for at least two years from the date of the transfer. DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 70,567.
- *Frequency of response: 354.273244* (calculated average).
- *Number of responses:* 25,000,000.
- *Burden per response:* 0.05 hour.
- *Total annual hour burden:* 1,250,000.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

If you need 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: (571) 776–2265.

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 comments refer to RIN 1117–AB64/Docket No. DEA–637.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 20, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons stated in the preamble, DEA amends 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

■ 2. Amend § 1306.08 by adding paragraphs (e) through (i) to read as follows:

§ 1306.08 Electronic prescriptions.

* * * * *

(e) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II–V is permissible between retail pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(f) The transfer of an electronic prescription for a controlled substance in Schedule II–V between retail pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription required by this part must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) The transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist must add the following to the electronic prescription record:

(i) Information that the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(iii) The date of the transfer and the name of the pharmacist transferring the prescription information.

(5) The receiving pharmacist must do the following:

(i) Add the word "transfer" to the electronic prescription record at the receiving pharmacy.

(ii) Annotate the prescription record with the name, address, and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription.

(iii) Record the date of the transfer and the name of the pharmacist receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph (f), from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(g) The transfer of an electronic prescription for a controlled substance in Schedule II–V for the purpose of initial dispensing is permissible only if allowable under existing State or other applicable law.

(h) The electronic records documenting the transfer of the electronic prescription must be maintained for a period of two years

from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the electronic prescription.

(i) A pharmacy may transfer electronic prescription information for a controlled substance in Schedule III, IV, and V to another pharmacy for the purpose of refill dispensing pursuant to § 1306.25.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–15847 Filed 7–26–23; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 222 and 235

[Docket No. 2023–4]

Copyright Claims Board: Agreement-Based Counterclaims

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: Pursuant to the Copyright Alternative in Small-Claims Enforcement Act, the U.S. Copyright Office is adopting as final a May 3, 2023, proposed rule governing the filing of agreement-based counterclaims and related discovery requirements in Copyright Claims Board proceedings.

DATES: Effective August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION: The Copyright Alternative in Small-Claims Enforcement Act of 2020 (the "CASE Act") [1] directed the Copyright Office to establish the Copyright Claims Board (the "CCB"), an alternative and voluntary forum for parties seeking to resolve certain copyright-related disputes that have a total monetary value of $30,000 or less. After receiving and considering comments from the public, the Office published final rules addressing various aspects of CCB proceedings.[2] On June 16, 2022, the CCB began receiving claims.

On May 3, 2023, the Office published a notice of proposed rulemaking ("NPRM") seeking public comment on a proposed rule addressing the filing of agreement-based counterclaims and related discovery requirements in the CCB.[3] The proposed regulations set out the requirements for the content of such counterclaims and any responses to them.[4] The Office also proposed standard interrogatories and standard requests for the production of documents for use in connection with such counterclaims.[5]

The Office received one comment that addressed the proposed rulemaking, but did not recommend any changes to the proposed regulatory text.[6] The Copyright Alliance's comment stated that "[a]t this time, we have no substantive objections to the Office's proposal to add regulations specifically governing agreement-based counterclaims," [7] but requested "the opportunity to comment further on the rules established in this notice of proposed rulemaking as well as the other regulations governing the CCB once there is more qualitative and quantitative data to consider." [8] The Copyright Alliance "reiterate[d] the importance of ensuring that the rules and regulations do not become so cumbersome and complex such that they make the CCB inaccessible to pro se litigants, who comprise a significant portion of the system's users, and whom the statute was designed to accommodate." [9]

The Office appreciates these comments and will take them under advisement. Because the Office did not receive any comments recommending changes to the proposed rule, it adopts the rule as final.

List of Subjects in 37 CFR Parts 222, 225

Claims, Copyright.

Final Regulations

For the reasons stated in the preamble, the U.S. Copyright Office amends 37 CFR parts 222 and 225 as follows:

PART 222—PROCEEDINGS

■ 1. The authority citation for part 222 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 2. Amend § 222.9 as follows:

■ a. Redesignate paragraphs (c)(6) through (8) as paragraphs (c)(7) through (9), respectively.

■ b. Add paragraph (c)(6) as follows:

§ 222.9 Counterclaim.

* * * * *

(c) * * *

(6) For a counterclaim arising under an agreement asserted under paragraph (c)(2)(iv) of this section—

(i) A description of the agreement that the counterclaim is based upon;

(ii) A brief statement describing how the agreement pertains to the same transaction or occurrence that is the subject of the infringement claim against the counterclaimant; and

(iii) A brief statement describing how the agreement could affect the relief awarded to the claimant;

* * * * *

■ 3. Amend § 222.10 as follows:

■ a. Redesignate paragraph (b)(6) as paragraph (b)(7).

