

2022 South Dakota Legislature

Senate Bill 163**AMENDMENT 163D FOR THE SENATE HEALTH AND HUMAN SERVICES ENGROSSED BILL**1 **An Act to address transparency in prescription drug pricing.**

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

3 **Section 1. That § 58-29E-1 be AMENDED:**4 **58-29E-1.** Terms used in this chapter mean:

- 5 (1) ~~"Covered entity," a nonprofit hospital or medical service corporation, health insurer,~~
6 ~~health benefit plan, or health maintenance organization; a health program~~
7 ~~administered by a department or the state in the capacity of provider of health~~
8 ~~coverage; or an employer, labor union, or other group of persons organized in the~~
9 ~~state that provides health coverage to covered individuals who are employed or~~
10 ~~reside in the state. The term does not include a self-funded plan that is exempt~~
11 ~~from state regulation pursuant to ERISA, a plan issued for coverage for federal~~
12 ~~employees, or a health plan that provides coverage only for accidental injury,~~
13 ~~specified disease, hospital indemnity, medicare supplement, disability income,~~
14 ~~long-term care, or other limited benefit health insurance policies and contracts;~~
- 15 (2) "Covered individual," a member, participant, enrollee, contract holder, policy
16 holder, or beneficiary of a covered entity third-party payor who is provided health
17 coverage by the covered entity third-party payor. The term includes a dependent
18 or other person provided health coverage through a policy, contract, or plan for a
19 covered individual;
- 20 (2) "Director," the director of the Division of Insurance;
- 21 (3) "Generic drug," a chemically equivalent copy of a brand-name drug with an expired
22 patent;
- 23 (4) "Labeler," an entity or person that receives prescription drugs from a manufacturer
24 or wholesaler and repackages those drugs for later retail sale and that has a labeler
25 code from the federal Food and Drug Administration under 21 C.F.R. § 270.20
26 (1999);

- 1 ~~(6)~~(5) "Maximum allowable cost list," any listing of pharmaceutical products, or method
2 for calculating reimbursement amounts, used by a pharmacy benefit manager,
3 directly or indirectly, to establish the maximum allowable cost on which
4 reimbursement payment, to a pharmacy or pharmacist, may be based for
5 dispensing a prescription pharmaceutical product, including:
6 (a) Average acquisition cost;
7 (b) Average manufacturer price;
8 (c) Average wholesale price;
9 (d) Brand effective rate or generic effective rate;
10 (e) Discount indexing;
11 (f) Federal upper limits;
12 (g) National average drug acquisition cost;
13 (h) Wholesale acquisition cost; and
14 (i) Any other factor used by a pharmacy benefit manager or a third-party payor
15 to establish reimbursement rates to a pharmacy or pharmacist for
16 pharmaceutical products;
17 (6) "National Drug Code," a unique, three-segment numeric identifier assigned to each
18 medication in accordance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.
19 § 360 (as of January 1, 2022);
20 (7) "Pharmaceutical product," a generic drug, brand-name drug, biologic, or other
21 prescription drug, vaccine, or device;
22 (8) "Pharmaceutical wholesaler," a person who:
23 (a) Sells and distributes, directly or indirectly, pharmaceutical products and
24 over-the-counter pharmaceuticals; and
25 (b) Offers regular or private delivery to a pharmacy;
26 (9) "Pharmacy acquisition cost," the amount that a pharmaceutical wholesaler charges
27 for a pharmaceutical product, as listed on the pharmacy's billing invoice;
28 (10) "Pharmacy ~~benefits~~-benefit management," the procurement of prescription drugs at
29 a negotiated rate for dispensation within this state to ~~covered~~ individuals, the
30 administration or management of prescription drug benefits provided by a ~~covered~~
31 entity ~~third-party payor~~ for the benefit of ~~covered~~ individuals, or any of the
32 following services provided with regard to the administration of the following
33 pharmacy benefits:
34 (a) Mail service pharmacy;

