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Tony Evers, Governor
Dawn B. Crim, Secretary

PHARMACY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Debra Sybell (608) 266-2112
October 23, 2019

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

10:00 A.M.
(OR IMMEDIATELY FOLLOWING PHARMACY RULES COMMITTEE MEETING)

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of September 25, 2019 (5-7)

C. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Board Members – Term Expiration Dates

D. 10:00 A.M. PUBLIC HEARING: Clearinghouse Rule 1915 Relating to Pharmacist to Delegate Ratio (8-11)
1) Review and Respond to Public Hearing Comments and Clearinghouse Report

E. 10:00 A.M. PUBLIC HEARING: Clearinghouse Rule 1916 Relating to Automated Technology Product Verification Check (12-16)
1) Review and Respond to Public Hearing Comments and Clearinghouse Report

F. 10:00 A.M. PUBLIC HEARING: Clearinghouse Rule 1917 Relating to Delegate-Check-Delegate (17-23)
1) Review and Respond to Public Hearing Comments and Clearinghouse Report

G. Legislative and Policy Matters – Discussion and Consideration

H. Administrative Rule Matters – Discussion and Consideration
1) Adoption of Phar 7 Relating to Pharmacist to Delegate Ratio **(24-27)**
2) Adoption of Phar 7 Relating to Automated Technology Product Verification Check **(28-31)**
3) Adoption of Phar 7 Relating to Delegate-Check-Delegate **(32-37)**
4) Phar 7 Relating to Practice of Pharmacy **(38-54)**
5) Review of 21 CFR 1305 (New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances) **(55-64)**

6) Pending or Possible Rulemaking Projects

I. APPEARANCE – Susan Brischler Trujillo, Quarles and Brady: Request to List Multiple Office Locations on Physician Licenses – Discussion and Consideration (65-67)

J. **Education and Examination Matters – Discussion and Consideration**
1) MPJE Item Review and Related Matters **(68-73)**

K. **Newsletter Planning – Discussion and Consideration**

L. **Speaking Engagements, Travel, or Public Relation Requests, and Reports – Discussion and Consideration**
1) Travel Report: 2019 NABP/AACP District IV Meeting on October 16-18, 2019 in Indianapolis, IN – Franklin LaDien

M. Discussion and Consideration of 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 Administrative Rule Matters
11) Liaison Reports
12) Board Liaison Training and Appointment of Mentors
13) Informational Items
14) Division of Legal Services and Compliance (DLSC) Matters
15) Presentations of Petitions for Summary Suspension
16) Petitions for Designation of Hearing Examiner
17) Presentation of Stipulations, Final Decisions and Orders
18) Presentation of Proposed Final Decisions and Orders
19) Presentation of Interim Orders
20) Pilot Program Matters
21) Petitions for Re-Hearing
22) Petitions for Assessments
23) Petitions to Vacate Orders
24) Requests for Disciplinary Proceeding Presentations
25) Motions
26) Petitions
27) Appearances from Requests Received or Renewed
28) Speaking Engagements, Travel, or Public Relation Requests, and Reports

N. 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.).

O. Deliberation on Division of Legal Services and Compliance Matters

1) Proposed Stipulations, Final Decisions, and Orders

a. 17 PHM 158 – Richard D. Moe, R.Ph. **(74-79)**

2) Case Closings

a. 17 PHM 172 – W., J.T.K. & S.C.F. **(80-84)**

b. 18 PHM 026 – K.G.V. **(85-91)**

c. 18 PHM 056 – W. **(92-94)**

d. 19 PHM 103 – C. **(95-98)**

3) Monitoring Matters

a. Bradley Spross, R.Ph. – Requesting Reduction in Drug Screens and AA/NA Meeting Attendance **(99-131)**

P. 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

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

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

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

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

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

ADJOURNMENT

NEXT MEETING: DECEMBER 17, 2019

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

PHARMACY EXAMINING BOARD
MEETING MINUTES
SEPTEMBER 25, 2019

PRESENT: Franklin LaDien, Anthony Peterangelo, Philip Trapskin *(excused at 2:19 p.m.)*, John Weitekamp, Cathy Winters

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

CALL TO ORDER

Philip Trapskin, Chairperson, called the meeting to order at 12:54 a.m. A quorum was confirmed with five (5) members present.

ADOPTION OF AGENDA

Amendments to the Agenda:

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

APPROVAL OF MINUTES OF JULY 17, 2019

Amendments to the Minutes:

MOTION: Cathy Winters moved, seconded by Franklin LaDien, to approve the Minutes of July 17, 2019 as published. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Phar 6 Relating to Storage

MOTION: Cathy Winter moved, seconded by Franklin LaDien, to approve the preliminary rule draft of Phar 6, relating to Storage, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Phar 17 Relating to Internships

MOTION: Franklin LaDien moved, seconded by John Weitekamp, to authorize the Chairperson to approve the preliminary rule draft of Phar 17, relating to Internships, for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

(Philip Trapskin was excused at 2:19 p.m.)

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

Concordia University Wisconsin School of Pharmacy Speaking Engagement Invite

MOTION: Cathy Winter moved, seconded by Anthony Peterangelo, to designate Franklin LaDien to speak on the Board's behalf at Concordia University Wisconsin School of Pharmacy in Mequon, WI in November 2019 or date to be determined. Motion carried unanimously.

CLOSED SESSION

MOTION: John Weitekamp moved, seconded by Cathy Winter, 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.). Franklin LaDien, Vice Chairperson, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien-yes; Anthony Peterangelo-yes; John Weitekamp-yes; and Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 2:43 p.m.

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

Administrative Warnings

MOTION: Cathy Winter moved, seconded by Anthony Peterangelo, to issue an Administrative Warning in the matter of the following cases:

1. 17 PHM 112 – S.P.S.
2. 17 PHM 136 – K.A.S.

Motion carried unanimously.

Stipulations, Final Decisions and Orders

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings of the following cases:

1. 17 PHM 112 – Ai K. Nguyen, R.Ph.
2. 17 PHM 112 – Pick 'N Save Pharmacy #6879

Motion carried unanimously.

Case Closings

MOTION: John Weitekamp moved, seconded by Anthony Peterangelo, to close the DLSC cases for the reasons outlined below:

1. 17 PHM 090 – S.P. – Prosecutorial Discretion (P2)
2. 17 PHM 136 – W., M.H.P. – No Violation (NV)
3. 17 PHM 159 – P.A. – Prosecutorial Discretion (P2)
4. 17 PHM 159 – W. – No Violation (NV)
5. 18 PHM 024 – C.M.Y., M.A.D., A.P., & A.P. – No Violation (NV)
6. 18 PHM 027 – A.P.S.P. – No Violation (NV)
7. 18 PHM 032 – V.H.P. – Prosecutorial Discretion (P5)
8. 18 PHM 063 – M.P. - Prosecutorial Discretion (P5)
9. 18 PHM 091 – M.D.L. & W. – Prosecutorial Discretion (P2)
10. 18 PHM 213 – B.P. - No Violation (NV)
11. 19 PHM 013 – N.E.V., W. - No Violation (NV)
12. 19 PHM 044 – A.M.K., C. - No Violation (NV)

Motion carried unanimously.

Monitoring Matters

Angela Lane, R.Ph. – Compliance Review

MOTION: Cathy Winter moved, seconded by Anthony Peterangelo, to table Monitoring Matters of Angela Lane, R.Ph until the October 23, 2019 meeting. Motion carried unanimously.

RECONVENE TO OPEN SESSION

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

The Board reconvened into Open Session at 3:49 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

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

ADJOURNMENT

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

The meeting adjourned at 3:49 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:
Sharon Henes Administrative Rules Coordinator	14 October 2019 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?
23 October 2019	☒ Yes ☐ No	Public Hearing on Emergency Rule 1915 relating to Pharmacist to Delegate Ratio Public Hearing on Emergency Rule 1916 relating to Automated Technology Product Verification Check Public Hearing on Emergency Rule 1917 relating to Delegate-Check-Delegate

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

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

Hold Public Hearing at 10:00 a.m.

