LAWS

OF THE

STATE OF MAINE

AS PASSED BY THE

ONE HUNDRED AND TWENTY-EIGHTH LEGISLATURE

SECOND SPECIAL SESSION
June 19, 2018 to September 13, 2018

THE GENERAL EFFECTIVE DATE FOR
SECOND SPECIAL SESSION
NON-EMERGENCY LAWS IS
DECEMBER 13, 2018

ONE HUNDRED AND TWENTY-NINTH LEGISLATURE

FIRST REGULAR SESSION
December 5, 2018 to June 20, 2019

THE GENERAL EFFECTIVE DATE FOR
FIRST REGULAR SESSION
NON-EMERGENCY LAWS IS
SEPTEMBER 19, 2019

PUBLISHED BY THE REVISOR OF STATUTES
IN ACCORDANCE WITH THE MAINE REVISED STATUTES ANNOTATED,
TITLE 3, SECTION 163-A, SUBSECTION 4.

Augusta, Maine
2019

(1) Notice of its intent to commit state funds to an Internet service provider; and

(2) A written agreement from the Internet service provider that conforms to the requirements of paragraph A; and

C. The State Controller finds that the requirements of paragraphs A and B have been satisfied and authorizes the state agency or instrumentality to commit state funds.

Nothing in this section limits the authority of the State Controller under any other provision of law to limit or prohibit a state entity from committing state funds.

Nothing in this section prohibits reasonable efforts by an Internet service provider providing broadband Internet access service to address copyright infringement or other unlawful activity.

Nothing in this section supersedes any obligations, authorizations or restrictions on an Internet service provider providing broadband Internet access service to address the needs of emergency communications or law enforcement, public safety or national security authorities under the laws of the State and the United States of America and the United States Constitution and the Constitution of Maine.

Upon receipt of information or complaint from any person that an Internet service provider may be failing to meet the requirements of an agreement made under this section, the Attorney General may undertake an investigation and take any action the Attorney General determines appropriate, including, but not limited to, action pursuant to section 192.

See title page for effective date.

CHAPTER 469

S.P. 466 - L.D. 1504

An Act To Protect Consumers from Unfair Practices Related to Pharmacy Benefits Management

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1711-E, sub-§1, ¶G, as amended by PL 2011, c. 443, §1, is further amended to read:

G. "Pharmacy benefits manager" has the same meaning as in Title 24-A, section ~~1913~~ 4347, subsection ~~1, paragraph A~~ 17.

Sec. 2. 22 MRSA §8702, sub-§8-B, as amended by PL 2011, c. 443, §3, is further amended to read:

8-B. Pharmacy benefits manager. "Pharmacy benefits manager" has the same meaning as in Title 24-A, section ~~1913~~ 4347, subsection ~~1, paragraph A~~ 17.

Sec. 3. 24-A MRSA §601, sub-§28, as enacted by PL 2009, c. 581, §3, is repealed.

Sec. 4. 24-A MRSA §601, sub-§28-A is enacted to read:

28-A. Pharmacy benefits manager. Pharmacy benefits manager licensing fees may not exceed:

A. Original issuance fee, $100; and

B. Renewal fee, $100.

Sec. 5. 24-A MRSA §1913, as repealed and replaced by PL 2011, c. 443, §4, is repealed.

Sec. 6. 24-A MRSA §4317, sub-§12, as enacted by PL 2015, c. 450, §1, is repealed.

Sec. 7. 24-A MRSA §4317, sub-§13, as enacted by PL 2017, c. 44, §1, is repealed.

Sec. 8. 24-A MRSA c. 56-C is enacted to read:

CHAPTER 56-C

HEALTH PLANS THAT PROVIDE PRESCRIPTION DRUG BENEFITS

§4347. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Average wholesale price. "Average wholesale price" means the average wholesale price of a prescription drug as identified by a national drug pricing source selected by a health insurer. The average wholesale price must be identified by the 11-digit national drug code, as amended from time to time, for the prescription drug dispensed for the quantity dispensed.

2. Brand-name drug. "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

3. Carrier. "Carrier" has the same meaning as in section 4301-A, subsection 3, except that "carrier" does not include a multiple-employer welfare arrangement, as defined in section 6601, subsection 5, if the multiple-employer welfare arrangement contracts with a 3rd-party administrator to manage and administer health benefits, including benefits for prescription drugs. "Carrier" also includes the MaineCare program pursuant to Title 22, chapter 855 and the group health plan provided to state employees and other eligible persons pursuant to Title 5, section 285.

