

CHAPTER 510B

REGULATION OF PHARMACY BENEFITS MANAGERS

Referred to in [§87.4](#), [296.7](#), [331.301](#), [364.4](#), [505.28](#), [505.29](#), [669.14](#), [670.7](#)

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510B.1 Definitions.

As used in [this chapter](#), unless the context otherwise requires:

1. “*Commissioner*” means the commissioner of insurance.
2. “*Covered entity*” means a nonprofit hospital or medical services corporation, health insurer, health benefit plan, or health maintenance organization; a health program administered by a department or the state in the capacity of provider of health coverage; or an employer, labor union, or other group of persons organized in the state that provides health coverage. “*Covered entity*” does not include a self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA), as codified at 29 U.S.C. §1001 et seq.; a plan issued for health coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplemental, disability income, or long-term care, or other limited benefit health insurance policy or contract.
3. “*Covered individual*” means a member, participant, enrollee, contract holder, policyholder, or beneficiary of a covered entity who is provided health coverage by the covered entity, and includes a dependent or other person provided health coverage through a policy, contract, or plan for a covered individual.
4. “*Generic drug*” means a chemically equivalent copy of a brand-name drug with an expired patent.
5. “*Labeler*” means a person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration pursuant to [21 C.F.R. §207.20](#).
6. “*Maximum reimbursement amount*” means the maximum reimbursement amount for a therapeutically and pharmaceutically equivalent multiple-source prescription drug that is listed in the most recent edition of the publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations”, published by the United States food and drug administration, otherwise known as the orange book.
7. “*Pharmacy*” means pharmacy as defined in [section 155A.3](#).
8. “*Pharmacy benefits management*” means the administration or management of prescription drug benefits provided by a covered entity under the terms and conditions of the contract between the pharmacy benefits manager and the covered entity.
9. “*Pharmacy benefits manager*” means a person who performs pharmacy benefits management services. “*Pharmacy benefits manager*” includes a person acting on behalf of a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management services for a covered entity. “*Pharmacy benefits manager*” does not include a health insurer licensed in the state if the health insurer or its subsidiary is providing pharmacy benefits management services exclusively to its own insureds, or a public self-funded pool or a private single employer self-funded plan that provides such benefits or services directly to its beneficiaries.
10. “*Prescription drug*” means prescription drug as defined in [section 155A.3](#).

11. “*Prescription drug order*” means prescription drug order as defined in [section 155A.3](#). [2007 Acts, ch 193, §1, 9](#); [2014 Acts, ch 1016, §1](#)
Referred to in [§505.26](#)

510B.2 Certification as a third-party administrator required.

A pharmacy benefits manager doing business in this state shall obtain a certificate as a third-party administrator under [chapter 510](#), and the provisions relating to a third-party administrator pursuant to [chapter 510](#) shall apply to a pharmacy benefits manager.

[2007 Acts, ch 193, §2, 9](#)

510B.3 Enforcement — rules.

1. The commissioner shall enforce the provisions of [this chapter](#). After notice and hearing, the commissioner may impose any or all of the sanctions set out in [section 507B.7](#) and may suspend or revoke a pharmacy benefits manager’s certificate of registration as a third-party administrator pursuant to [chapter 510](#), upon finding that the pharmacy benefits manager violated any of the requirements of [this chapter](#) or of [chapter 510](#) pertaining to third-party administrators.

2. A pharmacy benefits manager, as an agent or vendor of an insurance company, is subject to the commissioner’s authority to conduct an examination pursuant to [chapter 507](#). The procedures set forth in [chapter 507](#) regarding examination reports shall apply to an examination of a pharmacy benefits manager under [this chapter](#).

3. A pharmacy benefits manager is subject to the commissioner’s authority to conduct an investigation pursuant to [chapter 507B](#). The procedures set forth in [chapter 507B](#) regarding investigations shall apply to an investigation of a pharmacy benefits manager under [this chapter](#).

4. A pharmacy benefits manager is subject to the commissioner’s authority to conduct an examination, audit, or inspection pursuant to [chapter 510](#) for third-party administrators. The procedures set forth in [chapter 510](#) for third-party administrators shall apply to an examination, audit, or inspection of a pharmacy benefits manager under [this chapter](#).

5. When the commissioner conducts an examination of a pharmacy benefits manager under [chapter 507](#); an investigation under [chapter 507B](#); or an examination, audit, or inspection under [chapter 510](#), all information received from the pharmacy benefits manager, and all notes, work papers, or other documents related to the examination, investigation, audit, or inspection of the pharmacy benefits manager are confidential records under [chapter 22](#) and shall be accorded the same confidentiality as notes, work papers, investigatory materials, or other documents related to the examination of an insurer as provided in [chapter 507](#).

6. The commissioner shall adopt rules pursuant to [chapter 17A](#) to administer [this chapter](#) including rules relating to all of the following:

a. Timely payment of pharmacy claims.

b. A process for adjudication of complaints and settlement of disputes between a pharmacy benefits manager and a licensed pharmacy related to pharmacy auditing practices, termination of pharmacy agreements, and timely payment of pharmacy claims.

c. A process for the submission of forms.

