Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

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

Tony Evers, Governor
Dawn B. Crim, Secretary

VIRTUAL/TELECONFERENCE
PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison, WI 53705
Contact: Brad Wojciechowski (608) 266-2112
June 16, 2022

Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. ***A quorum of the Board may be present during any committee meetings.***

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER

A. Approval of Agenda (1)

B. Administrative Rule Matters – Discussion and Consideration (2)

1) Phar 7 and 10, Relating to Consumer Disclosures **(3-14)**
2) Phar 18, Relating to Licensure of Third-Party Logistics Providers **(15-21)**
3) Pending or Possible Rulemaking Projects

C. Public Comments

ADJOURNMENT

****

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

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer at 608-266-2112, or the Meeting Staff at 608-266-5439.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**06/03/22** **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 Rules Committee

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
06/16/22	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. Phar 7 and 10, Relating to Consumer Disclosures** **2. Phar 18, Relating to Licensure of Third-Party Logistics Providers** **3. Pending or Possible Rulemaking Projects**

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

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

Attachments:

1. Phar 7 and 10 Preliminary Rule Draft
2. 2021 Wisconsin Act 9
3. Phar 18 Draft Rule Text
4. 2021 Wisconsin Act 25

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

11) Authorization

Nilajah D. Hardin — 06/03/22

Signature of person making this request **Date**

Supervisor (if required) **Date**

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

Directions for including supporting documents:

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

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

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

PROPOSED ORDER

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

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 15.08 (5) (b), 450.013 (5m), 450.013 (8m), Stats.

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

Explanation of agency authority:

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

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

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

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

Related statute or rule: 2021 Wisconsin Act 9

Plain language analysis: The objective of the proposed rule is to revise the Pharmacy administrative code, including but not necessarily limited to chs. Phar 7 and 10, to bring the code into compliance with current statutory provisions as modified by 2021 Wisconsin Act 9.

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

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

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

Comparison with rules in adjacent states:

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

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

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

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

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

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

The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:

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

Agency contact person:

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

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

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.15 is created to read:

Phar 7.15 Consumer Disclosures.

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

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

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

(3) Pursuant to s. 450.13 (5m) (c), Stats., each pharmacy shall have a list, available to the public, of the 100 most commonly prescribed drugs available for purchase and updated monthly, with all of the following information included:

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

(4) The list required under Phar 7.15 (3) may differ depending on

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

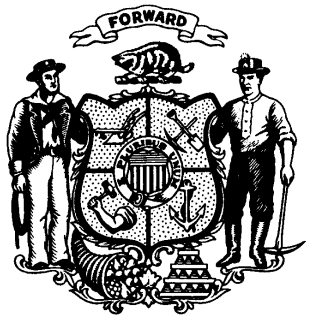
Phar 10.03 (20) Violating or attempting to violate any provision or term of ch. 450, Stats., or of any valid rule of the board.

Phar 10.03 (21) Failure to comply with ss 450.013 (5m) or 450.013 (8m), Stats.

SECTION 3. EFFECTIVE DATE. the rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

State of Wisconsin



Date of enactment: **March 26, 2021**
2021 Senate Bill 3 Date of publication*: **March 27, 2021**

2021 WISCONSIN ACT 9

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

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

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

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

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

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

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

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

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

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

120.13 **(2)** (g) Every self–insured plan under par. (b) shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.729, 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.798, 632.85, 632.853, 632.855,

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

632.861, 632.867, 632.87 (4) to (6), 632.885, 632.89, 632.895 (9) to (17), 632.896, and 767.513 (4).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 14. 632.86 of the statutes is repealed.

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

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

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

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

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

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

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

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

(2) ALLOWING DISCLOSURES. (a) A disability insurance policy or self–insured health plan that provides a prescription drug benefit may not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the policy or plan from informing, or penalize such pharmacy for informing, an enrollee of any differential between the out–of–pocket cost to the enrollee under the policy or plan with respect to acquisition of the drug and the amount an individual would pay

for acquisition of the drug without using any health plan or health insurance coverage.

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

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

(a) The cost−sharing amount for the prescription drug for the enrollee under the policy or plan.

