2023 South Dakota Legislature

House Bill 1135

ENROLLED

AN ACT

ENTITLED An Act to provide for transparency in the pricing of prescription drugs.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. That § 58-29E-1 be AMENDED:

58-29E-1. Terms used in this chapter mean:

(1) "Brand name," the same as set forth in § 36-11-2;

(2) "Covered individual," a member, participant, enrollee, contract holder, policy holder, or beneficiary of a third-party payor who is provided health coverage by the third-party payor. The term includes a dependent or other individual provided health coverage through a policy, contract, or plan for a covered individual;

(3) "Generic drug," a chemically equivalent copy of a brand name drug with an expired patent;

(4) "Health benefit plan," the same as set forth in § 58-17F-2;

(5) "Health carrier," the same as set forth in § 58-17F-1;

(6) "Interchangeable biological product," the same as set forth in § 36-11-2;

(7) "Maximum allowable cost," the maximum amount that a pharmacy may be reimbursed, as set by a pharmacy benefit manager or a third-party payor, for a brand name or a generic drug, an interchangeable biological product, or any other prescription drug and which may include:

(a) The average acquisition cost;

(b) The national average acquisition cost;

(c) The average manufacturer price;

(d) The average wholesale price;

(e) The brand effective rate;

(f) The generic effective rate;

(g) Discount indexing;

(h) Federal upper limits;

(i) The wholesale acquisition cost; and

(j) Any other term used by a pharmacy benefit manager or a health carrier to establish reimbursement rates for a pharmacy;

(8) "Maximum allowable cost list," a list of prescription drugs that:

(a) Includes the maximum allowable cost for each prescription drug; and

(b) Is used, directly or indirectly, by a pharmacy benefit manager;

(9) "Pharmaceutical manufacturer," any person engaged in the business of preparing, producing, converting, processing, packaging, labeling, or distributing a prescription drug, but not including a wholesale distributor or dispenser;

(10) "Pharmacist," the same as set forth in § 36-11-2;

(11) "Pharmacy," the same as set forth in § 36-11-2;

(12) "Pharmacy benefit management," the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals, the administration or management of prescription drug benefits provided by a third-party payor for the benefit of covered individuals, or any of the following services provided with regard to the administration of pharmacy benefits:

(a) Mail service pharmacy;

(b) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(c) Clinical formulary development and management services;

(d) Rebate contracting and administration;

(e) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(f) Disease management programs involving prescription drug utilization;

(13) "Pharmacy benefit management fee," a fee that covers the cost of providing pharmacy benefit management, but does not exceed the value of the service performed by the pharmacy benefit manager;

(14) "Pharmacy benefit manager," a person that performs pharmacy benefit management, pursuant to a contract or other relationship with a third-party payor and includes:

(a) A person acting in a contractual or employment relationship for a pharmacy benefit manager while providing pharmacy benefit management for a third party payor; and

(b) A mail service pharmacy;

(15) "Pharmacy benefit manager affiliate," a pharmacy that, or a pharmacist who, directly or indirectly, through one or more intermediaries, owns or controls, is owned and controlled by, or is under common ownership or control of, a pharmacy benefit manager;

(16) "Pharmacy network," pharmacies that have contracted with a pharmacy benefit manager to dispense or sell prescription drugs to covered individuals under a health benefit plan for which the prescription drug benefit is managed by a pharmacy benefit manager;

(17) "Prescription drug," a drug classified by the United States Food and Drug Administration as requiring a prescription by a health care practitioner, prior to being administered or dispensed to a patient, and including interchangeable biological products, brand names, and generic drugs;

(18) "Prescription drug benefit," a health benefit plan providing third-party payment or prepayment for prescription drugs;

(19) "Prescription drug order," the same as set forth in § 36-11-2;

(20) "Proprietary information," information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel held by a private entity and used for that private entity's business purposes;

(21) "Rebate," a discount or other negotiated price concession that is paid directly or indirectly to a pharmacy benefit manager by a pharmaceutical manufacturer or by an entity in the prescription drug supply chain, other than a covered individual, and which is:

(a) Based on a pharmaceutical manufacturer's list price for a prescription drug;

(b) Based on utilization;