- 1 (b) Claims processing, retail network management, and payment of claims to
2 pharmacies for prescription drugs dispensed to covered individuals;
3 (c) Clinical formulary development and management services;
4 (d) Rebate contracting and administration;
5 (e) Certain patient compliance, therapeutic intervention, and generic substitution
6 programs; and
7 (f) Disease management programs involving prescription drug utilization;
- 8 ~~(7)~~(11) "Pharmacy ~~benefits~~benefit manager," ~~an entity that~~a person who performs
9 pharmacy ~~benefits~~benefit management. The term includes a person or entity
10 acting for a pharmacy benefits manager in a contractual or employment
11 relationship in the performance of pharmacy benefits management for a covered
12 entity and includes mail service pharmacy. The term does not include a health
13 carrier that is licensed pursuant to Title 58 when the health carrier or its subsidiary
14 is ~~providing and relies on its own employees to provide~~ pharmacy ~~benefits~~benefit
15 management to its own insureds; or a public self-funded pool or a private single
16 employer self-funded plan that provides such benefits or services directly to its
17 beneficiaries services and does not rely on the services of an affiliate, subsidiary,
18 or any unrelated entity that otherwise qualifies as a pharmacy benefit manager
19 through the performance of pharmacy benefit management services;
- 20 ~~(8)~~(12) "Pharmacy benefit manager affiliate," a pharmacy that or a pharmacist who,
21 directly or indirectly, through one or more intermediaries:
22 (a) Owns or controls a pharmacy benefit manager;
23 (b) Is owned or controlled by a pharmacy benefit manager; or
24 (c) Is under common ownership or control with a pharmacy benefit manager;
- 25 (13) "Pharmacy benefit plan or program," a plan or program that pays for, reimburses,
26 covers the cost of, or otherwise provides for pharmaceutical products to individuals
27 who reside in, or are employed in, this state;
- 28 (14) "Pharmacy service administrative organization," an organization that has the
29 authority to contract with a pharmacy benefit manager on behalf of multiple
30 independently owned pharmacies;
- 31 (15) "Proprietary information," information on pricing, costs, revenue, taxes, market
32 share, negotiating strategies, customers, and personnel held by private entities
33 and used for that private entity's business purposes;
- 34 ~~(9)~~(16) "Third-party payor," any person involved in the financing of a pharmacy benefit
35 plan or program, other than:

- 1 (a) The patient;
 2 (b) A health care provider;
 3 (c) The sponsor of a plan that is subject to regulation under Medicare Part D,
 4 42 U.S.C. § 1395w-101, et seq., as of January 1, 2022; or
 5 (d) A plan administered by South Dakota Medicaid; and
 6 (17) "Trade secret," information, including a formula, pattern, compilation, program,
 7 device, method, technique, or process, that:
 8 (a) Derives independent economic value, actual or potential, from not being
 9 generally known to, and not being readily ascertainable by proper means
 10 by, other persons who can obtain economic value from its disclosure or use;
 11 and
 12 (b) Is the subject of efforts that are reasonable under the circumstances to
 13 maintain its secrecy;~~and~~
 14 ~~(18) "340B entity," an entity participating in the federal drug discount program, as~~
 15 ~~described in section 340B of the Public Health Service Act, 42 U.S.C. § 256b, as of~~
 16 ~~January 1, 2022.~~

17 **Section 2. That § 58-29E-3 be AMENDED:**

18 **58-29E-3.** Each pharmacy ~~benefits~~benefit manager shall perform its duties
 19 exercising good faith and fair dealing toward the ~~covered entity~~third-party payor.

20 **Section 3. That chapter 58-29E be amended with a NEW SECTION:**

21 Before a pharmacy benefit manager places or provides for the continued placement
 22 of a pharmaceutical product on a maximum allowable cost list, the pharmacy benefit
 23 manager shall ensure that:

- 24 (1) The product:
 25 (a) Is listed as therapeutically equivalent and pharmaceutically equivalent A-
 26 or B-rated in the United States Food and Drug Administration's most recent
 27 edition of Approved Drug Products with Therapeutic Equivalence Evaluations
 28 or on the United States Food and Drug Administration's most recent list of
 29 approved animal drug products; or
 30 (b) Has an NR rating, an NA rating, or a similar rating by a nationally recognized
 31 drug compendia provider;
 32 (2) The product is available for purchase by any pharmacy in this state, from national
 33 or regional wholesalers operating in this state; and

- 1 (3) The product is not obsolete.
2 For purposes of this section, the term, NR, means not rated, and the term, NA,
3 means not available.