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

(4) DRUG SUBSTITUTION. (a) Except as provided in par. (b), a disability insurance policy that offers a prescription drug benefit, a self−insured health plan that offers a prescription drug benefit, or a pharmacy benefit manager acting on behalf of a disability insurance policy or self−insured health plan shall provide to an enrollee advanced written notice of a formulary change that removes a prescription drug from the formulary of the policy or plan or that reassigns a prescription drug to a benefit tier for the policy or plan that has a higher deductible, copayment, or coinsurance. The advanced written notice of a formulary change under this paragraph shall be provided no fewer than 30 days before the expected date of the removal or reassignment and shall include information on the procedure for the enrollee to request an exception to the formulary change. The policy, plan, or pharmacy benefit manager is required to provide the advanced written notice under this paragraph only to those enrollees in the policy or plan who are using the drug at the time the notification must be sent according to available claims history.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. An insurer ~~or other~~.

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

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

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

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

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

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

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

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

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

(a) The original claim was submitted fraudulently.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and contact information for the entity or person that completed the audit so the pharmacist or pharmacy subject to the audit may review audit results, procedures, and discrepancies.

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

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

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

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

6. Exclude dispensing fees from calculations of overpayments.

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

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

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

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

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

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

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

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

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

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

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

CHAPTER 633
EMPLOYEE BENEFIT PLAN ADMINISTRATORS ~~AND~~, PRINCIPALS, AND PHARMACY BENEFIT MANAGERS

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

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

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

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

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

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

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

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

633.01 **(2g)** "~~Plan~~ Employee benefit plan" means an insured or wholly or partially self–insured employee

benefit plan which by means of direct payment, reimbursement or other arrangement provides to one or more employees who are residents of this state benefits or services that include, but are not limited to, benefits for medical, surgical or hospital care, benefits in the event of sickness, accident, disability or death, or benefits in the event of unemployment or retirement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) A principal that uses an administrator may inspect the books and records of the administrator, subject to any restrictions set forth in ss. 146.81 to 146.835 and in the written agreement required under s. 633.04, for the purpose of enabling the principal to fulfill its contractual obligations to ~~insureds~~ insured employees.

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) RESPONSIBILITIES OF PRINCIPAL. A principal may not use the services of an administrator unless the administrator furnishes proof of licensure under s. 633.14 or

exemption under sub. (2). An insurer or a self−insured health plan may not use the services of a pharmacy benefit manager unless the pharmacy benefit manager furnishes proof of licensure under s. 633.14.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

benefit manager's license, unless the order specifies a lesser period.

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

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

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

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

SECTION 45. Nonstatutory provisions.

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

SECTION 46. Initial applicability.

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

SECTION 46m. Effective dates. This act takes effect on January 1, 2022, except as follows:

(1) ALLOWING DISCLOSURES. The treatment of s. 632.861 (2) takes effect on the day after publication.

(2) COST–SHARING LIMITATION. The treatment of s. 632.861 (3) takes effect on June 30, 2021.

(3) AUDITS. The treatment of s. 632.865 (6) takes effect on June 30, 2021.

CHAPTER PHAR 18
THIRD-PARTY LOGISTICS PROVIDERS

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

Phar 18.02 Definitions. In this chapter:

(1) "Designated representative" means an individual who functions on behalf of a third-party logistics provider or an out-of-state third-party logistic provider as specified in Phar 18.05.
(2) "Facility" has the meaning given in s. 450.01 (11m), Stats.
(3) "Out-of-state third-party logistics provider" has the meaning given s. 450.01 (13w), Stats.
(4) "Third-party logistics provider" has the meaning given in s. 450.01 (21s), Stats.

Phar 18.03 Licensure, Renewal, and Reinstatement.

(1) LICENSE ALLOWED. A person acting as a third-party logistics provider or an out-of-state third-party logistics provider of any drug or device may apply to obtain a license from the board.
(2) LICENSURE. Except as provided under Phar 18.03 (4), the board shall grant a license to operate as a third-party logistics provider or out-of-state third-party logistics provider, to any applicant that satisfies all of the following requirements, as determined by the Board:
    (a) The applicant shall submit all of the following:
        1. A completed application form.
        Note: Application forms are available from the department of safety and professional services' website at http://dsps.wi.gov.
        2. The fee specified in s. 440.05, Stats.
        3. All of the following information relating to a designated representative:
            a. Name, address, and telephone number
            b. Date and place of birth
            c. A photograph of the person taken within the 12-month period immediately preceding the date of the application
            d. A personal information statement that includes all of the following for the 7-year period immediately preceding the application:
                i. Place of residence
                ii. Occupations, positions of employment, and offices held
                iii. The name and addresses for each business, corporation or entity listed in subs. ii.
                iv. Whether the person has been the subject of any proceeding for the revocation of any business or professional licensure and the disposition of that proceeding.
                v. Whether the person has been enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction

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

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

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

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

~~(b) The inspections required under Phar 18.04.~~

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

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

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

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

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

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

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

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

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

Phar 18.04 Inspections. A third-party logistics provider or out-of-state third-party logistics provider licensed under this chapter shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and

Commented [HN-D1]: From Phar 13.17 (3)

delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to the third-party logistics provider or out-of-state third-party logistics provider's premises and delivery vehicles.

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

(a) Be at least 21 years old

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

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

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

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

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

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

(h) Has not been convicted of a felony

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

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

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

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

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

Commented [HN-D2]: From Phar 13.16

Formatted: Font: (Default) Times New Roman, 12 pt

Commented [HN-D3]: From 21 USC s. 360eee-3
21 U.S. Code § 360eee–3 - National standards for third-party logistics providers | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

(a) Address receipt, security, storage, inventory, shipment, and distribution of a product;
(b) Identify, record, and report confirmed losses or thefts;
(c) Correct errors and inaccuracies in inventories;
(d) Provide support for manufacturer recalls;
(e) Prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;
(f) Ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;
(g) Maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and
(h) Quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency.

Formatted: Font: Not Bold

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

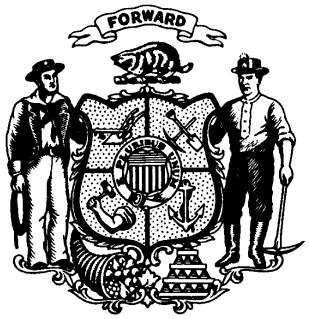
Commented [HN-D4]: From Phar 13.10

(1) Access from outside the premises is kept to a minimum and is well controlled;
(2) The outside perimeter of the premises is well lighted;
(3) Entry into areas where prescription drugs are held is limited to authorized personnel;
(4) An alarm system is maintained to detect entry after hours; and
(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Formatted: Font: Not Bold

Phar 18.0~~8~~6 Compliance. A licensee who fails to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

State of Wisconsin



Date of enactment: **April 15, 2021**
2021 Assembly Bill 120 Date of publication*: **April 16, 2021**

2021 WISCONSIN ACT 25

AN ACT ***to amend*** 440.15, 450.01 (11m), 450.01 (21s) and 450.02 (1); and ***to create*** 440.08 (2) (a) 69g., 450.01 (13w), 450.01 (23) (p) and 450.075 of the statutes; **relating to:** third−party logistics providers, extending the time limit for emergency rule procedures, providing an exemption from emergency rule procedures, and granting rule−making authority.

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

SECTION 1. 440.08 (2) (a) 69g. of the statutes is created to read:

440.08 **(2)** (a) 69g. Third−party logistics provider: July 1 of each even−numbered year.

SECTION 2. 440.15 of the statutes is amended to read:

440.15 No fingerprinting. Except as provided under ss. 440.03 (13) (c), 441.51 (5) (a) 5., 448.980 (5) (b) 3., ~~and~~ 448.985 (3) (a) 4., 450.071 (3) (c) 9., and 450.075 (3) (c) 9., the department or a credentialing board may not require that an applicant for a credential or a credential holder be fingerprinted or submit fingerprints in connection with the department's or the credentialing board's credentialing.

SECTION 3. 450.01 (11m) of the statutes is amended to read:

450.01 **(11m)** "Facility" means a location where a wholesale distributor or 3rd−party logistics provider stores, distributes, handles, repackages, or offers ~~for sale~~ other services related to prescription drugs.

SECTION 4. 450.01 (13w) of the statutes is created to read:

450.01 **(13w)** "Out−of−state 3rd−party logistics provider" means a person located outside this state that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services within this state on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 5. 450.01 (21s) of the statutes is amended to read:

450.01 **(21s)** "~~Third party~~ Third−party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

SECTION 6. 450.01 (23) (p) of the statutes is created to read:

450.01 **(23)** (p) The services of a 3rd−party logistics provider or out−of−state 3rd−party logistics provider.

