CERTIFICATION OF ENROLLMENT

ENGROSSED SECOND SUBSTITUTE SENATE BILL 5981

Chapter 227, Laws of 2026

69th Legislature
2026 Regular Session

340B DRUG PRICING PROGRAM—VARIOUS PROVISIONS

EFFECTIVE DATE: June 11, 2026

Passed by the Senate March 9, 2026
Yeas 30 Nays 19

DENNY HECK

President of the Senate

Passed by the House March 6, 2026
Yeas 67 Nays 30

LAURIE JINKINS

Speaker of the House of Representatives

Approved March 25, 2026 11:46 AM

BOB FERGUSON

Governor of the State of Washington

CERTIFICATE

I, Sarah Bannister, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **ENGROSSED SECOND SUBSTITUTE SENATE BILL 5981** as passed by the Senate and the House of Representatives on the dates hereon set forth.

SARAH BANNISTER

Secretary

FILED

March 25, 2026

Secretary of State
State of Washington

ENGROSSED SECOND SUBSTITUTE SENATE BILL 5981

AS AMENDED BY THE HOUSE

Passed Legislature - 2026 Regular Session

State of Washington 69th Legislature 2026 Regular Session

By Senate Ways & Means (originally sponsored by Senators Cleveland, Slatter, Harris, Bateman, Alvarado, Chapman, Dhingra, Frame, Hasegawa, Liias, Pedersen, Saldaña, and Valdez)

READ FIRST TIME 02/09/26.

AN ACT Relating to protecting the integrity of the 340B drug pricing program; amending RCW 43.71C.010, 43.71C.050, 43.71C.090, and 43.71C.100; adding new sections to chapter 43.71C RCW; adding a new chapter to Title 69 RCW; and prescribing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** (1) The legislature finds that the federal 340B drug pricing program is essential for providing health care access to low-income and uninsured populations. The 340B drug pricing program requires drug manufacturers to offer discounts on outpatient medications to eligible providers that serve these populations. They include federally qualified health centers, Ryan White (HIV) clinics, tribal and urban Indian health centers, critical access hospitals, and other safety net hospitals that meet stringent federal criteria.

(2) Congress created the 340B drug pricing program in 1992, stating that the program's benefits enable covered "entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384 (II), at 12 (1992)). The 340B drug pricing program allows certain safety net providers to sustain underfunded services and reinvest savings into essential community benefits, such as financial assistance for low-income patients, no-cost wellness

visits, screenings, vaccinations, transportation to appointments, health education classes, case management, medication adherence services, and workforce development programs.

(3) The federal health resources and services administration permits 340B covered entities to contract with pharmacies to enable access to life-saving drugs and drugs that preserve quality of life to eligible patients, including for those who otherwise have limited access.

(4) The 340B drug pricing program and contract pharmacies are crucial to Washington's safety net providers by ensuring patients can access their prescribed medications, while providing additional resources to 340B covered entities to serve vulnerable and underserved populations.

(5) More than 20 other states have recognized the importance of contract pharmacies to the 340B drug pricing program and have taken action to prohibit drug manufacturers from imposing restrictions on 340B covered entities' ability to serve patients through contract pharmacies.

(6) Federal courts, including the fifth and eighth circuit courts of appeals, have upheld states' authority to legislate on the distribution of 340B drugs through contract pharmacies.

(7) The current restrictions imposed by drug manufacturers not only limit a patient's access to affordable medication but also jeopardize the financial savings that safety net providers depend on to reinvest in their operations, expand services, and support underserved communities.

(8) The legislature, therefore, finds that prohibiting drug manufacturers from imposing restrictions on 340B covered entities is necessary to ensure the integrity of the 340B program and protect Washington's vulnerable patients, their access to medications, and safety net providers' ability to serve their patients.

(9) The legislature also finds that there is a vested state and public interest in providing transparency across the spectrum of 340B program participants to ensure the program is operating within the original intent set forth by congress.

(10) The legislature, therefore, finds that 340B program reporting capturing covered entities, contract pharmacies, and manufacturers is necessary to ensure the integrity of the program.