Discuss any public hearing comments.

11) Authorization

Sharon Henes *10/14/19*

Signature of person making this request — Date

Supervisor (if required) — Date

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

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

The statement of scope for this rule, SS #058-19, was approved by the Governor on July 29, 2019, published in Register 764A1 on August 5, 2019, and approved by the Pharmacy Examining Board on August 15, 2019. This emergency rule as approved by the Governor on September 19, 2019.

ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (3) relating to pharmacist to delegate ratios.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

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

The Pharmacy Examining Board may authorize a pilot program and grant a waiver or variance in connection with the pilot program from any rule promulgated by the Board and the pilot program may not last longer than 3 years pursuant to s. 450.02 (3r), Stats. The pilot program waives Phar 7.01 (3), Wis. Admin. Code. Pharmacies have been operating in the pilot program since October 1, 2016.

Without a rule in place when the pilot program expires, pharmacies will be required to hire more pharmacists to continue current operations.

CR 19-022 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3)(a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

Under current pharmacy rules, there is a one pharmacist to four delegate ratio for staffing pharmacies. Wisconsin does not credential technicians although a delegate is often referred to as a technician. This rule repeals the requirement establishing a pharmacist to technician or intern ratio.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding pharmacist to technician ratio.

Iowa: Iowa does not have rules regarding pharmacist to technician ratio.

Michigan: Michigan does not have rules regarding pharmacist to technician ratio.

Minnesota: Minnesota has a ratio of one pharmacist to two technicians except the ratio is one pharmacist to three technicians when the technicians are doing the following: intravenous admixture preparation; setting up or preparing patient specific in unit dose or modified unit dose packaging; prepacking; or compounding.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate ratios on October 1, 2016. The purpose was to study the supervision and staffing of delegates in order to determine if a minimum ratio is necessary to ensure safety, quality and efficiency of the pharmacy and allow the availability of a pharmacist to be involved in other patient care activities The Pharmacy Examining Board determined that a rule establishing a ratio was not necessary.

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

This rule was posted for economic comments and none were received. This rule will not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before October 23, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.01 (3) is repealed.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated September 25, 2019 Agency _____

Chair of the Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

The statement of scope for this rule, SS #059-19, was approved by the Governor on July 29, 2019, published in Register 764A1 on August 5, 2019, and approved by the Pharmacy Examining Board on August 15, 2019. This emergency rule as approved by the Governor on September 19, 2019

ORDER

An order of the Pharmacy Examining Board to create Phar 7.20 relating to automated technology product verification check.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

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

The Pharmacy Examining Board may authorize a pilot program and grant a waiver or variance in connection with the pilot program from any rule promulgated by the Board and the pilot program may not last longer than 3 years pursuant to s. 450.02 (3r), Stats. The pilot program waives Phar 7.01(1)(c) and (d), Wis. Admin. Code. Pharmacies have been operating in the pilot program since October 1, 2016.

Without a rule in place when the pilot program expires, pharmacies will be unable to utilize automated technology to complete the final check. This will have a negative impact on patient services.

CR 19-023 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3) (a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

This rule allows for the product verification of a prescription to be completed by automated technology.

Automated technology can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine-readable technology and the automated technology is validated for accuracy.

Product verifications can be done by automated technology if it is contained in a final package from a manufacturer or if a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, strength, form, control or lot number and beyond use date.

The medication is required to be administered by a health care provider or a person authorized to administer drugs within an institution.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not allow for automated technology to complete the product verification.

Iowa: Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the

product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient.

Michigan: Michigan does not allow for automated technology to complete the product verification.

Minnesota: Minnesota does not allow for automated technology to complete the product verification.

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

This rule was posted for economic comments and none were received. This rule does not require a pharmacy to utilize automated technology product verification process in the pharmacy.

Fiscal Estimate:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before October 23, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.20 is created to read:

Phar 7.20 Automated technology product verification (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.

3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated September 25, 2019 Agency _____

Chair of the Pharmacy Examining Board

[STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

The statement of scope for this rule, SS #060-19, was approved by the Governor on July 29, 2019, published in Register 764A1 on August 5, 2019, and approved by the Pharmacy Examining Board on August 15, 2019. This emergency rule as approved by the Governor on September 19, 2019.

ORDER

An order of the Pharmacy Examining Board to create Phar 7.21 relating to delegate check delegate.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

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

The Pharmacy Examining Board may authorize a pilot program and grant a waiver or variance in connection with the pilot program from any rule promulgated by the Board and the pilot program may not last longer than 3 years pursuant to s. 450.02 (3r), Stats. The pilot program waives Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Wis. Admin. Code. Pharmacies, including those operating in hospitals, have been operating in the pilot program since October 1, 2016.

Testimony received at the public hearing held on April 12, 2019 on the permanent rule CR 19-024 included comments indicating that hospital patient care services would be negatively impacted without the rule.

CR 19-024 was submitted to the legislature on July 16, 2019. The pilot program will expire prior to the completion of legislative review and adoption.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3)(a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

This rule allows for the product verification to be completed by delegate-check-delegate.

Delegate-check-delegate allows a person delegated by the pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist.

In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.

The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%.

A product is eligible in institution pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administration drugs at the institution.

Product verifications can be done by delegates in community pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to include a description of the

medication on the prescription label that allows for a patient to check the accuracy of the medication.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding technician-check-technician.

Iowa: Iowa has rules regarding technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration.

Michigan: Michigan does not have rules regarding technician-check-technician.

Minnesota: Minnesota does not have rules regarding technician-check-technician.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate-check-delegate on October 1, 2016. The purpose was to study the accuracy and determine whether delegate-check-delegate improves the safety, quality or efficiency of the practice of pharmacy. The Pharmacy Examining Board determined that the procedures utilized in the pilot program were sufficient for the safety of the public and is amending the rules to allow for this practice.

The Pharmacy Examining Board also received information from the Pharmacy Society of Wisconsin's community delegate-check-delegate study.

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

This rule was posted for economic comments and none were received. This rule does not require a pharmacy to utilize delegate-check-delegate process in the pharmacy.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before October 23, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.21 is created to read:

Phar 7.21 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
    a. Drug name.
    b. Strength.
    c. Formulation.
    d. Expiration date.
    e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong strength.
    c. Wrong formulation.
    d. Extra or insufficient quantity.
    e. Omitted medications if utilizing unit dose or compliance packaging.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
3. Eligible medications for delegate-check-delegate.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
    a. Wrong drug.
    b. Wrong strength.
    c. Wrong formulation.
    d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(e) Notwithstanding, par (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016 and September 30, 2019 meets the

delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4)

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medications meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Includes a description of the medication on the prescription label that allows for a non pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

SECTION 2. EFFECTIVE DATE. This emergency rule shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

Dated September 25, 2019 Agency _____

Chair of the Pharmacy Examining Board

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Sharon Henes Administrative Rules Coordinator	14 October 2019 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?
23 October 2019	☒ Yes ☐ No	Administrative Rule Matters 1. Adoption of Phar 7 relating to Pharmacist to Delegate Ratio 2. Adoption of Phar 7 relating to Automated Technology Product Verification Check 3. Adoption of Phar 7 relating to Delegate-Check-Delegate 4. Phar 7 Relating to Practice of Pharmacy 5. Review of 21 CFR 1305 (New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances) 6. Pending or Possible Rulemaking Projects

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

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

11) Authorization

Sharon Henes *10/14/19*

Signature of person making this request **Date**

Supervisor (if required) **Date**

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

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

Revised 12/2016

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-022)

ORDER

An order of the Pharmacy Examining Board to repeal Phar 7.01 (3) relating to pharmacist to delegate ratios.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3)(a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

Under current pharmacy rules, there is a one pharmacist to four delegate ratio for staffing pharmacies. Wisconsin does not credential technicians although a delegate is often referred to as a technician. This rule repeals the requirement establishing a pharmacist to technician or intern ratio.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding pharmacist to technician ratio.

