

State of Misconsin 2021 - 2022 LEGISLATURE

DOA:.....Lessner, BB00164 – Pharmacy benefit manager regulation FOR 2021-2023 BUDGET -- NOT READY FOR INTRODUCTION

AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau INSURANCE

Pharmacy benefit manager and prescription drug benefit regulation

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

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

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

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

Current law requires pharmacy benefit managers to agree in their contracts to make certain disclosures regarding prescription drug reimbursement, including updating maximum allowable cost pricing information for prescribed drugs or devices at least every seven business days, reimbursing pharmacies or pharmacists subject to the updated maximum allowable cost pricing, and modifying information in the maximum allowable cost information in a timely fashion. Pharmacy benefit managers currently must also include in each contract with a pharmacy a process to appeal, investigate, and resolve pricing disputes in accordance with the specifics in current law. These current law requirements are unchanged by the bill. Under the bill, a health insurance policy or a governmental self-insured health plan may not, and a policy or plan must ensure that a pharmacy benefit manager does not, restrict a pharmacy from or penalize a pharmacy for informing an enrollee under the policy or plan of any differential between the out-of-pocket cost of a drug to the enrollee under the policy or plan and the cost an individual would pay for the drug without using insurance. Health insurance policies are referred to in the bill as disability insurance policies. The bill prohibits a policy, plan, or pharmacy benefit manager from requiring an enrollee under the policy or plan to pay more for a covered drug than either the cost-sharing amount for the prescription drug under the policy or plan or the amount the enrollee would pay for the drug without using insurance, whichever amount is lower.

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

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

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

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

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

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

SECTION 1. 40.51 (8) of the statutes, as affected by 2021 Wisconsin Act (this

act), 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), 632.728, 632.729, 632.746 (1) to (8) and (10), 632.747, 632.748, 632.798, 632.83, 632.835, 632.855, 632.855, 632.861, 632.862, 632.867, 632.87 (3) to (6), 632.871, 632.885, 632.89, 632.895 (5m) and (8) to (17), and 632.896.

****Note: This is reconciled s. 40.51 (8). This Section has been affected by drafts with the following LRB numbers: -0579/P1, -0922/P1, -0581/P1, and -0884/P1.

SECTION 2. 40.51 (8m) of the statutes, as affected by 2021 Wisconsin Act (this act), is amended to read:

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40.51 (8m) Every health care coverage plan offered by the group insurance board under sub. (7) shall comply with ss. 631.95, 632.728, 632.729, 632.746 (1) to (8) and (10), 632.747, 632.748, 632.798, 632.83, 632.835, 632.855, 632.851, 632.862, 632.867, 632.871, 632.885, 632.89, and 632.895 (8) and (10) to (17).

****Note: This is reconciled s. 40.51 (8m). This Section has been affected by drafts with the following LRB numbers: -0579/P2, -0922/P1, -0581/P1, and -0884/P1.

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

SECTION 4. 66.0137 (4) of the statutes, as affected by 2021 Wisconsin Act (this act), 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), 632.728, 632.729, 632.746 (1) and (10) (a) 2. and (b) 2., 632.747 (3), 632.798, 632.85, 632.853, 632.855, <u>632.861</u>, 632.862, 632.867, 632.87 (4) to (6), 632.871, 632.885, 632.89, 632.895 (8) to (17), 632.896, and 767.513 (4).

****Note: This is reconciled s. 66.0137 (4). This Section has been affected by drafts with the following LRB numbers: -0579/P1, -0922/P1, -0581/P1, and -0884/P1.

SECTION 5. 120.13 (2) (g) of the statutes, as affected by 2021 Wisconsin Act (this act), 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), 632.728, 632.729, 632.746 (1) and (10) (a) 2. and (b) 2., 632.747 (3), 632.798, 632.85, 632.853, 632.855, <u>632.861</u>, 632.862, 632.867, 632.87 (4) to (6), 632.871, 632.885, 632.89, 632.895 (8) to (17), 632.896, and 767.513 (4).

****Note: This is reconciled s. 120.13 (2) (g). This Section has been affected by drafts with the following LRB numbers: -0579/P1, -0922/P1, -0581/P1, and -0884/P1.

SECTION 6. 185.983 (1) (intro.) of the statutes, as affected by 2021 Wisconsin Act (this act), 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), 632.728, 632.729, 632.745 to 632.749, 632.775, 632.79, 632.795, 632.798, 632.855, 632.855, 632.855, 632.861, 632.862, 632.867, 632.87 (2) to (6), 632.871, 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:

****Note: This is reconciled s. 185.983 (1) (intro.). This Section has been affected by drafts with the following LRB numbers: -0579/P1, -0922/P1, -0581/P1, and -0884/P1.