(c) Designed to maintain, for the pharmacy benefit manager, a net price for a prescription drug, during a specified period of time, in the event the pharmaceutical manufacturer's list price increases; or

(d) Based on estimates regarding the quantity of a prescribed drug that will be dispensed by a pharmacy to covered individuals;

(22) "Spread pricing," an amount charged or claimed by a pharmacy benefit manager that is in excess of the ingredient cost for a dispensed prescription drug, plus a dispensing fee paid directly or indirectly to a pharmacy, pharmacist, or other provider, on behalf of the third-party payor, less a pharmacy benefit management fee;

(23) "Third-party payor," any entity, other than a covered individual, a covered individual's representative, or a healthcare provider, which is responsible for any amount of reimbursement for a prescription drug benefit, provided the term includes a health carrier and a health benefit plan;

(24) "Trade secret," the same as set forth in § 37-29-1;

(25) "Unaffiliated pharmacy," a dispensing pharmacy that is not:

(a) Owned, in whole or in part, by a pharmacy benefit manager;

(b) A subsidiary of a pharmacy benefit manager; or

(c) An affiliate of a pharmacy benefit manager; and

(26) "Wholesale distributor," the same as set forth in § 36-11A-25.

Section 2. That § 58-29E-2 be AMENDED:

58-29E-2. A person may not act as a pharmacy benefit manager in this state without a license to operate as a third party administrator pursuant to chapter 58-29D. Sections 58-29D-26, 58-29D-27, and 58-29D-29 do not apply to pharmacy benefits managers.

Section 3. That § 58-29E-3 be AMENDED:

58-29E-3. Each pharmacy benefit manager shall perform its duties in good faith and with fair dealing toward the third-party payor.

Section 4. That § 58-29E-4 be AMENDED:

58-29E-4. A third-party payor may request that a pharmacy benefit manager, with which it has a pharmacy benefit management services contract, disclose to the third-party payor the amount of all rebate revenues and the nature, type, and amounts of all other revenues that the pharmacy benefit manager receives from each pharmaceutical manufacturer with which the pharmacy benefit manager has a contract.

Annually, at the time of contract renewal, the pharmacy benefit manager shall disclose in writing:

(1) The aggregate amount, and for a list of drugs to be specified in the contract, the specific amount, of all rebates and other retrospective utilization discounts that are received by the pharmacy benefit manager, directly or indirectly, from each pharmaceutical manufacturer, and which are earned in connection with the dispensing of prescription drugs to covered individuals of the health benefit plans

issued by the third-party payor or for which the third-party payor is the designated administrator;

(2) The nature, type, and amount of all other revenue received by the pharmacy benefit manager, directly or indirectly, from each pharmaceutical manufacturer, for any other products or services, provided to the pharmaceutical manufacturer by the pharmacy benefit manager, with respect to programs that the third-party payor offers or provides to its covered individuals; and

(3) Any prescription drug utilization information requested by the third-party payor and relating to covered individuals.

A pharmacy benefit manager shall, within thirty days, provide the information requested in accordance with this section.

If requested, the information must be provided no less than once each year.

The contract entered into between the pharmacy benefit manager and the third-party payor must set forth any fees to be charged for drug utilization reports requested by the third-party payor.

Section 5. That § 58-29E-5 be AMENDED:

58-29E-5. A pharmacy benefit manager, unless authorized pursuant to the terms of its contract with a third-party payor, may not contact any covered individual, without the express written permission of the third-party payor.

Section 6. That § 58-29E-6 be AMENDED:

58-29E-6. Except for utilization information, a third-party payor shall maintain information disclosed in response to a request under § 58-29E-4 as confidential and proprietary information, and may not use that information for any other purpose or disclose that information to any other person, except as provided in this chapter or in the pharmacy benefit management services contract between the parties.

A third-party payor that discloses information, in violation of this section, is subject to an action for injunctive relief and is liable for any damages that are the direct and proximate result of the disclosure.

Nothing in this section prohibits a third-party payor from disclosing confidential or proprietary information to the director, upon request. Information obtained by the director in accordance with this section is confidential and privileged, and is not open to public inspection or disclosure.