Iowa: Iowa does not have rules regarding pharmacist to technician ratio.

Michigan: Michigan does not have rules regarding pharmacist to technician ratio.

Minnesota: Minnesota has a ratio of one pharmacist to two technicians except the ratio is one pharmacist to three technicians when the technicians are doing the following: intravenous admixture preparation; setting up or preparing patient specific in unit dose or modified unit dose packaging; prepacking; or compounding.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate ratios on October 1, 2016. The purpose was to study the supervision and staffing of delegates in order to determine if a minimum ratio is necessary to ensure safety, quality and efficiency of the pharmacy and allow the availability of a pharmacist to be involved in other patient care activities The Pharmacy Examining Board determined that a rule establishing a ratio was not necessary.

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

This rule was posted for economic comments and none were received. This rule will not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 7.01 (3) is repealed.

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

(END OF TEXT OF RULE)

Dated _____ Agency _____

Chair of the Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 19-023)

ORDER

An order of the Pharmacy Examining Board to create Phar 7.20 relating to automated technology product verification check.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3) (a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

This rule allows for the product verification of a prescription to be completed by automated technology.

Automated technology can be utilized for the product verification of a prescription if the machine is located within the pharmacy, utilizes barcodes or other machine-readable technology and the automated technology is validated for accuracy.

Product verifications can be done by automated technology if it is contained in a final package from a manufacturer or if a licensed pharmacist has ensured that the packaging process results in

a final package that is labeled with the correct drug name, strength, form, control or lot number and beyond use date.

The medication is required to be administered by a health care provider or a person authorized to administer drugs within an institution.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, names of supervising pharmacist, managing and supervising pharmacist responsibilities, manufacturer's recommended maintenance and quality assurance measures, dates of all software upgrades, and documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not allow for automated technology to complete the product verification.

Iowa: Iowa allows automated technology to conduct the product verification if the system utilizes barcode scanning technology and the product is prestocked and no manipulation of drug or package other than affixing a patient label is taking place. If the product is going to require further manipulation than a pharmacist is required to do the product verification prior to dispensing to a patient.

Michigan: Michigan does not allow for automated technology to complete the product verification.

Minnesota: Minnesota does not allow for automated technology to complete the product verification.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for automated technology to complete product verification on October 1, 2016. The purpose was to study the accuracy and determine whether allowing automated technology improves the safety, quality or efficiency of the practice of pharmacy. The Pharmacy Examining Board determined that the procedures utilized in the pilot program were sufficient for the safety of the public and is amending the rules to allow for this practice.

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

This rule was posted for economic comments and none were received. This rule does not require a pharmacy to utilize automated technology product verification process in the pharmacy.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 7.20 is created to read:

Phar 7.20 Automated technology product verification (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.
3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.
4. Documentation of the dates of all software upgrades.
5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

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)

Dated _____ Agency _____

Chair of the Pharmacy Examining Board

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE 19-024)

ORDER

An order of the Pharmacy Examining Board to create Phar 7.21 relating to delegate check delegate.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 450.11, Stats.

Statutory authority: ss. 450.02 (2) and (3)(a), (d) and (e), Stats.

Explanation of agency authority:

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

The board may promulgate rules:
(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.
(d) Necessary for the administration and enforcement of this chapter and ch. 961.
(e) Establishing minimum standards for the practice of pharmacy.
[ss. 450.02 (3) (a), (d) and (e), Stats.]

Related statute or rule: ch. Phar 7

Plain language analysis:

This rule allows for the product verification to be completed by delegate-check-delegate.

Delegate-check-delegate allows a person delegated by the pharmacist to check the product verification of a product prepared by another person delegated by the pharmacist.

In order for a person to be delegated product verification, the individual must meet all of the following: be 18 years of age; completed an accredited technician training program or has a minimum of 500 hours of experience in product selection labeling and packaging; completed a didactic and practical training curriculum; and completed a validation process.

The didactic and practical training curriculum must include elements of a package label; medication and pharmacy abbreviations needed to match ordered medication with dispensed medication; common dispensing medication errors and concepts; eligible medications; policies and procedures on reporting of medication errors; overview of the pharmacy's medication use process and a practical training designed to assess the competency of the individual. The validation process requires a check of 500 product verifications over at least 5 days with an accuracy rate of at least 99.8%.

A product is eligible in institution pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In an institutional pharmacy the medication is required to be administered by a health care provider or a person authorized to administration drugs at the institution.

Product verifications can be done by delegates in community pharmacies if the medication is contained in a final package from a manufacturer or if the licensed pharmacist has ensured that the repackaging process of stock is labeled with the correct drug name, dose, strength, form, control or lot number and beyond use date. In a community pharmacy the medication is required to include a description of the medication on the prescription label that allows for a patient to check the accuracy of the medication.

Each pharmacy is required to maintain policies, procedures, and training materials. The following records are required to be kept: all validation records, documentation of supervising and managing pharmacist responsibilities and dates of supervision responsibilities.

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

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules regarding technician-check-technician.

Iowa: Iowa has rules regarding technician-check-technician. The technician must have active Iowa registration, hold national technician certification, have experience as a technician and trained in technician-check-technician (including medication errors). There shall be a supervising pharmacist. The pharmacy is required to have policies and procedures in place and maintain records. The drug utilization review must be performed by a pharmacist. The medication checked by a technician must be checked by a licensed health care practitioner prior to administration.

Michigan: Michigan does not have rules regarding technician-check-technician.

Minnesota: Minnesota does not have rules regarding technician-check-technician.

Summary of factual data and analytical methodologies:

The Pharmacy Examining Board began a pilot program for delegate-check-delegate on October 1, 2016. The purpose was to study the accuracy and determine whether delegate-check-delegate improves the safety, quality or efficiency of the practice of pharmacy. The Pharmacy Examining Board determined that the procedures utilized in the pilot program were sufficient for the safety of the public and is amending the rules to allow for this practice.

The Pharmacy Examining Board also received information from the Pharmacy Society of Wisconsin's community delegate-check-delegate study.

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

This rule was posted for economic comments and none were received. This rule does not require a pharmacy to utilize delegate-check-delegate process in the pharmacy.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

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

Agency contact person:

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

TEXT OF RULE

SECTION 1. Phar 7.21 is created to read:

Phar 7.21 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
    a. Drug name.
    b. Strength.
    c. Formulation.
    d. Expiration date.
    e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong strength.
    c. Wrong formulation.
    d. Extra or insufficient quantity.
    e. Omitted medications if utilizing unit dose or compliance packaging.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
3. Eligible medications for delegate-check-delegate.
4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
    a. Wrong drug.
    b. Wrong strength.
    c. Wrong formulation.
    d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(e) Notwithstanding, par (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4)

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medications meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Includes a description of the medication on the prescription label that allows for a non pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.
6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.

3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

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)

Dated _____ Agency _____

Chair of the Pharmacy Examining Board

TEXT OF RULE

SECTION 1. Chapter 7 is repealed and recreated to read:

Subchapter I — General

7.01 Definitions.
(1) "Managing pharmacist" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy, and who is personally in full and actual charge of the pharmacy and personnel.
(2) "Standing order" means an order transmitted electronically or in writing by a practitioner for a drug or device for multiple patients or for one or more groups of patients.

7.02 Prescription (1) REQUIREMENTS. A prescription drug order shall include all of the following:

1. Date of issue
2. Name and address of the practitioner.
3. Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name and address of the practitioner.
4. Name, strength, dosage, form and quantity of the drug.
5. Directions for use of the drug.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), the name and address of the authorized entity.
10. Practitioner's written signature, or electronic or digital signature.