4 **Section 4. That chapter 58-29E be amended with a NEW SECTION:**

- 5 A pharmacy benefit manager shall:
6 (1) Provide each pharmacy that is subject to the maximum allowable cost list with
7 notification of any changes to the list;
8 (2) Provide each pharmacy that is subject to the maximum allowable cost list with
9 access to the list; and
10 (3) Update the maximum allowable cost list within seven calendar days if:
11 (a) Pharmacy acquisition costs from at least sixty percent of the pharmaceutical
12 wholesalers doing business in the state increase by ten percent or more
13 over the previously listed cost;
14 (b) There is a change in the methodology on which the maximum allowable cost
15 list is based; or
16 (c) There is a change in the value of a variable involved in the methodology.

17 **Section 5. That chapter 58-29E be amended with a NEW SECTION:**

- 18 A pharmacy benefit manager shall establish an administrative procedure by which
19 a pharmacy may appeal determinations regarding the maximum allowable costs and
20 reimbursements for a specific pharmaceutical product as:
21 (1) Not meeting the requirements set forth in this chapter; or
22 (2) Being below the pharmacy acquisition cost.

23 **Section 6. That chapter 58-29E be amended with a NEW SECTION:**

- 24 The administrative procedure required under section 5 of this Act must:
25 (1) Provide a telephone number, email address, and website, for initiating an appeal;
26 (2) Provide that an appeal may be filed directly with the pharmacy benefit manger or
27 through a pharmacy service administrative organization; and
28 (3) Establish a period within which any appeal is to be filed, provided the period is at
29 least seven days.

30 **Section 7. That chapter 58-29E be amended with a NEW SECTION:**

1 If an appeal is filed in accordance with the administrative procedure set forth in
2 section 5 of this Act, the pharmacy benefit manager shall, within seven days of receipt:

3 (1) Find that the appeal is merited and:

4 (a) Make the change in the maximum allowable cost;

5 (b) Permit the appealing pharmacy or pharmacist to reverse and re-bill the
6 claim in question;

7 (c) Provide to the pharmacy or pharmacist the National Drug Code on which
8 the change is based; and

9 (d) Ensure that the change made under this subsection is effective for each
10 similarly situated pharmacy, as defined by the payor, subject to the
11 maximum allowable cost list; or

12 (2) Find that the appeal is not merited and provide to the appealing pharmacy or
13 pharmacist the National Drug Code and the name of the national or regional
14 pharmaceutical wholesalers who are operating in this state and have the drug in
15 stock at a price below that on the maximum allowable cost list.

16 If the National Drug Code provided by the pharmacy benefit manager is not
17 available below the pharmacy acquisition cost of the pharmaceutical wholesaler from
18 whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale,
19 the pharmacy benefit manager shall adjust the maximum allowable cost, as listed on the
20 maximum allowable cost list, above the appealing pharmacy's acquisition cost and permit
21 the appealing pharmacy to reverse and re-bill each claim affected by the inability to
22 procure the drug at a cost that is equal to or less than the previously appealed maximum
23 allowable cost.

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

25 A pharmacy benefit manager may not reimburse a pharmacy or pharmacist in the
26 state an amount less than the amount that the pharmacy benefit manager reimburses a
27 pharmacy benefit manager affiliate for providing the same pharmacist services.

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

30 **Section 9. That chapter 58-29E be amended with a NEW SECTION:**

31 A pharmacy or pharmacist may decline to provide a pharmaceutical product to a
32 patient or pharmacy benefit manager if, as a result of a maximum allowable cost list, a

1 pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the
2 pharmacy providing the pharmaceutical product.