Section 7. That § 58-29E-7 be AMENDED:

58-29E-7. A third-party payor that has contracted with a licensed pharmacy benefit manager may audit the pharmacy benefit manager once each calendar year. The audit authorized by this section is in addition to any other statutory or contractual audit rights. As part of the audit, a third-party payor may request:

(1) All reimbursements paid to retail pharmacies, on a claim level, for all customers of the pharmacy benefit manager in this state, including ancillary charges, claw backs, dispensing fees, drug-specific reimbursements, other fees, rebates, and reimbursement adjustments;

(2) Differences in reimbursement amounts paid to affiliated and unaffiliated pharmacies, including differences in dispensing fees and reimbursed ingredient costs;

(3) Historical claims data, including:

(a) Acquisition costs;

(b) Administrative fees associated with claims;

(c) Amounts paid by a covered individual;

(d) Amounts paid by a third-party payor;

(e) Channels, whether mail or retail;

(f) Dispensing fees;

(g) Formulary tiers;

(h) Ingredient costs;

(i) Ingredient quantity;

(j) Sales tax;

(k) Supply availability by the number of days; and

(l) Usual and customary prices; and

(4) Aggregate rebate amounts, received by calendar quarter, directly or indirectly from manufacturers, including rebates from other entities affiliated with or related to the pharmacy benefit manager, if those entities negotiate or contract with manufacturers.

A pharmacy benefit manager shall, within thirty days, provide the information requested in accordance with this section, together with a certification, signed by the chief executive officer or the chief financial officer of the pharmacy benefit manager, attesting to the accuracy and completeness of the information.

Section 8. That chapter 58-29E be amended with a NEW SECTION:

Except as provided in chapter 58-17K, and in accordance with the audit provisions in § 58-29E-7, a third-party payor that has contracted with a licensed pharmacy benefit manager may not publish, or directly or indirectly disclose:

(1) Any information that reveals the identity of a specific third-party payor or manufacturer;

(2) Prices charged for a specific drug or class of drugs;

(3) The amount of any rebates provided for a specific drug or class of drugs; or

(4) Any information that has the potential to compromise the financial, competitive, or proprietary nature of the pharmacy benefit manager's business.

The information referenced in § 58-29E-7 is protected from disclosure as confidential and proprietary. The information is privileged and not open to public inspection or disclosure.

A third-party payor that has contracted with a licensed pharmacy benefit manager shall impose the confidentiality protections set forth in § 58-29E-7 on any vendor or third party that may receive or have access to the information.

Section 9. That § 58-29E-8 be AMENDED:

58-29E-8. A pharmacy benefit manager may request that a lower-priced generic and therapeutically equivalent prescription drug be dispensed to a covered individual, as a substitute for a higher-priced prescription drug.

If the substitute prescription drug's net cost is higher for the covered individual or the third-party payor than the originally prescribed drug, the substitution may be made only for medical reasons that benefit the covered individual.

If a substitution is being requested pursuant to this section, the pharmacy benefit manager must obtain the approval of the prescribing health professional.

Nothing in this section permits the substitution of an equivalent drug product contrary to § 36-11-46.2.

Section 10. That § 58-29E-8.1 be AMENDED:

58-29E-8.1. A pharmacy benefit manager may neither prohibit a pharmacist or pharmacy from, nor penalize a pharmacist or pharmacy for , informing a covered individual about:

(1) The cost of a prescription drug;

(2) The amount of reimbursement that the pharmacy will receive for dispensing the prescription drug;

(3) The cost and clinical efficacy of a more affordable alternative prescription drug, if one is available; and

(4) Any differential between the amount a covered individual would pay under the covered individual's prescription drug benefit and a lower price the covered individual would pay for the prescription drug, if the covered individual obtained the prescription drug without making a claim for benefits on the covered individual's prescription drug benefit.

Section 11. That § 58-29E-10 be AMENDED:

58-29E-10. A third-party payor may bring a civil action to enforce this chapter or seek civil damages for a violation of this chapter.

Section 12. That § 58-29E-12 be AMENDED:

58-29E-12. A pharmacy benefit manager may not contractually require a pharmacy that is a participating provider in a health benefit plan provided by a third-party payor, from charging a covered individual or collecting from a covered individual a cost share for a prescription drug or pharmacy service that exceeds the amount retained by the pharmacist or pharmacy from all payment sources, for filling the prescription or providing the pharmacy service.