■ b. Add paragraph (b)(6) as follows:

§ 222.10 Response to counterclaim.

* * * * *

(b) * * *

(6) For counterclaims arising under an agreement, as set forth in 37 CFR 222.9(c)(2)(iv), a statement describing in detail the dispute regarding the contractual counterclaim, including any defenses as well as an explanation of why the counterclaim respondent believes the counterclaimant's position regarding the agreement lacks merit; and

* * * * *

PART 225—DISCOVERY

■ 4. The authority citation for part 225 continues to read as follows:

Authority: 17 U.S.C. 702, 1510.

■ 5. Amend § 225.2 as follows:

■ a. Redesignate paragraph (f) as paragraph (h).

■ b. Add paragraphs (f) and (g) as follows:

§ 225.2 Standard interrogatories.

* * * * *

(f) *For a counterclaimant asserting a counterclaim arising under an agreement.* In addition to the information in paragraph (a) of this section, the *standard interrogatories* for

[1] Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

[2] 87 FR 20707 (Apr. 8, 2022) (law student representation final rule); 87 FR 12861 (Mar. 8, 2022) (initial proceedings partial final rule); 87 FR 16989 (Mar. 25, 2022) (initial proceedings final rule); 87 FR 24056 (Apr. 22, 2022) (initial proceedings correction); 87 FR 30060 (May 17, 2022) (active proceedings final rule); 87 FR 36060 (June 15, 2022) (active proceedings correction). The Office sought public comments prior to the adoption of these final rules. *See, e.g.,* 86 FR 74394 (Dec. 30, 2021); 86 FR 53897 (Sept. 29, 2021); 86 FR 69890 (Dec. 8, 2021).

[3] 88 FR 27845 (May 3, 2023).

[4] 88 FR 27845, 27846–47.

[5] 88 FR 27845, 27846–48.

[6] *See* Copyright Alliance Comments. The Office received a second comment, which addressed songwriter-related royalty claims that are outside of the scope of this rulemaking. *See* Timothy Gilmore Comments at 1.

[7] Copyright Alliance Comments at 1.

[8] Copyright Alliance Comments at 1–2.

[9] Copyright Alliance Comments at 2.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, on behalf of Tiffany O'Hagan and Susan Kleppin		**2) Date when request submitted:** 8/17/2023 **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: 8/31/2023	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** DSPS Pharmacy Inspection Process – Discussion and Consideration 1)DSPS Pharmacy Inspection meeting 2) Inspections and Guidance relating to Controlled Substances	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>	
10) Describe the issue and action that should be addressed: <Click Here to Add Description>			
11) Authorization			
			**8/17/2023**
Signature of person making this request			**Date**
Supervisor (Only required for post agenda deadline items)			**Date**
Executive Director signature (Indicates approval for post agenda deadline items)			**Date**

Directions for including supporting documents:

1. This form should be saved with any other documents submitted to the Agenda Items folders.
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:
Brad Wojciechowski	8/22/2023
	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?
8/31/2023	☒ Yes ☐ No	Credentialing Matters – Discussion and Consideration

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 applicable:
☒ Open Session ☐ Closed Session	☐ Yes <Appearance Name(s)> ☒ No	<Click Here to Add Case Advisor Name or N/A>

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

<Click Here to Add Description>

11) Authorization

Signature of person making this request	8/22/2023 Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:

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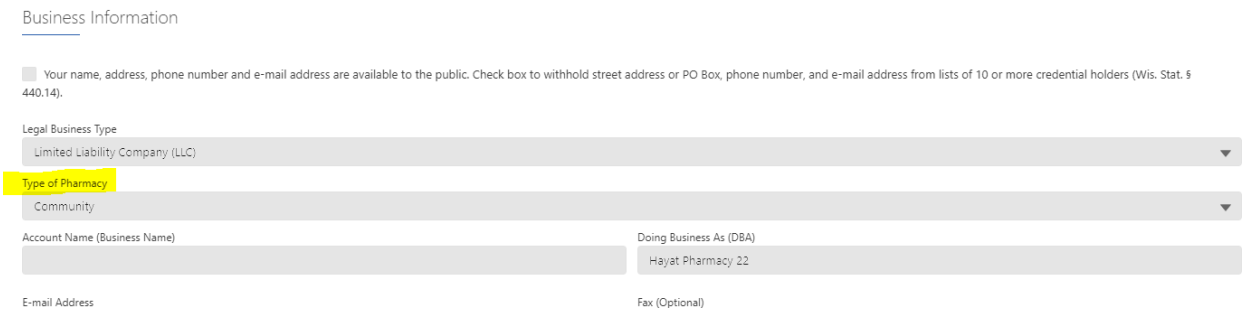
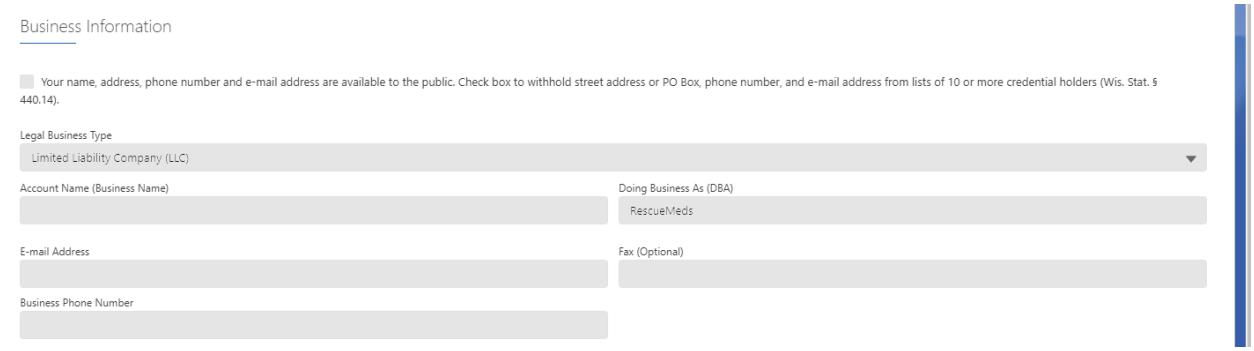
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.



However, we do not ask what type of pharmacy for out-of-state Pharmacies.



State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		2) Date when request submitted: 08/18/23 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: 08/31/2023	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Correspondence to Legislature regarding 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160 – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes ☒ No		9) Name of Case Advisor(s), if applicable: N/A

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

Discussion of Correspondence to Legislature regarding 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160

11) Authorization

Whitney DeVoe	08/18/23
Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

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

PHARMACY EXAMINING BOARD

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

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

[Legislature's Name]
[Address]
[City], [State], [ZIP Code]

RE: Wisconsin Pharmacy Examining Board's Opposition to 2023 WI Assembly Bill 143 and 2023 WI Senate Bill 160 regarding terminating the MPJE requirement for Pharmacist Licensure

Dear [Legislature's Name],

I am writing to you on behalf of the Wisconsin Pharmacy Examining Board to express our strong opposition to the proposed law that seeks to terminate the Multistate Pharmacy Jurisprudence Examination (MPJE) requirement for pharmacist licensure in Wisconsin. As an essential component of pharmacy licensure, the MPJE plays a vital role in ensuring patient safety, promoting professional competence, and upholding the highest legal standards within the pharmacy profession.

The MPJE serves as a comprehensive evaluation tool that assesses an individual's knowledge of state and federal pharmacy laws, regulations, and ethical considerations. By successfully passing this examination, aspiring pharmacists demonstrate their competency and understanding of the legal framework governing the practice of pharmacy. It serves as a safeguard to protect patients from potential harm resulting from medication errors, misinterpretation of regulations, or non-compliance with existing laws.

The MPJE covers a wide range of topics, including controlled substance regulations, dispensing guidelines, recordkeeping requirements, and patient confidentiality, among others. These areas are critical for pharmacists to understand and adhere to in order to ensure optimal patient care and to maintain public trust in the pharmacy profession.

Moreover, the MPJE acts as a unifying standard for all aspiring pharmacists, regardless of their educational background or state of licensure. It provides a consistent measure of competence, allowing for the seamless mobility of pharmacists across state lines. This portability is particularly important in times of public health emergencies or natural disasters when pharmacists may need to provide their services in different jurisdictions swiftly.

By eliminating the MPJE, we risk compromising patient safety and the integrity of the pharmacy profession. The examination's removal could result in a lack of uniformity among state regulations, potentially leading to confusion and increased risks for patients. It could also create

barriers for pharmacists seeking to practice in different states, hindering their ability to respond effectively to public health emergencies or fill gaps in healthcare access.

In conclusion, the Wisconsin Pharmacy Examining Board strongly opposes the law aiming to terminate the MPJE. We firmly believe that the examination is an indispensable tool for maintaining high standards within the pharmacy profession, protecting patient safety and ensuring the mobility of qualified pharmacists across state lines. We respectfully request that you consider our concerns and support the continued use and improvement of the MPJE.

Thank you for your attention to this matter. We would be happy to provide any additional information or clarification required. Your support in preserving the MPJE would be greatly appreciated.

Sincerely,

John Weitekamp R.Ph.
Chairperson, Wisconsin Pharmacy Examining Board