3 **Section 10. That chapter 58-29E be amended with a NEW SECTION:**

4 A pharmacy benefit manager may not:

5 (1) Assess, charge, or collect any form of remuneration or fees from a pharmacy or
6 pharmacist, including brand effective rate fees, claim processing fees,
7 credentialling fees, dispensing fee effective rate fees, generic effective rate fees,
8 network participation fees, and performance-based fees; or

9 (2) Directly or indirectly deny or reduce a claim after the claim has been adjudicated,
10 unless:

11 (a) The original claim was submitted fraudulently; or

12 (b) The original claim payment was incorrect because the pharmacy or
13 pharmacist had already been paid for the pharmaceutical product.

14 **~~Section 11. That chapter 58-29E be amended with a NEW SECTION:~~**

15 ~~A pharmacy benefit manager may not:~~

16 ~~(1) Take any action that prevents a 340B entity from dispensing drugs purchased under~~
17 ~~section 340B of the Public Health Service Act, 42 U.S.C. § 256b, as of January 1, 2022, to~~
18 ~~patients of the 340B entity;~~

19 ~~(2) Refuse to contract with a 340B entity or impose on a 340B entity any contracting standards~~
20 ~~that differ from those imposed on a non-340B entity;~~

21 ~~(3) By contract, provider manual, or any other means:~~

22 ~~(a) Modify the definition of a pharmacy, as set forth in chapter 36-11;~~

23 ~~(b) Provide a lower reimbursement for a drug purchased under section 340B than that~~
24 ~~provided for the same drug if purchased by a non-340B entity pharmacy in the same class of~~
25 ~~trade;~~

26 ~~(c) Impose, on a 340B entity, any fee, chargeback, financial or other adjustment, or claims-~~
27 ~~related information, which is not imposed, in the same manner, on a non-340B entity;~~

- 1 ~~(d) Prevent or otherwise interfere with the ability of covered individuals to receive drugs from~~
2 ~~a 340B entity of the individual's choice, including through mail order pharmacy services; or~~
- 3 ~~(e) Require or compel the submission of ingredient costs, pricing data, or any other data~~
4 ~~pertaining to drugs purchased under section 340B.~~

5 **Section 11. That § 58-29E-4 be AMENDED:**

6 **58-29E-4.** A ~~covered entity~~third-party payor may request that any pharmacy
7 ~~benefits-benefit manager~~ with which it has a pharmacy ~~benefits-benefit management~~
8 services contract disclose to ~~the covered entity~~ it, the amount of all rebate revenues and
9 the nature, type, and amounts of all other revenues that the pharmacy ~~benefits-benefit~~
10 manager receives from each pharmaceutical manufacturer or labeler with whom the
11 pharmacy ~~benefits-benefit manager~~ has a contract. The pharmacy ~~benefits-benefit~~
12 manager shall disclose in writing:

- 13 (1) The aggregate amount, and for a list of drugs to be specified in the contract, the
14 specific amount, of all rebates and other retrospective utilization discounts received
15 by the pharmacy ~~benefits-benefit manager~~, directly or indirectly, from each
16 pharmaceutical manufacturer or labeler ~~that~~, which are earned in connection with
17 the dispensing of prescription drugs to covered individuals of the health benefit
18 plans issued by the ~~covered entity~~third-party payor, or for which the ~~covered entity~~
19 third-party payor is the designated administrator;
- 20 (2) The nature, type, and amount of all other revenue received by the pharmacy
21 ~~benefits-benefit manager~~, directly or indirectly, from each pharmaceutical
22 manufacturer or labeler for any other products or services provided to the
23 pharmaceutical manufacturer or labeler by the pharmacy ~~benefits-benefit manager~~,
24 with respect to programs that the ~~covered entity~~third-party payor offers or
25 provides to its enrollees; and
- 26 (3) Any prescription drug utilization information requested by the ~~covered entity~~third-
27 party payor, relating to covered individuals.