(2) STANDING ORDER. (a) A prescription pursuant to a standing order shall include all of the following:

1. Date of issue
2. Name and address of the practitioner.
3. Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name and address of the practitioner.
4. Name, strength, dosage, form and quantity of the drug.
5. Directions for use of the drug.
6. Refills, if any.
7. Name and address of the patient except as provided in ss. 118.2925 (3), 255.07 (2), 441.18 (2)(a)1., 448.035 (2) and 448.037 (2) (a) 1., Stats.
8. If prescription is issued under s. 118.2925 (3), Stats., the name and address of the school.
9. If prescription is issued under s. 255.07 (2), the name and address of the authorized entity.
10. Indicate the prescription is pursuant to a standing order.

(b) A copy of the standing order shall be retained under Phar 7.11.

(3) ELECTRONIC PRESCRIPTION. (a) Except as provided in s. 89.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy

via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(b) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:

1. Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.
2. Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.
3. Contains all other information that is required in a prescription order.

(c) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) ORAL PRESCRIPTION. Oral prescription orders may be received at a pharmacy via a telephone answering device or voice mail. The oral prescription shall be reduced to writing or an electronic prescription and indicate that the prescription is an oral prescription.

(5) ALTERNATIONS. Any alterations that modify the original intent, with the exception of quantity, in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration and the individual who authorized the alteration.

7.03 Drug utilization review. (1) A pharmacist shall complete a drug utilization review by reviewing the patient record prior to dispensing each prescription drug order for all of the following:

(a) Known allergies.
(b) Rational therapy
(c) Contraindications.
(c) Proper dose, duration of use, and route of administration, considering the age, gender, and other patient factors.
(d) Proper directions for use.
(e) Potential or actual adverse drug reactions.
(f) Drug interactions with food, beverages, other drugs or medical conditions.
(i) Therapeutic duplication;
(j) Proper utilization and optimum therapeutic outcomes.
(k) Potential abuse or misuse.

(2) Upon recognizing a concern with any of the items in sub. (1) (a) to (k), the pharmacist shall take steps to mitigate or resolve the problem.

7.04 Transferring Prescription Order Information. (1) GENERAL REQUIREMENTS. A transfer of prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing of non-controlled substances and refills of controlled substances, if all of the following conditions are satisfied:

(a) The transfer is communicated in one of the following ways:

1. Oral communication between two pharmacists.
2. Electronically or by facsimile machine between the two pharmacies.

(b) The pharmacist receiving the oral transfer of prescription order information for either a controlled or a non-controlled substance transcribes the transferred information into a written or electronic prescription.

(c) All transferred prescription records are maintained for a period of 5 years from the date of the last refill. {under recordkeeping}

(2) NON-CONTROLLED SUBSTANCES. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The transfer record shall include the following information:

1. The word “VOID" is on the face of the invalidated prescription order or recorded in a similar manner to “VOID" on a prescription order in a computer system meeting the requirements of sub. (4).
2. The name and address of the pharmacy to which it was transferred, the full name of the pharmacist receiving the prescription order, the date and the full name of the pharmacist transferring the information are recorded on the invalidated prescription order or in a computer system meeting the requirements sub. (4).

(b) Unless a computer system meeting the requirements in sub. (4) is used, the pharmacist, or delegate, receiving the transferred prescription order information shall record the following:

1. The word “TRANSFER" on the face of the transferred prescription order or recorded in a similar manner in a computer system.
2. The name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
3. The date of issuance of the original prescription order.
4. The original number of refills authorized on the original prescription order.
5. The date of original dispensing if the prescription order has previously been dispensed.
6. The number of valid refills or total quantity remaining and the date of the last refill.
7. The pharmacy’s name, address, and the prescription order number from which the prescription order information was transferred.
8. The full name of the pharmacist authorizing the transfer.

(3) CONTROLLED SUBSTANCES. The transfer of prescription order information for schedule III to V controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

(a) The requirements in sub. (2).

(b) The transfer of prescription order information is permissible only on a one time basis unless a computer system meeting the requirements of sub. (4) is used.

(c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

1. The name, address and DEA registration number of the pharmacy to which it was transferred.
2. The name of the pharmacist receiving the prescription order.
3. The date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

1. The word “TRANSFER" on the face of the transferred prescription order.
2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
3. The date of issuance of the original prescription order.
4. The original number of refills authorized on the original prescription order.

5. The date of original dispensing.
6. The number of valid refills remaining.
7. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.
8. The name of the pharmacist making the transfer.

(4) Use of computer system. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.11(2) (a), contain a shared real time electronic file database with complete prescription record filled and dispensed.

Phar 7.05 Label Requirements (1) In this section, ambulatory patient does not include those in a correctional facility.

(2) All prescribed drugs or devices for outpatient, ambulatory patient shall have a label attached to the container disclosing all of the following:

(a) Identification of the patient by one of the following:
1. Except as provided in subd. 1. b to e., the full name of the patient
2. For an antimicrobial drug dispensed under s. 450.11 (1g), Stats., the full name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT".
3. For an opioid antagonist when delivered under s. 450.11 (1i), Stats., the name of the person to whom the opioid antagonist is delivered.
4. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), the name of the school, authorized entity, or other person specified under s. 255.07 (3).
5. If the patient is an animal the last name of the owner, name of the animal and animal species.

(b) Directions for use as indicated by the prescriber using numeric instead of alphabetic characters for numbers.

(c) Symptom or purpose if the patient indicates in writing to the prescriber that the patient wants the information on the label.

(d) Drug name, unless the prescribing practitioner requests omission of the name of the drug. Both the generic brand name of the drug product equivalent and the brand name specified in the prescription order may be listed on the label if the brand name is listed on the prescription and the drug product equivalent is dispensed, unless the prescribing practitioner requests that the brand name be omitted from the label.

(e) Drug strength, unless the prescribing practitioner requests omission of the strength of the drug dispensed.

(f) The use by date indicating the date after which the medication shall not be used.

(g) Pharmacy name.

(h) Pharmacy telephone number.

(i) Prescriber name.

(j) Date the prescription was filled.

(k) Prescription number.

(L) Drug quantity.

(m) Number of remaining refills.

(n) Written or graphic product descriptions.

(o) Any cautions or other provisions.

(3) Sub. (2) does not apply to complimentary samples of drug products or devices dispensed in original packaging by a practitioner to his or her patients.

Phar 7.06 Repackaging. (1) In this section, "repackaging" means taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.

(2) A pharmacy repackaging drugs shall do all of the following:

(a) The repackaging processes are conducted under conditions that ensure the integrity of the drug.

(b) In the absence of stability data for the drug product in the repackaged container, the beyond-use dating period is one year or the time remaining until the expiration date, whichever is shorter. If current stability data is available for the drug product in the repackaged container, the length of time established by the stability study may be used to establish the beyond use date, but may not exceed the manufacturer's expiration date.

(c) The repackaged container shall meet or exceed the original container's specification for light resistance.

(d) The conditions or storage shall meet the storage specifications as described in the labeling of the original container received for repackaging. Where no specific storage conditions are specified, the product must be maintained at controlled room temperature and in a dry place during the repackaging process, including storage.

(e) The repackaged drugs are labeled with all the following components:

1. Drug name, strength and dosage form.
2. Pharmacy control and manufacturer lot number.
3. Name of the manufacturer or distributor of the drug or NDC number.
4. Beyond use date.

(f) Records of all repackaging operations are maintained and include all the following:

1. Name, strength, dosage form, quantity per container, and quantity of containers of the drug being prepackaged.
2. Name of the manufacturer or distributor of the drug or NDC number.
3. Pharmacy control and manufacturer lot number.
4. Expiration date of the drug according to the original manufacturer or distributor container and the beyond-use date.
5. Full name of the pharmacist or delegate that prepackaged the drug and the full name of the pharmacist that verified the appropriateness of the prepackaged drug.
6. Date the drug is prepackaged.