[2007 Acts, ch 193, §3, 9](#); [2014 Acts, ch 1140, §99, 101](#); [2015 Acts, ch 24, §1 – 3](#)

510B.4 Performance of duties — good faith — conflict of interest.

1. A pharmacy benefits manager shall perform the pharmacy benefits manager’s duties exercising good faith and fair dealing in the performance of its contractual obligations toward the covered entity.

2. A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy, practice ownership interest, or affiliation of the pharmacy benefits manager that presents any conflict of interest.

[2007 Acts, ch 193, §4, 9](#)

510B.5 Contacting covered individual — requirements.

A pharmacy benefits manager, unless authorized pursuant to the terms of its contract with a covered entity, shall not contact any covered individual without the express written permission of the covered entity.

2007 Acts, ch 193, §5, 9

510B.6 Dispensing of substitute prescription drug for prescribed drug.

1. The following provisions shall apply when a pharmacy benefits manager requests the dispensing of a substitute prescription drug for a prescribed drug to a covered individual:

a. The pharmacy benefits manager may request the substitution of a lower priced generic and therapeutically equivalent drug for a higher priced prescribed drug.

b. If the substitute drug's net cost to the covered individual or covered entity exceeds the cost of the prescribed drug, the substitution shall be made only for medical reasons that benefit the covered individual.

2. A pharmacy benefits manager shall obtain the approval of the prescribing practitioner prior to requesting any substitution under [this section](#).

3. A pharmacy benefits manager shall not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution.

2007 Acts, ch 193, §6, 9

510B.7 Duties to pharmacy network providers.

1. A pharmacy benefits manager shall not mandate basic recordkeeping that is more stringent than that required by state or federal law or regulation.

2. If a pharmacy benefits manager receives notice from a covered entity of termination of the covered entity's contract, the pharmacy benefits manager shall notify, within ten working days of the notice, all pharmacy network providers of the effective date of the termination.

3. Within three business days of a price increase notification by a manufacturer or supplier, a pharmacy benefits manager shall adjust its payment to the pharmacy network provider consistent with the price increase.

2007 Acts, ch 193, §7, 9

510B.8 Pricing methodology for maximum reimbursement amount.

1. The commissioner may require a pharmacy benefits manager to submit information to the commissioner related to the pharmacy benefits manager's pricing methodology for maximum reimbursement amount.

2. For purposes of the disclosure of pricing methodology, maximum reimbursement amounts shall be implemented as follows:

a. Established for multiple-source prescription drugs prescribed after the expiration of any generic exclusivity period.

b. Established for any prescription drug with at least two or more A-rated therapeutically equivalent, multiple-source prescription drugs with a significant cost difference.

c. Determined using comparable prescription drug prices obtained from multiple nationally recognized comprehensive data sources including wholesalers, prescription drug file vendors, and pharmaceutical manufacturers for prescription drugs that are nationally available and available for purchase locally by multiple pharmacies in the state.

3. For those prescription drugs to which maximum reimbursement amount pricing applies, a pharmacy benefits manager shall include in a contract with a pharmacy information regarding which of the national compendia is used to obtain pricing data used in the calculation of the maximum reimbursement amount pricing and shall provide a process to allow a pharmacy to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list. The right to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list shall be limited in duration and allow for retroactive payment in the event that it is determined that maximum reimbursement amount pricing has been applied incorrectly.

2014 Acts, ch 1016, §2

510B.9 Submission, approval, and use of prior authorization form.

A pharmacy benefits manager shall file with and have approved by the commissioner a single prior authorization form as provided in [section 505.26](#). A pharmacy benefits manager shall use the single prior authorization form as provided in [section 505.26](#).

[2014 Acts, ch 1140, §100, 101](#)

510B.10 Rights related to covered individuals.

1. A pharmacy or pharmacist, as defined in [section 155A.3](#), has the right to provide a covered individual information regarding the amount of the covered individual's cost share for a prescription drug. A pharmacy benefits manager shall not prohibit a pharmacy or pharmacist from discussing any such information or from selling a more affordable alternative to the covered individual, if one is available.

2. A health benefit plan, as defined in [section 514J.102](#), issued or renewed on or after July 1, 2018, that provides coverage for pharmacy benefits shall not require a covered individual to pay a copayment for pharmacy benefits that exceeds the pharmacy's or pharmacist's submitted charges.

3. Any amount paid by a covered individual for a covered prescription drug pursuant to [this section](#) shall be applied toward any deductible imposed by the covered individual's health benefit plan in accordance with the covered individual's health benefit plan coverage documents.

4. To the extent that any provision of [this section](#) is inconsistent or conflicts with applicable federal law, rule, or regulation, such federal law, rule, or regulation shall prevail to the extent necessary to eliminate the inconsistency or conflict.

[2018 Acts, ch 1165, §140](#)

NEW section