(11) To address the costs of such reporting, the legislature finds it necessary to implement a filing fee for the covered entities

and manufacturers that are required to report, which as of 2026, includes approximately 110 340B covered entities and 780 manufacturers. The legislature intends for responsibility for payment of filing fees to be based on this differential between covered entities and manufacturers.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "340B drug" means a drug that has been subject to an offer for reduced prices by a manufacturer under 42 U.S.C. Sec. 256b and is purchased by a covered entity.

(2) "Covered entity" means an entity authorized to participate in the federal 340B drug pricing program, as defined in 42 U.S.C. Sec. 256b(a)(4) as of the effective date of this section.

(3) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices. It includes an agent, contractor, or affiliate of a manufacturer.

(4) "Package" has the same meaning as in 21 U.S.C. Sec. 360eee(11)(A) as of the effective date of this section.

(5) "Pharmacy" has the same meaning as in RCW 18.64.011.

NEW SECTION. **Sec. 3.** (1) A manufacturer or a third party acting on behalf of a manufacturer may not, directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy that is under contract with a covered entity to receive and dispense a 340B drug on behalf of the covered entity, or any location authorized by a covered entity to receive such 340B drug, unless federal law prohibits receipt of the 340B drug.

(2) A manufacturer or a third party acting on behalf of a manufacturer may not, directly or indirectly, require a covered entity to submit any claims, utilization, purchasing, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy that is under contract with a covered entity to receive and dispense a 340B drug on behalf of the covered entity, or any location authorized by a covered entity to receive such 340B drug, unless federal law requires such data sharing.

NEW SECTION. **Sec. 4.** (1) In addition to any other remedy provided by law, a covered entity may file a civil action against a manufacturer or a third party acting on behalf of a manufacturer for a violation of this chapter. If a court finds that the manufacturer or third party acting on behalf of a manufacturer violated this chapter, the court may enjoin the violation and award a civil penalty of up to $5,000 per day for each violation, as well as reasonable attorneys' fees and costs. Each package of 340B drugs subject to a prohibited act under this chapter constitutes a separate violation.

(2) The attorney general may bring an action in the name of the state, or as parens patriae on behalf of persons residing in the state, to enforce this chapter. For actions brought by the attorney general to enforce the provisions of this chapter, the legislature finds that the practices covered by this chapter are matters vitally affecting the public interest for the purpose of applying the consumer protection act, chapter 19.86 RCW. For actions brought by the attorney general to enforce this chapter, a violation of this chapter is not reasonable in relation to the development and preservation of business and is an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying the consumer protection act, chapter 19.86 RCW.

(3) Nothing in this chapter is to be construed or applied to conflict with federal law and related regulations, including 21 U.S.C. Sec. 355-1, or other laws of this state, if the state law is compatible with applicable federal law.

NEW SECTION. **Sec. 5.** A new section is added to chapter 43.71C RCW to read as follows:

(1) Annually, on or before April 1st following the conclusion of the covered entity's fiscal year, a covered entity located in Washington that is a federally qualified health center as defined in 42 U.S.C. Sec. 1396d(l)(2)(B) or a hospital defined in 42 U.S.C. Sec. 256b(a)(4)(L) through (O) shall report the following information to the authority concerning the covered entity's participation in the 340B program for the previous fiscal year:

(a) The following information for the covered entity:

(i) Name;

(ii) Service address;

(iii) 340B program identification number;

(iv) Designation of entity type, as specified in 42 U.S.C. Sec. 256b(a)(4); and

(v) The national taxpayer identification number;

(b) The aggregate acquisition cost for all 340B drugs obtained under the 340B program and dispensed to applicable patients;

(c) The aggregate payment amount received for all 340B drugs obtained under the 340B program and dispensed to applicable patients;

(d) The aggregate acquisition cost for administered outpatient 340B drugs obtained under the 340B program and administered to applicable patients;

(e) The total savings on the 340B administered outpatient drugs based on the calculation of the difference between the aggregate acquisition cost of 340B drugs and the aggregate price of the drugs if not purchased through the 340B program;