4. Compensation. "Compensation" means any direct or indirect financial benefit, including, but not limited to, rebates, discounts, credits, fees, grants, charge-backs or other payments or benefits of any kind.

5. Cost-sharing amount. "Cost-sharing amount" means the amount paid by a covered person as required under the covered person's health plan for a prescription drug at the point of sale.

6. Covered person. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health plan. "Covered person" includes the authorized representative of a covered person.

7. Dispensing fee. "Dispensing fee" means the professional fee incurred at the point of sale or service that pays for pharmacy costs, in excess of ingredient cost, associated with ensuring that possession of the appropriate prescription drug is transferred to a covered person.

8. Formulary. "Formulary" means a list of prescription drugs covered by a health plan and any tier levels applicable to a prescription drug.

9. Generic drug. "Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. "Generic drug" includes a biosimilar product.

10. Health plan. "Health plan" has the same meaning as in section 4301-A, subsection 7.

11. Ingredient cost. "Ingredient cost" means the actual amount paid to a pharmacy provider by a carrier or the carrier's pharmacy benefits manager for a prescription drug, not including the dispensing fee or cost-sharing amount.

12. Mail order pharmacy. "Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, by fax or through electronic submissions and to dispense medication to covered persons through the use of the United States mail or other common or contract carrier services and that provides any consultation with patients electronically rather than face to face.

13. Maximum allowable cost. "Maximum allowable cost" means the maximum amount a health insurer will pay for a generic drug or brand-name drug that has at least one generic alternative available.

14. Network pharmacy. "Network pharmacy" means a licensed retail pharmacy or other pharmacy provider that contracts with a pharmacy benefits manager.

15. Pharmacy. "Pharmacy" means an established location, either physical or electronic, that is licensed by the State and that has entered into a network pharmacy contract with a pharmacy benefits manager or carrier.

16. Pharmacy and therapeutics committee. "Pharmacy and therapeutics committee" means a committee, board or equivalent body established by a carrier to develop and maintain formularies.

17. Pharmacy benefits manager. "Pharmacy benefits manager" means a person, business or other entity that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan or other 3rd-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, self-insurance plan or other 3rd-party payer, including, but not limited to, processing and paying claims for prescription drugs, performing drug utilization review, processing drug prior authorization requests, adjudicating appeals or grievances related to prescription drug coverage, contracting with network pharmacies and controlling the cost of covered prescription drugs.

18. Pharmacy provider. "Pharmacy provider" means a retail pharmacy, mail order pharmacy or licensed pharmacist.

19. Retail pharmacy. "Retail pharmacy" means a chain pharmacy, a supermarket pharmacy, a mass merchandiser pharmacy, an independent pharmacy or a network of independent pharmacies that is licensed as a pharmacy by this State and that dispenses medications to the public.

§4348. Licensure of pharmacy benefits managers

Beginning January 1, 2020, a person may not act as a pharmacy benefits manager in this State without first obtaining a license from the superintendent in accordance with this section and paying the licensing fee required under section 601, subsection 28-A.

1. Applicant information. An applicant for licensure as a pharmacy benefits manager must file with the superintendent at least the following information:

A. The name of the applicant;

B. The address and telephone number of the applicant;

C. The name and address of the applicant's agent for service of process in the State;

D. The name and address of each person beneficially interested in the applicant; and

E. The name and address of each person with management or control over the applicant.

2. Qualification. The superintendent may issue a pharmacy benefits manager license to an applicant only if the superintendent is satisfied that the applicant

possesses the necessary organization, expertise and financial integrity to supply the services sought to be offered.

3. Restrictions permitted. The superintendent may issue a pharmacy benefits manager license subject to restrictions or limitations, including the type of services that may be supplied or the activities in which the pharmacy benefits manager may engage.

4. Valid for 3 years. A license issued pursuant to this section is valid for a period of 3 years and must be renewed.

5. Nontransferable. A license issued pursuant to this section is not transferable.

6. Suspension, revocation or probationary license. The superintendent may suspend, revoke or place on probation a pharmacy benefits manager license under any of the following circumstances:

A. The pharmacy benefits manager has engaged in fraudulent activity that constitutes a violation of state or federal law;

B. The superintendent has received consumer complaints that justify an action under this subsection to protect the safety and interests of consumers;

C. The pharmacy benefits manager fails to pay the original issuance or renewal fee for the license; or

D. The pharmacy benefits manager fails to comply with a requirement set forth in this chapter.

7. Penalty for failure to obtain license. If a pharmacy benefits manager acts without obtaining a license pursuant to this section, the pharmacy benefits manager is subject to a fine of $5,000 per day for the period the pharmacy benefits manager is found to be in violation.