28 A pharmacy ~~benefits-benefit manager~~ shall provide ~~such~~the information requested
29 by the ~~covered entity~~third-party payor for ~~such~~ disclosure within thirty days of receipt of
30 the request. If requested, the information ~~shall~~must be provided no less than once each
31 year. The contract entered into between the pharmacy ~~benefits-benefit manager~~ and the
32 ~~covered entity~~third-party payor must set forth any fees to be charged for drug
33 utilization reports requested by the ~~covered entity~~third-party payor.

1 **Section 12. That § 58-29E-5 be AMENDED:**

2 **58-29E-5.** A pharmacy benefits manager, unless authorized pursuant to the terms
3 of its contract with a ~~covered entity~~third-party payor, may not contact any covered
4 individual without express written permission of the ~~covered entity~~third-party payor.

5 **Section 13. That § 58-29E-6 be AMENDED:**

6 **58-29E-6.** Except for utilization information, a ~~covered entity~~third-party payor
7 shall maintain any information disclosed in response to a request pursuant to § 58-29E-4
8 as confidential and proprietary information, and may not use such information for any
9 other purpose, or disclose ~~such that~~ information to any other person, except as provided
10 in this chapter, or in the pharmacy ~~benefits~~benefit management services contract
11 between the parties.~~Any covered entity who~~

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

15 Nothing in this section prohibits a ~~covered entity~~third-party payor from disclosing
16 confidential or proprietary information to the director, upon request. Any ~~such~~ information
17 obtained by the director is confidential and privileged and is not open to public inspection
18 or disclosure.

19 **Section 14. That § 58-29E-7 be AMENDED:**

20 **58-29E-7.** ~~The covered entity~~A third-party payor may have the pharmacy ~~benefits~~
21 benefit manager's books and records related to the rebates or other information described
22 in subdivisions ~~58-29E-4(1), (2), and (3)~~§ 58-29E-4, to the extent the information relates
23 directly or indirectly to ~~such covered entity's~~the third-party payor's contract, audited in
24 accordance with the terms of the pharmacy ~~benefits~~benefit management services contract
25 between the parties. ~~However, if~~If the parties have not expressly provided for audit rights
26 and the pharmacy ~~benefits~~benefit manager has advised the ~~covered entity~~third-party
27 payor that other reasonable options are available and subject to negotiation, the ~~covered~~
28 entitythird-party payor may have ~~such the~~ books and records audited as follows:

29 (1) ~~Such~~The audits may be conducted no more frequently than once in each
30 twelve-month period, upon ~~not less than~~at least thirty business days' written notice
31 to the pharmacy ~~benefits~~benefit manager;

- 1 (2) The ~~covered entity third-party payor~~ may select an independent firm to conduct
2 ~~such the~~ audit, ~~and such~~. The independent firm shall sign a confidentiality
3 agreement with the ~~covered entity third-party payor~~ and the pharmacy ~~benefits~~
4 benefit manager, ensuring that all information obtained during ~~such the~~ audit will
5 be treated as confidential. The firm may not use, disclose, or otherwise reveal any
6 ~~such of the~~ information, in any manner or form, to any person ~~or entity~~, except as
7 otherwise permitted under the confidentiality agreement. The ~~covered entity third-~~
8 party payor shall treat all information obtained as a result of the audit as
9 confidential, and may not use or disclose ~~such that~~ information, except as ~~may be~~
10 ~~otherwise~~ permitted under the terms of the contract between the ~~covered entity~~
11 third-party payor and the pharmacy ~~benefits~~ benefit manager, or if ordered by a
12 court of competent jurisdiction, for good cause shown;
- 13 (3) ~~Any such~~ An audit ~~shall under this section must be~~ conducted at the pharmacy
14 ~~benefits~~ benefit manager's office where ~~such the~~ records are located, during normal
15 business hours, without undue interference with the pharmacy ~~benefits~~ benefit
16 manager's business activities, and in accordance with reasonable audit procedures.