Phar 7.07 Final Check (1) The final check on the accuracy and correctness of the prescription includes all of the following:

(a) Label requirements.

(b) Correct product.

(c) Ensures completion of the drug utilization review.

(2) For all prescriptions, the prescription record shall identify the pharmacist responsible for each part of the final check of the prescription. If sub. (1) (a) or (b) is completed by automated technology under s. Phar 7.13 or delegate check delegate under s. Phar 7.14, the prescription record shall identify the pharmacist supervising the delegation.

Phar 7.08 Patient Counseling. (1) Patient counseling shall include at least one of the following:

(a) Name and description of the drug.

(b) Dosage form, dose, route of administration and duration for drug therapy.

(c) Intended use of the drug and expected action.

(d) Special directions and precautions for preparation, administration and use by the patient.

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(f) Techniques for self-monitoring drug therapy.

(g) Proper storage and appropriate disposal method of unwanted or unused medication.

(i) Action to be taken in the event of a missed dose.

(j) Assessment of the drug's effectiveness in meeting the patient's treatment goals and any adverse effects related to the prescription.

(2) A pharmacist shall give the patient or patient's agent appropriate consultation relative to the prescription for all new or renewal of a prescription, change in the patient's therapy, and the first refill after a new prescription or change in patient's therapy. The consultation shall occur before the transfer of the drug to the patient. This requirement is not satisfied by only offering to provide consultation.

(3) Sub. (2) applies regardless of the method of delivery of the drug.

(4) Consultation is required upon patient request.

(5) A pharmacist shall utilize professional judgement in determining whether to give the patient or patient's agent appropriate consultation relative to the prescription for any refill.

(6) Notwithstanding sub. (2), a consultation is not required when a health care provider is administering the medication.

Phar 7.09 Procurement, recall and out-of-date prescription drugs and devices.

(1) Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board or U.S. food and drug administration to distribute to pharmacies or from another licensed pharmacy or licensed practitioner located in the United States.

(2) There shall be a system for identifying any prescription drugs and devices subjected to a product recall and for taking appropriate steps as required by the recall notice.

(3) Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

7.10 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(c) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:

(a) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed after their beyond use date.

(b) When in the professional judgment of the pharmacist substantial harm could result to the public or patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(c) A health item that is prepackaged for consumer use without a prescription and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.
2. The pharmacist determines the contents are not adulterated.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(3) Health items returned to a pharmacy pursuant to sub. (2) (a) and (b), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device is for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a return of a health care item if a patient or agent of a patient delivers a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

Phar 7.11 Pharmacy Records. (1) GENERAL. Pharmacy records shall be maintained for five years.

(2) PRESCRIPTION RECORDS. (a) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system:

1. Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining.
2. Is equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

(b) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last refill.

(c) All systems used for maintaining a record of any prescription dispensing shall contain all items required in the medical profile record system.

(d) Electronic prescription records may be maintained instead of paper records if the prescription is scanned into the record.

(3) MEDICATION PROFILE RECORD SYSTEM. (a) An individual medication profile record system shall be maintained in all pharmacies for humans and non-humans for whom prescriptions, original or renewal, are dispensed. This section does not apply to prescriptions which are administered in a health care facility. The system shall be capable of permitting the retrieval of information.

(b) The following minimum information shall be retrievable:

1. Full patient name, or if not human name of pet, species and last name of owner.
2. Address of the patient.
3. Birth date of the patient or if not human birthdate of the owner.
4. Name of the drug product dispensed.
5. Strength of the drug product dispensed.
6. Dosage form of the drug product dispensed.
7. Quantity of the drug product dispensed.
8. Directions for use.
9. Prescription identification number or institution unit number
10. Date of all instances of dispensing, for original and renewal prescriptions.

11. Prescriber national provider identifier number

(c) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(d) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

(e) Medication profile records shall be maintained for a period of not less than 5 years following the date of the last entry.

Phar 7.12 Delegation by a Physician. The pharmacist shall document the delegation. The delegated act may be started prior to the documentation. Documentation of the delegated act may be in a contract or agreement.

Phar 7.13 Automated technology product verification (1) DEFINITIONS. In this section:

(a) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(b) "Supervising pharmacist" means the pharmacist licensed in this state who is responsible for the operations and outcomes of the product verification done by an automated technology.

(2) AUTOMATED TECHNOLOGY PRODUCT VERIFICATION QUALIFICATIONS. Product verification may be done only by an automated technology which meets all of the following:

(a) Located within a licensed pharmacy.

(b) Utilizing barcodes or another machine-readable technology to complete the product verification.

(c) Validated by the following process:

1. The automated technology shall make a product verification for accuracy and correctness of a minimum of 2500 product verifications and achieve an accuracy rate of at least 99.8%.

2. A pharmacist shall audit 100% of the product verifications made by the automated technology during the validation process.

(d) Revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy and correctness of the product verification is replaced or serviced outside of the manufacturer's standard maintenance recommendations.

(3) ELIGIBLE PRODUCT. The automated technology may do the product verification if the product meets all of the following:

(a) Is dispensed in the original package from a manufacturer or if a licensed pharmacist has ensured that any repackaging results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and expiration or beyond use date.

(b) Has a drug utilization review performed by a pharmacist prior to delivery.

(c) Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(4) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the automated technology product verification which shall be made available to the board upon request.

(5) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each automated technology that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.

2. Documentation indicating acceptance of responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising pharmacist, indicating the name of the supervising pharmacist and start and end dates of supervision.

3. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures.

4. Documentation of the dates of all software upgrades.

5. Documentation of all service performed outside of the manufacturer's standard maintenance recommendations.

(b) Records shall be made available to the board upon request.

Phar 7.14 Delegate-check-delegate. (1) DEFINITIONS. In this section:

(a) "Delegate" means a person to whom the pharmacist has delegated the task of product verification.

(b) "Delegate-check-delegate" means the process in which one delegate conducts the task of product verification of technical dispensing functions completed by an unlicensed individual. A delegate may not conduct product verification as part of the final check of their own product preparation.

(c) "Product verification" means doing a check of the accuracy and correctness of a product, including drug, strength, formulation, and expiration or beyond use date, as part of the final check.

(d) "Supervising pharmacist" means the pharmacist licensed in this state, who is responsible for the operations and outcomes of product verification done by a delegate and ensuring for direct supervision of the delegate.

(2) DELEGATE QUALIFICATIONS. A pharmacist may delegate the product verification of a prescription or chart order to a delegate who meets all of the following:

(a) Is at least 18 years old.

(b) Completed an accredited technician training program or has a minimum of 500 hours of experience in product selection, labeling and packaging.

(c) Completed a didactic and practical training curriculum approved by the supervising and managing pharmacist that includes training in all of the following:

1. Elements of correct product including all of the following:
    a. Drug name.
    b. Strength.
    c. Formulation.
    d. Expiration date.
    e. Beyond use date.
2. Common dispensing medication errors and concepts including all of the following:
    a. Wrong medication.
    b. Wrong strength.
    c. Wrong formulation.
    d. Extra or insufficient quantity.
    e. Omitted medications if utilizing unit dose or compliance packaging.
    f. Expired medication.
    g. Look-alike or sound-alike errors.
    h. High-alert medications.
3. Eligible medications for delegate-check-delegate.

4. Organizational policies and procedures on reporting of medication errors.
5. Overview of the medication use process including all of the following:
    a. Procurement.
    b. Ordering.
    c. Dispensing.
    d. Administration.
    e. Monitoring.
6. A practical training designed to assess the competency of the delegate prior to starting the validation process. The practical training shall include simulation of at least two occurrences of each of the following:
    a. Wrong drug.
    b. Wrong strength.
    c. Wrong formulation.
    d. Omitted medication, if utilizing unit dose or compliance packaging.