(f) The aggregate acquisition cost for 340B drugs and aggregate payments made to pharmacies that are under contract with the covered entity to receive and dispense 340B drugs on behalf of the covered entity;

(g) The number of claims for prescription drugs described in (c) and (d) of this subsection;

(h) Using the most up-to-date and available data, how the covered entity uses any savings from participating in the 340B program including, but not limited to, the amount of savings used for the provision of charity care, community benefits, or a similar program of providing unreimbursed or subsidized health care;

(i) The aggregate payments made to any other entity that is not a covered entity and is not a contract pharmacy as described in (f) of this subsection for managing any aspect of the covered entity's 340B program;

(j) The aggregate payment made or expense for administering the 340B program;

(k) The aggregate number of prescription drugs dispensed to patients for which a payment was reported under (c) of this subsection and the estimated number of prescription drugs administered to patients for which a cost was reported under (d) of this subsection;

(l) The percentage of the covered entity's pharmacy claims that were for prescription drugs obtained under the 340B program; and

(m) The number and percentage of low-income patients of the covered entity that were served by a sliding fee scale for a prescription drug dispensed or administered under the 340B program.

(2) The information required to be reported under subsection (1) of this section must be reported by payer type, if the information is available to the covered entity, including the following:

(a) Commercial;

(b) Medicaid;

(c) Medicare; and

(d) Uninsured.

(3) The authority shall prepare a template reporting form for covered entities to use to fulfill the reporting requirements of this section.

(4)(a) The authority may issue a fine, in accordance with RCW 43.71C.090, of $1,000 per day for a covered entity that fails to provide the information required by this section by the date required.

(b) A covered entity must be afforded an opportunity to correct a violation of this section before a fine may be issued. If the covered entity provides the information required by this section within 30 calendar days of receiving the written notice of a violation, then the authority shall not issue a penalty.

NEW SECTION. **Sec. 6.** A new section is added to chapter 43.71C RCW to read as follows:

(1) For manufacturers and covered entities required to report 340B data to the authority under section 5 of this act and RCW 43.71C.050, the authority may establish a filing fee to support costs to administer the 340B data collection and reporting required by this chapter.

(2) The filing fee shall be set by the authority at a level necessary to cover the cost to the authority for collecting and reporting the 340B data. Manufacturers required to report data under RCW 43.71C.050 and covered entities required to report data under section 5 of this act shall pay the fee annually, in a form and manner determined by the authority.

(3) The filing fees must be established in accordance with the following:

(a) The filing fee for covered entities must be tiered based on the covered entity's gross operating revenue;

(b) The filing fee for manufacturers must be tiered in a manner determined by the authority; and

(c) The filing fees for covered entities and manufacturers must be set at levels that generally reflect the numbers of covered entities and manufacturers required to report under section 5 of this act and RCW 43.71C.050 and the authority's relative costs in collecting and reporting data from covered entities and manufacturers, except that the filing fee for covered entities must not be set at a level intended to cover more than 25 percent of the authority's costs for collecting and reporting 340B data.

(4) The authority may recommend modifications to the filing fee structure for covered entities and manufacturers in its annual report under RCW 43.71C.100.

(5) The filing fees must be deposited in the 340B program reporting account created under section 7 of this act.

(6) The authority may adopt rules to implement this section.

NEW SECTION. **Sec. 7.** A new section is added to chapter 43.71C RCW to read as follows:

The 340B program reporting account is created in the state treasury. All receipts from filing fees collected pursuant to section 6 of this act must be deposited into the account. Moneys in the account may be spent only after appropriation. Expenditures from the account may be used only by the authority and only for collecting and reporting data relating to the 340B drug pricing program.

Sec. 8. RCW 43.71C.010 and 2019 c 334 s 2 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "340B drug" means a drug that has been subject to an offer for reduced prices by a manufacturer under 42 U.S.C. Sec. 256b and is purchased by a covered entity.

(2) "Authority" means the health care authority.