8. Rules. The superintendent may adopt routine technical rules pursuant to Title 5, chapter 375, subchapter 2-A to administer and enforce the requirements of this section.

9. Enforcement. The superintendent may enforce this section under sections 220 and 223 and other provisions of this Title.

10. Registration remains effective until January 1, 2020 or registration date. The registration of a pharmacy benefits manager issued during 2019 in accordance with former section 1913 remains valid until January 1, 2020 or the next yearly anniversary of the registration date, whichever is later. Upon expiration of that registration, the pharmacy benefits manager shall obtain a license under this section in order to do business in this State.

§4349. Oversight and contracting responsibilities

1. Compliance. A carrier is responsible for monitoring all activities carried out by the carrier, or all activities carried out on behalf of the carrier by a pharmacy benefits manager if the carrier contracts with a pharmacy benefits manager, related to a carrier's prescription drug benefits and for ensuring that all requirements of this chapter are met.

2. Fiduciary duty. A carrier that contracts with a pharmacy benefits manager to perform any activities related to the carrier's prescription drug benefits is responsible for ensuring that, under the contract, the pharmacy benefits manager acts as the carrier's agent and owes a fiduciary duty to the carrier in the pharmacy benefits manager's management of activities related to the carrier's prescription drug benefits.

3. Contract requirements. A carrier may not enter into a contract or agreement or allow a pharmacy benefits manager or any person acting on the carrier's behalf to enter into a contract or agreement that prohibits a pharmacy provider from:

A. Providing a covered person with the option of paying the pharmacy provider's cash price for the purchase of a prescription drug and not filing a claim with the covered person's carrier if the cash price is less than the covered person's cost-sharing amount; or

B. Providing information to a state or federal agency, law enforcement agency or the superintendent when such information is required by law.

4. Excess payments at point of sale prohibited. A carrier or pharmacy benefits manager may not require a covered person to make a payment at the point of sale for a covered prescription drug in an amount greater than the least of:

A. The applicable cost-sharing amount for the prescription drug;

B. The amount a covered person would pay for the prescription drug if the covered person purchased the prescription drug without using a health plan or any other source of prescription drug benefits or discounts; and

C. The total amount the pharmacy will be reimbursed for the prescription drug from the pharmacy benefits manager or carrier, including the cost-sharing amount paid by a covered person.

5. Adequate network. A carrier shall provide a reasonably adequate retail pharmacy network for the provision of prescription drugs for its covered persons. A mail order pharmacy may not be included in determining the adequacy of a retail pharmacy network. The superintendent may adopt rules as necessary to carry out the purposes of this subsection. Rules adopted pursuant to this subsection are routine technical

rules as defined in Title 5, chapter 375, subchapter 2-A.

§4350. Prescription drug pricing; maximum allowable cost

1. Single maximum allowable cost list. A carrier, or a pharmacy benefits manager under contract with a carrier, shall use a single maximum allowable cost list to establish the maximum amount to be paid by a health plan to a pharmacy provider for a generic drug or a brand-name drug that has at least one generic alternative available. A carrier, or a pharmacy benefits manager under contract with a carrier, shall use the same maximum allowable cost list for each pharmacy provider.

2. Listing of prescription drug. A maximum allowable cost may be set for a prescription drug, or a prescription drug may be allowed to continue on a maximum allowable cost list, only if that prescription drug:

A. Is rated as "A" or "B" in the most recent version of the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as "the Orange Book," or an equivalent rating from a successor publication, or is rated as "NR" or "NA" or a similar rating by a nationally recognized pricing reference; and

B. Is not obsolete and is generally available for purchase in this State from a national or regional wholesale distributor by pharmacies having a contract with the pharmacy benefits manager.

3. Changes to maximum allowable cost list. A carrier, or a pharmacy benefits manager under contract with a carrier, shall establish a process for removing a prescription drug from a maximum allowable cost list or modifying a maximum allowable cost for a prescription drug in a timely manner to remain consistent with changes to such costs and the availability of the drug in the national marketplace.