Section 13. That § 58-29E-13 be AMENDED:

58-29E-13. A pharmacy benefit manager may not, directly or indirectly, retroactively adjust a claim for reimbursement submitted by a pharmacy for a prescription drug, unless:

(1) The adjustment is necessitated by a pharmacy audit conducted in accordance with chapter 58-29F;

(2) The adjustment is necessitated by a technical billing error;

(3) The original claim was found to have been fraudulently submitted; or

(4) The claim submission was a duplicate for which the pharmacy had already received payment.

Section 14. That chapter 58-29E be amended with a NEW SECTION:

A pharmacy benefit manager may not assess, charge, or collect, from a pharmacy or pharmacist, any remuneration or fee, including:

(1) An accreditation fee;
(2) A brand effective rate fee;
(3) A claim processing fee;
(4) A credentialing fee;
(5) A dispensing fee;
(6) An effective rate fee;
(7) A generic effective rate fee;
(8) A pharmacy network participation fee; and
(9) A performance-based fee.

Section 15. That chapter 58-29E be amended with a NEW SECTION:

Prior to placing a prescription drug on a maximum allowable cost list, a pharmacy benefit manager shall ensure that the prescription drug is:

(1) Listed as therapeutically and pharmaceutically equivalent in the latest edition of, or any supplement to, the Food and Drug Administration's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, as adopted by the State Board of Pharmacy, in rules promulgated pursuant to chapter 1-26;
(2) Not obsolete or temporarily unavailable; and
(3) Available for purchase, without limitation, by every pharmacy in this state, from a national or regional wholesale distributor licensed in this state.

Section 16. That chapter 58-29E be amended with a NEW SECTION:

A pharmacy benefit manager shall:

(1) Provide each pharmacy in a pharmacy network with reasonable access to each maximum allowable cost list to which the pharmacy is subject;
(2) Update a maximum allowable cost list, within seven calendar days from the date of any increase, at or above ten percent, in the price charged for a prescription drug on the list by one or more wholesale distributors doing business in this state;
(3) Update the maximum allowable cost list, within seven calendar days from the date of any change in the methodology, or any change in the value of a variable applied in the methodology, on which the maximum allowable cost list is based; and
(4) Provide a process under which each pharmacy in a pharmacy network may receive prompt notice of any change in a maximum allowable cost list to which the pharmacy is subject.

Section 17. That chapter 58-29E be amended with a NEW SECTION:

A pharmacy benefit manager may not reimburse any pharmacy located in this state an amount that is less than that which the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for dispensing the same prescription drug as that dispensed by the pharmacy.

The reimbursement amount must be calculated on a per unit basis, using the same generic product identifier or generic code number.

Section 18. That chapter 58-29E be amended with a NEW SECTION:

A pharmacy benefit manager licensed under this chapter shall, at the request of the Division of Insurance, provide:

(1) The amount charged or claimed by the pharmacy benefit manager, in a format that allows the division to identify all instances of spread pricing; and

(2) Information regarding a shared ownership interest by any person defined in § 58-29E-1.

Section 19. That chapter 58-29E be amended with a NEW SECTION:

In addition to any grounds set forth in § 58-29D-31, the director may deny a pharmacy benefit manager's application for an initial or a renewed license, and may suspend or revoke a pharmacy benefit manager's license, if the director determines that the pharmacy benefit manager, or an applicant for a license, failed to provide information as required by this chapter.

Section 20. That § 58-29E-11 be REPEALED.

An Act to provide for transparency in the pricing of prescription drugs.

I certify that the attached Act originated in the:

House as Bill No. 1135

_____
Chief Clerk

_____
Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1135
File No. ____
Chapter No. _____

Received at this Executive Office
this _____ day of _____,

2023 at _____M.

By _____
for the Governor

The attached Act is hereby
approved this _____ day of
_____, A.D., 2023

_____
Governor

STATE OF SOUTH DAKOTA,

ss.

Office of the Secretary of State

Filed _____, 2023
at _____ o'clock __M.

_____
Secretary of State

By _____
Asst. Secretary of State