(d) Completed the following validation process:

1. The delegate being validated shall make a product verification on the work of a pharmacist or unlicensed person for accuracy and correctness of a minimum of 500 product verifications over a minimum of 5 separate days and achieve an accuracy rate of at least 99.8%.
2. A pharmacist shall audit 100% of the product verifications made by the delegate during the validation process.

(e) Notwithstanding, par (a) to (d), a delegate who completed the pilot program validation process between October 1, 2016 and September 30, 2019 meets the delegation qualifications unless the delegate fails to meet the quality assurance standards under sub. (4).

(3) ELIGIBLE PRODUCT. (a) *Institutional pharmacies.* The delegate may do the product verification in an institutional pharmacy if the product meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Will be administered by an individual authorized to administer medications at the institution where the medication is administered.

(b) *Community pharmacies.* The delegate may do the product verification in a community pharmacy if the medications meets all of the following:

1. Is in an original package from a manufacturer or if the licensed pharmacist has ensured that any repackaging of stock results in a package that is labeled with the correct drug name, strength, formulation, control or lot number, and beyond use date.
2. Has a drug utilization review performed by a pharmacist prior to dispensing.
3. Includes a description of the medication on the prescription label that allows for a non pharmacist to check the accuracy of the medication after it is delivered.

(4) QUALITY ASSURANCE. (a) A minimum of 5% of each delegate's product verifications shall be audited by a licensed pharmacist. The accuracy of each delegate shall be tracked individually.

(b) A record of each delegate-check-delegate audit shall include all of the following:

1. Name of the product verification delegate.
2. Total number of product verifications performed.
3. Number of product verifications audited by the pharmacist.
4. Percentage of product verifications audited by pharmacist.
5. Percentage of accuracy.

6. Number of product verification errors identified.
7. Type of error under sub. (2) (c) 3.

(c) On a quarterly basis, the supervising pharmacist shall perform an assessment of each delegate's previous 12 months accuracy and correctness of delegate-check-delegate product verifications including a review of the quality assurance log.

(d) A delegate shall be revalidated if the delegate fails to maintain a product verification accuracy rate of 99.8% based on the quarterly assessment of the previous 12 months or has not performed delegate-check-delegate product verifications within the last 6 months.

(5) POLICIES AND PROCEDURES. Each pharmacy shall maintain policies, procedures, and training materials for the delegate-check-delegate which shall be made available to the board upon request.

(6) RECORDS. (a) Each pharmacy shall maintain for 5 years the following records:

1. All validation records of each delegate that include the dates that the validation occurred, the number of product verifications performed, the number of product verification errors, and overall accuracy rate.
2. Documentation indicating accepting responsibility for compliance with this section, signed and dated by both the managing pharmacist and supervising delegate-check-delegate pharmacist, indicating the name of the supervising delegate-check-delegate pharmacist, and the dates the supervision responsibilities begin and end.
3. Quality assurance audits and quarterly assessments.

(b) Records shall be made available to the board upon request.

Subchapter III — Central Fill

7.30 Definitions. In this section:

(1) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(2) "Dispensing pharmacy" means the central fill pharmacy or originating pharmacy which delivers the prescribed drug or device to the ultimate user.

(3) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

7.31 Requirements. A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(1) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(2) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(3) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(4) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(5) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug utilization review, refill authorizations, interventions and drug interactions.
(6) The prescription label attached to the container shall contain the name and address of the dispensing pharmacy. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.
(7) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.
(8) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.
(9) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.
(10) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.
(11) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

Subchapter IV — Delivery Systems and Remote Dispensing

Phar 7.40 Definition. In this subchapter:
(1) "Delivery system" means a structure, located outside of the pharmacy, that a prescription is placed in for patient pick-up. Delivery system does not include delivery by vehicle to the patient's place of choice.
(2) "Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of remote dispensing.

Phar 7.41 Delivery System. (1) Prescription is filled by the dispensing pharmacy.
(2) Prescription shall be stored in a secure delivery system immediately upon delivery to the location of the delivery system. Only the patient or patient's designee shall be able to open the door or locker containing the individual's prescription bag.
(3) The delivery system shall be designed in a manner which does not disclose protected health information or reveals contents of the prescription.
(4) The delivery system shall maintain appropriate environmental controls, including temperature and humidity, to prevent drug adulteration.
(5) The use of a delivery system does not create an exemption to s. 450.11 (1b), Stats.
(6) A log shall be maintained by the dispensing pharmacy of all prescriptions delivered to the delivery system.
(7) The delivery system shall be inventoried at least weekly and a list of unclaimed prescriptions shall be provided to the dispensing pharmacy.
(8) The managing pharmacist shall establish written policies and procedures for all of the following:
(a) Stocking of the delivery system, including identifying the responsible pharmacist.
(b) Determining access to the delivery system.

(c) Detection and mitigation of controlled substance diversion.

Phar 7.42 Automated direct-to-patient dispensing system. (1) A pharmacy may utilize an automated direct-to-patient dispensing system in a secure and professionally appropriate environment in any of the locations under s. 450.062 (1) to (4), Stats.
(2) An automated direct-to-patient dispensing system shall be associated with a pharmacy. A prescriber may not dispense utilizing an automated direct-to-patient dispensing system. A prescriber may authorize the dispensing of a drug utilizing an automated direct-to-patient dispensing system.
(3) Individuals with access to the automated direct-to-patient dispensing system for the purpose of stocking, inventory, and monitoring shall be limited to pharmacist or a pharmacist delegate.
(4) The automated direct-to-patient dispensing system shall label the prescription in compliance with s. Phar 7.05.
(5) The automated direct-to-patient dispensing system shall maintain prescription records in compliance with s. Phar 7.11 (1).
(6) The pharmacist shall do a prospective drug use review before a prescription can be dispensed by an automated direct-to-direct patient dispensing system.
(7) The pharmacist is responsible is responsible for compliance with consulting requirements in s. Phar 7.08.
(7) The managing pharmacist is responsible for maintaining records of the automated direct-to-patient dispensing system.

Phar 7.43 Remote Dispensing. (1) LOCATION**.** A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i) may dispense at any of the locations under s. 450.062 (1) to (4), Stats.
(2) TITLE**.** No person may use or display the title "pharmacy", "drugstore," "apothecary," or any other title, symbol or insignia having the same or similar meanings in connection with remote dispensing.
(3) REQUIREMENTS. (a) A remote dispensing location shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This remote dispensing location is being supervised by a pharmacist located at all of the following:
    a. Name of pharmacy.
    b. Address of pharmacy.
    c. Telephone of pharmacy.
3. The pharmacist is required to consult with you each time you pick up a prescription.

(b) Remote dispensing may not occur if the supervising pharmacy is closed.
(c) A prescribed drug or device may not be dispensed in the absence of the ability of a patient to communicate with a pharmacist.
(d) Remote dispensing locations shall have a centrally monitored alarm. For all after hour entries, the personnel entering the location shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(4) Dispensing requirements. Remote dispensing shall meet comply with all of the following:
(a) Visually inspecting all prescription orders, labels and dispensed product.
(b) Labeling requirements under s. Phar 7.05. The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.
(c) Federal law if dispensing controlled substances.

(5) RESPONSIBILITIES OF MANAGING PHARMACIST. (a) The managing pharmacist of the supervising pharmacy shall do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.
2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion, and documentation of remedial training to prevent future errors.
3. Visit the remote dispensing location at least biweekly to confirm delivery status of all drugs, to ensure written policies and procedures are being followed, and to ensure that remote dispensing personnel comply with all federal and state laws regulating the practice of pharmacy.
4. Retain documentation of the visits at the remote dispensing location for 2 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing connected to the supervising pharmacy.