4. Disclosure. With regard to a pharmacy with which the carrier, or the pharmacy benefits manager under contract with a carrier, has entered into a contract, a carrier, or a pharmacy benefits manager under contract with a carrier, shall:

A. Upon request, disclose the sources used to establish the maximum allowable costs;

B. Provide a process for a pharmacy to readily obtain the maximum allowable payment available to that pharmacy under a maximum allowable cost list; and

C. At least once every 7 business days, review and update maximum allowable cost list information to reflect any modification of the maximum allowable payment available to a pharmacy under a maximum allowable cost list used by the carrier or the pharmacy benefits manager under contract with a carrier.

5. Appeal procedure. A carrier, or a pharmacy benefits manager under contract with a carrier, shall provide a reasonable administrative appeal procedure, including a right to appeal that is limited to 14 days following the initial claim, to allow pharmacies with which the carrier or pharmacy benefits manager has a contract to challenge maximum allowable costs for a specified drug.

6. Resolution of appeals. A carrier, or a pharmacy benefits manager under contract with a carrier, shall respond to, investigate and resolve an appeal under subsection 5 within 14 days after the receipt of the appeal. The carrier or pharmacy benefits manager shall respond to an appeal as follows:

A. If the appeal is upheld, the carrier or pharmacy benefits manager shall make the appropriate adjustment in the maximum allowable cost and permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question; or

B. If the appeal is denied, the carrier or pharmacy benefits manager shall provide the challenging pharmacy or pharmacist the national drug code from national or regional wholesalers of a comparable prescription drug that may be purchased at or below the maximum allowable cost.

7. Average wholesale price; use of a prescription drug not on maximum allowable cost list. A carrier, or a pharmacy benefits manager under contract with a carrier, shall use the average wholesale price to establish the maximum payment for a brand-name drug for which a generic equivalent is not available or a prescription drug not included on a maximum allowable cost list. In order to use the average wholesale price of a brand-name drug or prescription drug not included on a maximum allowable cost list, a carrier, or a pharmacy benefits manager under contract with a carrier, must use only one national drug pricing source during a calendar year, except that a carrier, or a pharmacy benefits manager under contract with a carrier, may use a different national drug pricing source if the original pricing source is no longer available. A carrier, or a pharmacy benefits manager under contract with a carrier, shall use the same national drug pricing source for each pharmacy provider and identify on its publicly accessible website the name of the national drug pricing source used to determine the average wholesale price of a prescription drug not included on the maximum allowable cost list.

8. Payment. This subsection governs payments between a carrier or a carrier's pharmacy benefits manager and a pharmacy provider.

A. The amount paid by a carrier or a carrier's pharmacy benefits manager to a pharmacy provid-

er under contract with the carrier or the carrier's pharmacy benefits manager for dispensing a prescription drug must be the ingredient cost plus the dispensing fee less any cost-sharing amount paid by a covered person.

B. The ingredient cost may not exceed the maximum allowable cost or average wholesale price, as applicable, and must be disclosed by the carrier's pharmacy benefits manager to the carrier.

C. Only the pharmacy provider that dispensed the prescription drug may retain the payment described in this subsection.

D. A pharmacy provider may not be denied payment or be subject to a reduced payment retroactively unless the original claim was submitted fraudulently or in error.

§4350-A. Responsibility to use compensation for benefit of covered persons

1. Compensation used to reduce point-of-sale costs, improve benefits or lower premiums. All compensation remitted by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, to a carrier, or to a pharmacy benefits manager under contract with a carrier, related to its prescription drug benefits must be:

A. Remitted directly to the covered person at the point of sale to reduce the out-of-pocket cost to the covered person associated with a particular prescription drug; or

B. Remitted to, and retained by, the carrier. Compensation remitted to the carrier must be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons.

2. Compliance. Beginning March 1, 2021 and annually thereafter, a carrier shall file with the superintendent a report in the manner and form determined by the superintendent demonstrating how the carrier has complied with this section.

§4350-B. Prescription drug formularies; pharmacy and therapeutics committee

1. Pharmacy and therapeutics committee; use of formulary. A carrier, or a pharmacy benefits manager under contract with a carrier, shall establish a pharmacy and therapeutics committee. A carrier shall require its pharmacy and therapeutics committee or the pharmacy and therapeutics committee of the carrier's pharmacy benefits manager to use one or more formularies.

2. Pharmacy and therapeutics committee; no conflict of interest for members. A carrier, or a pharmacy benefits manager under contract with a carrier, may not allow a person with a conflict of interest, as described in paragraph A or B, to be a member of its pharmacy and therapeutics committee. A person may not serve as a member of a pharmacy and therapeutics committee if the person:

A. Is employed, or was employed within the preceding year, by a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor; or

B. Receives compensation, or received compensation within the preceding year, from a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.