((~~(2)~~)) (3) "Covered drug" means any prescription drug that:

(a) A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of ((~~ten thousand dollars~~)) $10,000 or more for a course of treatment lasting less than one month or a ((~~thirty~~)) 30-day supply, whichever period is longer; or

(b) Is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than ((~~one hundred dollars~~)) $100 for a course of treatment lasting less than one month or a ((~~thirty~~)) 30-day supply, and, taking into account only price increases that take effect after July 28, 2019, the manufacturer increases the wholesale acquisition cost at least:

(i) Twenty percent, including the proposed increase and the cumulative increase over one calendar year prior to the date of the proposed increase; or

(ii) Fifty percent, including the proposed increase and the cumulative increase over three calendar years prior to the date of the proposed increase.

((~~(3)~~)) (4) "Covered entity" means an entity authorized to participate in the federal 340B drug pricing program, as defined in 42 U.S.C. Sec. 256b(a)(4) as of the effective date of this section and is located in Washington.

(5) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

((~~(4)~~)) (6) "Health care provider," "health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

((~~(5)~~)) (7) "Pharmacy benefit manager" means the same as in RCW ((~~19.340.010~~)) 48.200.020.

((~~(6)~~)) (8) "Pharmacy services administrative organization" means an entity that contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payor, or other entities and provides administrative services to pharmacies.

((~~(7)~~)) (9) "Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.

((~~(8)~~)) (10) "Qualifying price increase" means a price increase described in subsection ((~~(2)~~)) (3)(b) of this section.

((~~(9)~~)) (11) "Wholesale acquisition cost" or "price" means, with respect to a prescription drug, the manufacturer's list price for the

drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of prescription drug pricing.

Sec. 9. RCW 43.71C.050 and 2019 c 334 s 6 are each amended to read as follows:

(1) Beginning October 1, 2019, a covered manufacturer must submit to the authority the following data for each covered drug:

(a) A description of the specific financial and nonfinancial factors used to make the decision to set or increase the wholesale acquisition cost of the drug. In the event of a price increase, a covered manufacturer must also submit the amount of the increase and an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug;

(b) The patent expiration date of the drug if it is under patent;

(c) Whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;

(d) The itemized cost for production and sales, including the annual manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials and regulation, and total cost for acquisition of the drug; and

(e) The total financial assistance given by the manufacturer through assistance programs, rebates, and coupons.

(2) For all qualifying price increases of existing drugs, a manufacturer must submit the year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(3) If a manufacturer increases the price of an existing drug it has manufactured for the previous five years or more, it must submit a schedule of wholesale acquisition cost increases for the drug for the previous five years.

(4) If a manufacturer acquired the drug within the previous five years, it must submit:

(a) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition; and

(b) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(5) Except as provided in subsection (6) of this section, a covered manufacturer must submit the information required by this section:

(a) At least ((~~sixty~~)) 60 days in advance of a qualifying price increase for a covered drug; and

(b) Within ((~~thirty~~)) 30 days of release of a new covered drug to the market.

(6) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on July 28, 2019, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on July 28, 2019, if submitting data in accordance with subsection (5)(a) of this section is not possible ((~~sixty~~)) 60 days before the price increase, that submission must be made as soon as known but not later than the date of the price increase.

(7) Before April 1st of each year, a manufacturer shall report the following information concerning the manufacturer's participation in the federal 340B drug pricing program, as established in 42 U.S.C. Sec. 256b, for the previous calendar year in a manner and format prescribed by the authority:

(a) The number of units, by drug, of 340B drugs distributed to each covered entity and contract pharmacy in Washington;

(b) The aggregate discounts, by drug, provided to each covered entity and contract pharmacy on 340B drugs reported in (a) of this subsection; and

(c) The average 340B discount on each of the top 25 340B drugs dispensed in the state by each manufacturer, including the percentage of the discount imposed due to inflationary rebate, as described in 42 U.S.C. Sec. 1396r-8(c)(2) (A) and (C), and the discount if it were not capped with a maximum rebate amount, as described in 42 U.S.C. Sec. 1396r-8(c)(2)(D).

(8) The information submitted pursuant to this section is not subject to public disclosure under chapter 42.56 RCW.