(6) Delegate requirements. A person engaged in the practice of pharmacy under s. 450.03 (1) (f), (g), or (i) shall meet the following requirements to remote dispense:

(a) Be 18 years of age or older.
(b) Be a high school graduate or have equivalent education.
(c) Have completed 1500 hours of work as a delegate within the 3 years prior to engaging in remote dispensing or completed a training program approved by the board.

Subchapter V — Institutional Pharmacies

Phar 7.50 Definitions. In this subchapter:
(1) "Chart order" means an order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or delegate for a drug or device
(2) "Institutional facility" means a facility, as defined in s. 647.01 (4), Stats.; any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other placed licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09, Stats.; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10, Stats.; and a hospice facility under s. 50.90 (1) (c), Stats.
(3) "Institutional pharmacy" means a pharmacy that provides pharmacy services to an institutional facility.

Phar 7.51 Chart orders. A chart order shall contain all of the following:
(1) Full name of the patient.
(2) Date of issuance.
(3) Name, strength, and dosage form of the drug prescribed.
(4) Directions for use.
(5) Practitioner's written signature, or electronic or digital signature.
(6) Prescriptions written by a delegate of the practitioner shall include the name and signature of the delegate and the name of the practitioner.

Phar 7.52 Labels. All prescribed drugs and devices for prescriptions or devices for use by inpatients of a hospital, or health care facility shall have a label attached to the container disclosing all of the following:
(1) Patient's legal name.
(2) Drug name.

(3) Route of administration, if not oral.
(4) Drug Strength.
(**5**) Prescriber name.
(6) Date of dispensing.
(7) Dispensing pharmacy.
(8) If the drug was repackaged, the name of the person who repackaged it.
(9) Special storage conditions, if required.

Phar 7.53 Contingency Supply. (1) Arrangements shall be made in advance by the managing pharmacist for access of drugs by the health care staff of the institutional facility when a dispensing by a pharmacist is not available.
(2) In the absence of a pharmacist, drugs shall be stored in a manner in which only authorized personnel may obtain access and is sufficiently secure to deny access to unauthorized persons.
(3) The managing pharmacist shall develop inventory listings of those drugs to be included in the cabinet, determine who may have access and have systems in place to mitigate and prevent diversion.

7.54 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.

(c) "Original container" means the container in which a health item was sold, distributed, or dispensed.

(d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by s. DHS 83.37

(e) "Secured institutional health care patient" means any of the following:

1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.

2. A juvenile patient who resides in a juvenile correctional facility, as defined in s. 938.02 (10p), Stats.; a secured residential care center for children and youth, as defined in s. 938.02 (15g), Stats.; a juvenile detention facility, as defined in s. 938.02 (10r), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

(f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for a reason under Phar 7.10 (2) or any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.

2. The health item was sold, distributed or dispensed in a tamper-evident package and, for a drug, includes the beyond use date and manufacturer's lot number.

3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.

4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

(3) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (b), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

Subchapter VI — Unlicensed Persons

7.60 Direct Supervision. (1) A person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats. is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

(2) Direct supervision means immediate availability to continually coordinate, direct and inspect in real time the practice of another.

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7.61 Unlicensed Persons (1) This section does not apply to a person practicing pharmacy under s. 450.03 (1) (f) or (g), Stats.

(2) A pharmacist shall provide supervision of unlicensed personnel. A pharmacist shall be available to the unlicensed person for consultation either in person or contact by telecommunication means.

(3) An unlicensed person may not perform any of the following:

(a) Provide the final verification for the accuracy, validity, completeness of a filled prescription or medication order unless the person is validated for delegate-check-delegate under s. Phar 7.14.

(b) Perform any of the following tasks:

1. Complete the drug utilization review under Phar 7.03.

2. Administer any prescribed drug products, devices or vaccines under s. 450.035, Stats.

(c) Provide patient specific counseling or consultation.

(4) The prohibitions in sub. (3), do not apply to a person completing an internship under ch. Phar 17 for purposes of meeting the internship requirement under s. 450.03 (2) (b).

(5) A pharmacist who delegates to an unlicensed person shall first provide training to or verify competency of the person in performing the delegated act.

(6) The pharmacist shall document the responsibilities delegated to an unlicensed person. This record shall be provided to the board upon request.

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)

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1305

[Docket No. DEA–453]

RIN 1117–AB44

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

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

DATES: This rule is effective October 30, 2019.

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

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

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

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

Discussion of Comments

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

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

Power of Attorney Issues

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

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

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

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

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

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

Anonymous Comment

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

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

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

Comment by Healthcare Distribution Alliance (HDA)

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

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

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

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

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

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

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

Response: The new form will include 20 order lines, double the previous number, and will fit on a standard 8.5″ x 11″ sheet. The DEA is aware of the pending changes to the NDC format, and, although no changes are being made to the NDC field on the new Form 222, the DEA will be monitoring the FDA's rulemaking on the matter, and will update the Form 222 as necessary in the future. Based on the current state of that rulemaking, any changes to the NDC format would only require minor modifications to the single-sheet Form 222.

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

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

Comment by CVS Health

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

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

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

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

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

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

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

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

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

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

Comment by Costco

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

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

Comment by National Association of Chain Drug Stores (NACDS)

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

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

Comment by Novartis

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

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

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

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

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

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

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

Comment by Kroger Health

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

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

Comment by Janssen

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

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

Comment by American Pharmacists Association (APhA)

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

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

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

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

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

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

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

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

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

Changes in the Final Rule

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

Section 1305.05

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

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

Section 1305.11

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

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

Section 1305.13

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

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

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

Section 1305.17

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

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

Section 1305.18

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

Section 1305.20

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

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

Regulatory Analysis

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

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

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

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

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

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

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

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

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

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

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

Regulatory Flexibility Act

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

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. The DEA is amending its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by the DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. The DEA is also making a number of minor procedural changes, including, among other things, who can issue the power of attorney that is required for others to sign DEA Form 222. This final rule affects all parties (purchaser and suppliers) to transactions where a DEA Form 222 is used.

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

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

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

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

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

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

Unfunded Mandates Reform Act of 1995

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

Paperwork Reduction Act of 1995

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

A. Collections of Information Associated With the Final Rule

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

OMB Control Number: 1117–0010.

Form Number: DEA–222.

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

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

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

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

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

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

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

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

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

Congressional Review Act

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

List of Subjects in 21 CFR Part 1305

Drug traffic control, Reporting and recordkeeping requirements.

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

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1305.05 by revising paragraph (d) and adding paragraph (f) to read as follows:

§ 1305.05 Power of attorney.

* * * * *

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

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

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

(3) Two witnesses.

* * * * *

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

■ 3. Revise § 1305.11 to read as follows:

§ 1305.11 Procedure for obtaining DEA Forms 222.

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

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

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

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

■ 4. Amend § 1305.12 by revising paragraph (a) to read as follows:

§ 1305.12 Procedure for executing DEA Forms 222.

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

* * * * *

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

§ 1305.13 Procedure for filling DEA Forms 222.

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

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

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

* * * * *

(d) The supplier must retain the original DEA Form 222 for the supplier's files in accordance with § 1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to *DEA.Orderforms@usdoj.gov*. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

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

* * * * *

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

§ 1305.14 Procedure for endorsing DEA Forms 222.

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

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

■ 7. Amend § 1305.15 by revising paragraphs (b) and (d) to read as follows:

§ 1305.15 Unaccepted and defective DEA Forms 222.

* * * * *

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

* * * * *

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

■ 8. Amend § 1305.16 by revising paragraphs (a) and (d) to read as follows:

§ 1305.16 Lost and stolen DEA Forms 222.

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

* * * * *

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

* * * * *

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

§ 1305.17 Preservation of DEA Forms 222.

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

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

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

* * * * *

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

■ 10. Revise § 1305.18 to read as follows:

§ 1305.18 Return of unused DEA Forms 222.

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

■ 11. Amend § 1305.19 by revising paragraph (a) to read as follows:

§ 1305.19 Cancellation and voiding of DEA Forms 222.