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

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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. <u>Each pharmacy shall</u> <u>make available for the public information on how to access the federal food and drug</u> <u>administration's lists of all currently approved interchangeable biological products</u> <u>through the department's Internet site.</u>

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 <u>or pharmacy benefit manager</u> 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, as affected by 2021 Wisconsin Act (this act), is amended to read:

Coverage of drugs and devices. 609.83 Limited service health organizations, preferred provider plans, and defined network plans are subject to ss. 632.853, 632.861, 632.862, and 632.895 (6) (b), (16t), and (16v).

****NOTE: This is reconciled s. 609.83. This SECTION has been affected by drafts with the following LRB numbers: -0579/P1, -0581/P1, and -0589/P2.

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 <u>of the following:</u>

<u>1. An</u> insurer or other.

<u>3. Another</u> 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.

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(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 <u>-a-</u> 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 <u>a an employee benefit</u> 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 <u>employee</u>" means an employee who is a resident of this state and who is covered under <u>a an employee benefit</u> 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 <u>-a</u> 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 <u>a an employee benefit</u> 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 <u>employee</u> 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 <u>employee</u> until the payment is received by the insured <u>employee</u>. This section does not limit any right of the insurer against the administrator for failure to make payments to the insurer or an insured <u>employee</u>.

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 <u>or pharmacy benefit manager</u> 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.

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(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 <u>a an employee benefit</u> 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 <u>a an employee benefit</u> plan policyholder for payment to a principal, the funds belonging to the principal.

3. To an insured <u>employee</u>, the funds belonging to the insured <u>employee</u>.

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

633.11 Claim adjustment compensation. If an administrator adjusts or settles claims under <u>a an employee benefit</u> plan, the commission, fees or charges that the principal pays the administrator may not be based on the <u>employee benefit</u> 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

<u>insured employees</u> or shall provide the copies to the principal for distribution to the <u>insureds insured employees</u>. The written notice shall contain all of the following:

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(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 <u>employee benefit</u> 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 <u>or a pharmacy benefit</u> <u>manager</u> unless the person has obtained a license under s. 633.14. <u>A pharmacy benefit manager that also performs services as an administrator need only obtain an administrator license under s. 633.14.</u>

(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 <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager</u> 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 <u>employee benefit</u> plan <u>or prescription drug benefit</u> 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 <u>employee benefit</u> plan <u>or</u> <u>prescription drug benefit</u>.

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

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 <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager</u> 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.

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(2) (a) 1. If an administrator <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager's</u> license effective the day following the last day when the annual renewal fee may be paid, if the commissioner has given the administrator <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager</u> 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 <u>or pharmacy benefit manager's</u> 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 <u>or pharmacy benefit manager's</u> license.

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

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

b. That the administrator <u>or pharmacy benefit manager</u> 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 <u>a an employee benefit</u> 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 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 <u>or pharmacy benefit manager's</u> 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 <u>a an employee benefit</u> plan that is exempt from state law under 29 USC 1144 (b).

SECTION 9123. Nonstatutory provisions; Insurance.

(1) PHARMACY BENEFIT MANAGER REGULATION. 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 9323. Initial applicability; Insurance.

(1) PHARMACY BENEFIT MANAGER REGULATION. For policies and plans containing provisions inconsistent with the treatment of ss. 632.861, 632.865 (3) to (7), 633.06, 633.13 (1) and (3), 633.14 (2) (intro.) and (c) 1. and 3. and (3), and 633.15 (1) (a), (1m), and (2) (a) 1., 2., and 3., (b) 1. d. and 2., and (f), that treatment first applies to policy or plan years beginning on the effective date of this subsection.

SECTION 9423. Effective dates; Insurance.

(1) PHARMACY BENEFIT MANAGER REGULATION. The treatment of ss. 40.51 (8) (by SECTION 1), (8m) (by SECTION 2), and (15m), 66.0137 (4) (by SECTION 4), 120.13 (2) (g) (by SECTION 5), 185.983 (1) (intro.) (by SECTION 6), 450.13 (5m), 450.135 (8m) and (9), 601.31 (1) (w), 601.46 (3) (b), 609.83 (by SECTION 12), 616.09 (1) (a) 2., 632.86, 632.861, 632.865 (1) (a), (ae), (ak), (c) 1. and 2., and (dm) and (3) to (7), 633.01 (1) (intro.) and (c), (2r), (3), (4), (4g), (4r), (5), and (6), 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., (b) 1.

d. and 2., and (f), and 633.16 and ch. 633 (title) and SECTIONS 9123 (1) and 9323 (1) of this act take effect on the date that is 14 months after the date of enactment.