Sec. 10. RCW 43.71C.090 and 2019 c 334 s 11 are each amended to read as follows:

The authority may assess a fine of up to ((~~one thousand dollars~~)) $1,000 per day for failure to comply with the requirements of RCW 43.71C.020 through 43.71C.080 and sections 5 and 6 of this act. The assessment of a fine under this section is subject to review under

the administrative procedure act, chapter 34.05 RCW. Fines collected under this section must be deposited in the medicaid fraud penalty account created in RCW 74.09.215.

Sec. 11. RCW 43.71C.100 and 2022 c 153 s 11 are each amended to read as follows:

(1)(a) The authority shall compile and analyze the data submitted by health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations pursuant to this chapter and prepare an annual report for the public and the legislature synthesizing the data to demonstrate the overall impact that drug costs, rebates, and other discounts have on health care premiums.

(b) For data related to the 340B drug pricing program, the annual report shall include:

(i) Data submitted under RCW 43.71C.050(7) aggregated to not reveal information from specific manufacturers;

(ii) Data submitted under section 5(1) (a), (h) through (j), and (m) of this act by covered entity; and

(iii) Data submitted pursuant to section 5(1) (b) through (g), (k), and (l) of this act aggregated by entity type, as specified in 42 U.S.C. Sec. 256b(a)(4).

(c) The annual report must also include:

(i) The authority's costs for the preceding calendar year to collect and report data related to the 340B drug pricing program;

(ii) A description of the foreseeable necessary costs to the authority for collecting and reporting data related to the 340B drug pricing program, as used as the basis for the filing fee described in section 6 of this act; and

(iii) The amount of filing fees collected under section 6 of this act.

(2) ((~~The~~)) (a) Except as provided in (b) of this subsection, the data in the report must be aggregated and must not reveal information specific to individual health carriers, pharmacy benefit managers, pharmacy services administrative organizations, individual prescription drugs, individual classes of prescription drugs, individual manufacturers, or discount amounts paid in connection with individual prescription drugs.

(b) Data reported under section 5(1) (a), (h) through (j), and (m) of this act may be reported without further aggregation and may identify the manufacturer, covered entity, and contract pharmacy.

(3) Beginning January 1, 2021, and by each January 1st thereafter, the authority must publish the report on its website.

(4) Except for the report, data submitted under section 5(1) (a), (h) through (j), and (m) of this act, and as provided in subsection (5) of this section, the authority shall keep confidential all data submitted pursuant to ((~~RCW 43.71C.020 through 43.71C.080~~)) this chapter.

(5) For purposes of public policy, upon request of a Washington state legislator, the authority must provide all data provided pursuant to RCW 43.71C.020 through 43.71C.080, and section 5 of this act and any analysis prepared by the authority to the requesting legislator. Any information provided pursuant to this subsection is not subject to public disclosure under chapter 42.56 RCW and must be kept confidential within the legislature ((~~and may not be publicly released~~)).

(6) For the purpose of reviewing drug prices and conducting affordability reviews, the prescription drug affordability board, as established in chapter 70.405 RCW, and the health care cost transparency board, established in chapter 70.390 RCW, may access all data collected pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

(7) ((~~The~~)) (a) Except as provided in (b) of this subsection, the data collected pursuant to this chapter is not subject to public disclosure under chapter 42.56 RCW. Any information provided pursuant to this section must be kept confidential and may not be publicly released. Recipients of data under subsection (6) of this section shall:

((~~(a)~~)) (i) Follow all rules adopted by the authority regarding appropriate data use and protection; and

((~~(b)~~)) (ii) Acknowledge that the recipient is responsible for any liability arising from misuse of the data and that the recipient does not have any conflicts under the ethics in public service act that would prevent the recipient from accessing or using the data.

(b) Data submitted by covered entities under section 5(1) (a), (h) through (j), and (m) of this act is not confidential and may be publicly released.

NEW SECTION. **Sec. 12.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 13.** Sections 1 through 4 of this act constitute a new chapter in Title 69 RCW.

Passed by the Senate March 9, 2026.
Passed by the House March 6, 2026.
Approved by the Governor March 25, 2026.
Filed in Office of Secretary of State March 25, 2026.

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