SECTION 7. 450.02 (1) of the statutes is amended to read:

450.02 **(1)** The department shall keep a record of the proceedings and a register of the names and places of practice or business of pharmacies, manufacturers, wholesale distributors, 3rd−party logistics providers,

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

out–of–state 3rd–party logistics providers, and other persons licensed under this chapter, and the books, registers and records of the department shall be prima facie evidence of the matters recorded.

Section 8. 450.075 of the statutes is created to read:

450.075 Third–party logistics providers; licensure. (1) License allowed. A person acting as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider of any drug or device may apply to obtain a license from the board under this section. Where operations are conducted at more than one facility, a person acting as a 3rd–party logistics provider or out–of–state 3rd–party logistics provider may apply to obtain a license from the board for each such facility.

(2) Application. An applicant for a license under this section shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the warehousing, distribution, or other services on behalf of the manufacturer of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's 3rd–party logistics provider business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's 3rd–party logistics provider business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's 3rd–party logistics provider business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to warehouse or distribute prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person identified as the designated representative in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's place of residence for the 7–year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7–year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7–year period immediately preceding the date of the application, enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person during the past 7 years with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

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

9. A photograph of the person taken within the 12–month period immediately preceding the date of the application.

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

(3) Licensure. The board shall grant a license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if all of the following apply:

(a) The applicant pays the fee specified in s. 440.05 (1).

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for 3rd–party logistics providers or out–of–state 3rd–party logistics providers.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing of and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial position.

4. The person is physically present at the 3rd–party logistics provider's or out–of–state 3rd–party logistics provider's facility during regular business hours and is

involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider. This subdivision does not preclude the person from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

5. The person is actively involved in and aware of the daily operation of the 3rd–party logistics provider or the out–of–state 3rd–party logistics provider.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one 3rd–party logistics provider or out–of–state 3rd–party logistics provider is located at the facility and the 3rd–party logistics providers or out–of–state 3rd–party logistics providers located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to distribution of a controlled substance.

8. The person has not been convicted of a felony.

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

(d) The applicant satisfies any other requirements established by the board by rule.

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

(5) ACCESS TO RECORDS. Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

(6) INSPECTIONS. A 3rd–party logistics provider or an out–of–state 3rd–party logistics provider shall allow the board and authorized federal, state, and local law enforcement officials to enter and inspect its facilities and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law, rule, or regulation.

(7) APPLICABILITY. (a) If the federal government establishes a licensing program for 3rd–party logistics providers, the board shall evaluate the federal licensing program to determine whether licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state. If the board determines under this subsection that licensing by this state is not required, this section does not apply.

(b) By 2 years after the effective date of this paragraph .... [LRB inserts date], and biennially thereafter, the board shall evaluate whether continued licensing by this state of resident 3rd–party logistics providers is required for a resident 3rd–party logistics provider to provide 3rd–party logistics provider services in another state and, if the board determines licensing in this state is required, submit to the legislative reference bureau for publication in the Wisconsin Administrative Register a notice continuing the licensing under this section. This section does not apply unless the board submits the notice under this paragraph.

SECTION 9. Nonstatutory provisions.

(1) EMERGENCY RULES RELATED TO 3RD–PARTY LOGISTICS PROVIDERS. The pharmacy examining board may promulgate emergency rules under s. 227.24 implementing s. 450.075. Notwithstanding s. 227.24 (1) (c) and (2), emergency rules promulgated under this subsection remain in effect until June 30, 2023, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 227.24 (1) (a) and (3), the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2) INTERIM LICENSURE OF 3RD–PARTY LOGISTICS PROVIDERS.

(a) In this subsection, the definitions under s. 450.01 apply.

(b) The board shall grant an interim license to an applicant to act as a 3rd–party logistics provider or an out–of–state 3rd–party logistics provider if, in the opinion of the board, the applicant is currently in compliance with federal law relating to 3rd–party logistics providers. The holder of an interim license under this subsection shall apply for a license under s. 450.075 on or after the date that emergency rules take effect under sub. (1), or the date on which permanent rules take effect, whichever is sooner. An interim license granted under this subsection expires 90 days after the date that emergency rules take effect under sub. (1), or 90 days after the date on which permanent rules take effect, whichever is sooner. Notwithstanding s. 440.05, no fee is required for an interim license issued under this subsection.