17 **Section 15. That § 58-29E-8 be AMENDED:**

18 **58-29E-8.** With regard to the dispensation of a substitute prescription drug for a
19 prescribed drug to a covered individual, when the pharmacy ~~benefits~~ benefit manager
20 requests a substitution, the following provisions apply:

- 21 (1) The pharmacy ~~benefits~~ benefit manager may request the substitution of a
22 lower- priced generic and therapeutically equivalent drug for a higher-priced
23 prescribed drug;
- 24 (2) With regard to substitutions in which the substitute drug's net cost is more for the
25 covered individual or the ~~covered entity third-party payor~~ than the prescribed drug,
26 the substitution must be made only for medical reasons that benefit the covered
27 individual. If a substitution is being requested pursuant to this subdivision, the
28 pharmacy ~~benefits~~ benefit manager shall obtain the approval of the prescribing
29 health professional.

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

32 **Section 16. That § 58-29E-8.1 be AMENDED:**

1 **58-29E-8.1.** A pharmacy ~~benefits benefit~~ manager may ~~neither prohibit nor not~~
2 ~~restrict or penalize a pharmacy or pharmacist or pharmacy for providing cost-sharing~~
3 ~~information on the amount a covered individual may pay for a particular prescription drug~~
4 ~~for informing a patient about:~~

5 (1) The cost of a prescription pharmaceutical product;

6 (2) The amount of reimbursement that the pharmacy will receive for dispensing the
7 prescription pharmaceutical product;

8 (3) The cost and clinical efficacy of a more affordable alternative pharmaceutical
9 product, if one is available; or

10 (4) Any differential between the amount the patient would pay under the patient's
11 prescription benefit plan or program and a lower price the patient would pay for
12 the prescription pharmaceutical product, if the patient obtained the pharmaceutical
13 product without making a claim for benefits on the patient's prescription benefit
14 plan or program.

15 **Section 17. That § 58-29E-9 be AMENDED:**

16 **58-29E-9.** The Division of Insurance shall promulgate rules, pursuant to chapter
17 1-26, to carry out the issuance of the license required by § 58-29E-2 and the enforcement
18 provisions of this chapter. The rules ~~may~~must include the following:

19 (1) Definition of terms;

20 (2) Use of prescribed forms;

21 (3) Reporting requirements;

22 (4) Enforcement procedures; and

23 (5) Protection of proprietary information and trade secrets.

24 **Section 18. That § 58-29E-10 be AMENDED:**

25 **58-29E-10.** Any ~~covered entity~~ third-party payor may bring a civil action to
26 enforce ~~the provisions of~~ this chapter or to seek civil damages for ~~the a~~ a violation of its
27 ~~provisions~~ this chapter.

28 **Section 19. That § 58-29E-11 be AMENDED:**

29 **58-29E-11.** ~~The provisions of~~ Except as otherwise provided in this section, this
30 chapter ~~apply~~ applies only to pharmacy ~~benefits benefit~~ management services contracts
31 entered into or renewed after June 30, 2004.

1 Sections 3 to 10, inclusive, of this Act, apply only to pharmacy benefit management
2 service contracts entered into or renewed after June 30, 2022.

3 **Section 20. That § 58-29E-12 be AMENDED:**

4 **58-29E-12.** ~~No~~ A pharmacy benefit manager ~~shall~~ may not contractually require
5 a pharmacy, who is a participating provider in a health plan provided by a ~~covered~~
6 ~~entity~~ third-party payor, to charge or collect, from an insured, a cost share for a
7 prescription or pharmacy service that exceeds the amount retained, by the pharmacist or
8 pharmacy, from all payment sources, for the filling of the prescription or providing the
9 pharmacy service.

10 **Section 21. That § 58-29E-13 be AMENDED:**

11 **58-29E-13.** ~~No~~ A pharmacy benefit manager contracting with a ~~covered~~ entity
12 ~~shall~~ third-party payor may not retroactively adjust a claim for reimbursement submitted
13 by a pharmacy for a prescription drug, unless the adjustment is a result of ~~either of the~~
14 following:

- 15 (1) A pharmacy audit conducted in accordance with chapter 58-29F; or
16 (2) A technical billing error.