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

* * * * *

■ 12. Add § 1305.20 to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

stating the serial number of each form stolen or lost.

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

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

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

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

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

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

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

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

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

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

Dated: September 23, 2019.

Uttam Dhillon,

Acting Administrator.

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

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1915 and 1926

[Docket No. OSHA–H005C–2006–0870]

RIN 1218–AD21

Occupational Exposure to Beryllium and Beryllium Compounds in Construction and Shipyard Sectors

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA is finalizing the proposed rule on occupational exposure to beryllium and beryllium compounds in construction and shipyards by delaying the compliance deadlines for nearly all provisions of the standards to September 30, 2020. The one exception to the September 30, 2020 compliance deadline is for the permissible exposure limit (PEL) and the short-term exposure limit (STEL), which OSHA has been enforcing since May 11, 2018. This rule confirms that the exposure limits remain in effect. OSHA is not adopting the portion of the proposed rule that would have revised OSHA's existing beryllium standards for construction and shipyards to revoke the ancillary provisions. OSHA finds that other OSHA standards do not duplicate the requirements of the ancillary provisions in the beryllium standards for construction and shipyards in their entirety. Thus revoking all of the ancillary provisions and leaving only the PEL and STEL would be inconsistent with OSHA's statutory mandate to protect workers from the demonstrated significant risks of material impairment of health resulting from exposure to beryllium and beryllium compounds. OSHA will publish a new proposal for the construction and shipyards beryllium standards, to seek comment on different changes OSHA is considering.

DATES: This rule is effective September 30, 2019.

ADDRESSES: For purposes of 28 U.S.C. 2112(a), OSHA designates Edmund C. Baird, Associate Solicitor of Labor for Occupational Safety and Health, to receive petitions for review of the final rule. Contact the Associate Solicitor at the Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–5445.

Copies of this ***Federal Register*** *document and news releases:* Electronic copies of these documents are available at OSHA's web page at *https://www.osha.gov.*

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, OSHA Office of Communications; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: Mr. William Perry or Ms. Maureen Ruskin, Directorate of Standards and Guidance, Occupational Safety and Health Administration; telephone: (202) 693–1950; email: *perry.bill@dol.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Citation Method

In the docket for the beryllium rulemaking, found at *http://www.regulations.gov,* every submission

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Kimberly Wood, Program Assistant Supervisor-Adv. on behalf of Debra Sybell, Executive Director	10/9/19 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/23/2019	☒ Yes ☐ No	Request to List Multiple Office Locations on Physician Licenses

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☒ Yes: Susan Brischler Trujillo, Quarles and Brady ☐ No	N/A

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

Susan Brischler Trujillo, Quarles and Brady, will appear before the Board to speak to the attached request.

11) Authorization

Kimberly Wood *10/9/2019*

Signature of person making this request **Date**

Supervisor (if required) **Date**

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

Directions for including supporting documents:

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

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E-Mail: susan.trujillo@quarles.com

September 18, 2019

VIA UPS & EMAIL TRANSMISSION
dsps@wisconsin.gov

Ms. Debra Sybell
Executive Director
Wisconsin Pharmacy Board
4822 Madison Yards Way
Madison, WI 53708-8366

Re: Request for Placement on September 25, 2019 Agenda

Dear Ms. Sybell:

We respectfully request that the requirement to deliver prescription drugs to the premises listed on a person's license or authorization be placed on the Wisconsin Board of Pharmacy's ("Board") September 25, 2019 agenda for discussion.

Under applicable Wisconsin law, wholesale distributors may not deliver prescription drugs "to a person that is not known to the [distributor] unless the [distributor] has verified with the board or with the licensing authority of the state in which the person is located that the person is licensed to receive prescription drugs." Wis. Stat. § 450.072(2)(a). In addition to requiring license verification, the statute requires wholesalers to deliver prescription drugs "only to the premises listed on the person's license or authorization." *Id.* This requirement creates uncertainty and confusion, particularly with regard to physicians.

Staff at the Wisconsin Medical Examining Board (Wisconsin Medical Board) indicate that no actual physical license document is sent to practitioners upon licensure. As such, there is no premises listed on a physician's license. Further, Wisconsin physicians can access online verification of licensure, and can print out a wall certificate or a wallet card. If a physician chooses to print a wall certificate, the physician's address is not included. If a physician chooses to print a wallet card, the physician's address is included; however, the wallet card is not the practitioner's license - it is simply proof that the practitioner is licensed. Additionally, the address that is listed on the wallet card is whatever default address the licensee has provided to the Wisconsin Medical Board and this can be a post-office box, a home address, or any address the practitioner chooses.

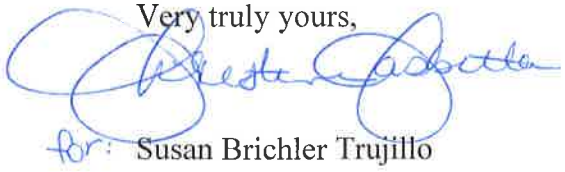
If the Board were to consider address on the wallet card as "the premises listed on the person's license or authorization," (which we would dispute because the wallet card is not the license) then wholesalers attempting to comply would need to first ensure that any practitioner ordering prescription drugs has a printed wallet card showing the practitioner's address. Wholesalers then could only make deliveries to the address listed on the practitioner's wallet card, and this may be a home where children are present.

Essentially, the statute requires delivery to an address on the person's license, but here, there is no address on the license. This is likely because a physician's right to practice is not specific to a location. Rather, the license is personal to the physician. A physician may work at any number of different practice addresses throughout his or her career; therefore, the limitation places a burden on both physicians and wholesalers attempting to deliver prescription drugs ordered by the physician. We believe that the statute did not contemplate that a physician's authority is not tied to a particular practice location nor did it contemplate that physicians have multiple practice locations at which they may administer prescription drugs. Also, because the statute requires an address on a license and there is no address on a physician's license, the requirement is inapplicable on its face.

The Board could easily remedy this problematic situation by indicating that, by its clear language, the requirements of § 420.72 do not apply when there is no location listed on the physician's license. As an added level of oversight, the Board could request that that wholesalers ship to only those addresses verified by practitioners in letters of attestation provided to the wholesaler verifying the practice addresses for the practitioner. The verified addresses then could be used for delivery of prescription drugs. A number of other states, including Illinois, have a requirement for delivery to the address on the license and, even when there is an address on the license, they have adopted this approach in recognition that physicians routinely have more than one practice address. These states allow wholesalers to deliver to practice addresses designated by a physician as a valid practice address. This approach serves public safety by ensuring that physicians have needed prescription drug products at their practice sites.

Thank you for your time and attention. We would appreciate the opportunity to further explain the above position at the Board meeting on September 25, 2019. If you have questions or require additional information prior to the Board meeting, please feel free to contact me.

Very truly yours,



for: Susan Brichler Trujillo

ST:jp

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Kimberly Wood, Program Assistant Supervisor-Adv. on behalf of Philip Trapskin	10/16/19 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

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

Pharmacy Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/23/2019	☒ Yes ☐ No	Education and Examination Matters 1. MPJE Item Review and Related Matters

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

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

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

11) Authorization

Kimberly Wood *10/16/2019*

Signature of person making this request — Date

Supervisor (if required) — Date

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

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

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

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Hi Deb,

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

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

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

Best regards,
Lisa

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

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

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

Hi Lisa,

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

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

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

Thanks!

Best,

Deb

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

NABP
National Association of Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
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F) 847/375-1114

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

FROM: Maureen Garrity, Competency Assessment Director

DATE: January 3, 2019

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

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

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

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

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

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

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

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

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

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

NABP
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TO: EXECUTIVE OFFICERS – MPJE Jurisdictions

FROM: Maureen Garrity, Competency Assessment Director

DATE: June 6, 2019

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

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

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

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

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

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

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

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

Attachment: 2019 MPJE State-Specific Review Participant Form

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