3. Compensation prohibited. A carrier, or a pharmacy benefits manager under contract with a carrier, shall prohibit its pharmacy and therapeutics committee or any member of the committee from receiving any compensation from a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.

§4350-C. Access to records; audits

1. Requirements; record keeping. A carrier shall maintain and have the ability to access all data related to the administration and provision of prescription drug benefits under a health plan of a carrier, including, but not limited to:

A. The names, addresses, member identification numbers, protected health information and other personal information of covered persons; and

B. All contracts, documentation and records, including transaction and pricing data, related to the dispensing of prescription drugs to covered persons under the health plan.

2. Compliance with federal law. A sale or transaction involving the transfer of any records, information or data described in subsection 1 must comply with the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and the federal Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 and any regulations adopted pursuant to those laws.

3. Audit records. A carrier may audit all transaction records related to the dispensing of prescription drugs to covered persons under a health plan of the carrier. A carrier may conduct audits at a location of its choosing and with an auditor of its choosing.

4. Maintenance of records. A carrier shall maintain all records, information and data described in subsection 1 and all audit records described in subsection 3 for a period of no less than 5 years.

5. Authority of superintendent. Upon request, a carrier shall provide to the superintendent any records, contracts, documents or data held by the carrier or the carrier's pharmacy benefits manager for inspection, examination or audit purposes.

§4350-D. Treatment of pharmacy benefits manager compensation

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Anticipated loss ratio" means the ratio of the present value of the future benefits payments to the present value of the future premiums of a policy form over the entire period for which rates are computed to provide health insurance coverage.

B. "Pharmacy benefits manager compensation" means the difference between:

(1) The value of payments made by a carrier of a health plan to its pharmacy benefits manager; and

(2) The value of payments made by the pharmacy benefits manager to dispensing pharmacists for the provision of prescription drugs or pharmacy services with regard to pharmacy benefits covered by the health plan.

2. Pharmacy benefits manager compensation included as administrative cost. If a carrier uses a pharmacy benefits manager to administer or manage prescription drug benefits provided for the benefit of covered persons, for purposes of calculating a carrier's anticipated loss ratio, any pharmacy benefits manager compensation:

A. Constitutes an administrative cost incurred by the carrier in connection with a health plan; and

B. May not constitute a benefit provided under a health plan.

A carrier may claim only the amounts paid by the pharmacy benefits manager to a pharmacy or pharmacist as an incurred claim.

3. Calculation of pharmacy benefits manager compensation. Each rate filing submitted by a carrier with respect to a health plan that provides coverage for prescription drugs or pharmacy services that is administered or managed by a pharmacy benefits manager must include:

A. A memorandum prepared by a qualified actuary describing the calculation of the pharmacy benefits manager compensation; and

B. Such records and supporting information as the superintendent reasonably determines is necessary to confirm the calculation of the pharmacy benefits manager compensation.

4. Records. Upon request, a carrier shall provide any records to the superintendent that relate to the calculation of the pharmacy benefits manager compensation.

5. Documentation from pharmacy benefits manager. A pharmacy benefits manager shall provide any necessary documentation requested by a carrier that relates to pharmacy benefits manager compensation in order to comply with the requirements of this section.

§4350-E. Effective date

This chapter takes effect January 1, 2020.

Sec. 9. Effective date. This Act takes effect January 1, 2020.

Effective January 1, 2020.

CHAPTER 470

S.P. 350 - L.D. 1162

An Act To Further Expand Drug Price Transparency

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §8703, sub-§1, as amended by PL 2003, c. 469, Pt. C, §22, is further amended to read:

1. Objective. The purposes of the organization are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in ~~section~~ sections 8712 and 8736. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. The organization shall collect, process, analyze and report clinical, financial, quality and restructuring data as defined in this chapter.

Sec. 2. 22 MRSA §8704, sub-§1, ¶A, as amended by PL 2003, c. 469, Pt. C, §23, is further amended to read:

A. The board shall develop and implement policies and procedures for the collection, processing, storage and analysis of clinical, financial, quality ~~and,~~ restructuring and prescription drug price data in accordance with this subsection for the following purposes:

(1) To use, build and improve upon and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts;

(2) To coordinate the development of a linked public and private sector information system;

(3) To emphasize data that is useful, relevant and not duplicative of existing data;