

WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 5682

By Delegate Young

[Introduced February 13, 2024; Referred to the
Committee on Health and Human Resources then
Government Organization]

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section,
 2 designated §16-8C-1, §16-8C-2, §16-8C-3, §16-8C-4, §16-8C-5, §16-8C-6, §16-8C-7,
 3 §16-8C-8, §16-8C-9, §16-8C-10, §16-8C-11, §16-8C-12, §16-8C-13, §16-8C-14, §16-8C-
 4 15, and §16-8C-16 relating to establishing the West Virginia Prescription Drug Affordability
 5 Board, providing definitions, listing membership requirements for the board, creating the
 6 Prescription Drug Affordability Stakeholder Council and establishing requirements for
 7 membership on that council, establishing meeting requirements, prohibiting the
 8 acceptance of gratuities for the board and council members, requiring a study and report
 9 from the board and the council, outlining how data is to be collected, requiring a cost review
 10 of prescription drug products with affordability challenges, listing confidentiality
 11 requirements, providing for enforcement, establishing a fund, listing the process for setting
 12 upper payment limits for prescription drug products, listing eligible drug products, providing
 13 remedies, and listing all report requirements

Be it enacted by the Legislature of West Virginia:

ARTICLE 8C. WEST VIRGINIA PRESCRIPTION DRUG AFFORDABILITY BOARD.

§16-8C-1. West Virginia Prescription Drug Affordability Board established.

1 The purpose of the board is to protect West Virginia residents, state and local
 2 governments, commercial health plans, health care providers, pharmacies licensed in the state,
 3 and other stakeholders within the health care system from the high costs of prescription drug
 4 products.

§16-8C-2. Definitions.

- 1 (a) In this subtitle the following words have the meanings indicated.
- 2 (b) "Biologic" means a drug that is produced or distributed in accordance with a biologics
 3 license application approved under 42 C.F.R. § 447.502.
- 4 (c) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics
 5 license application approved under 42 U.S.C. § 262(k)(3).

6 (d) "Board" means the West Virginia Prescription Drug Affordability Board.

7 (e)(1) "Brand name drug" means a drug that is produced or distributed in accordance with
8 an original new drug application approved under 21 U.S.C. § 355(c).

9 (2) "Brand name drug" does not include an authorized generic as defined by 42 C.F.R. §
10 447.502.

11 (f) "Generic drug" means:

12 (1) A retail drug that is marketed or distributed in accordance with an abbreviated new drug
13 application, approved under 21 U.S.C. § 355(j);

14 (2) An authorized generic as defined by 42 C.F.R. § 447.502; or

15 (3) A drug that entered the market before 1962 that was not originally marketed under a
16 new drug application.

17 (g) "Manufacturer" means an entity that:

18 (1)(A) Engages in the manufacture of a prescription drug product; or

19 (B) Enters into a lease with another manufacturer to market and distribute a prescription
20 drug product under the entity's own name; and

21 (2) Sets or changes the wholesale acquisition cost of the prescription drug product it
22 manufactures or markets.

23 (h) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a
24 biosimilar.

25 (i) "Stakeholder Council" means the Prescription Drug Affordability Stakeholder Council.

§16-8C-3. Board members.

1 (a)(1) The board consists of the following members, who must have expertise in health
2 care economics or clinical medicine:

3 (A) One member appointed by the Governor;

4 (B) One member appointed by the President of the Senate;

5 (C) One member appointed by the Speaker of the House of Delegates;

6 (D) One member appointed by the Attorney General; and

7 (E) One member appointed by the Insurance Commissioner.

8 (2) The board shall have the following alternate members, who must have expertise in
9 health care economics or clinical medicine and who shall be designated by the board chair to
10 participate in deliberations of the board when a member is recused:

11 (A) One alternate member appointed by the Governor;

12 (B) One alternate member appointed by the President of the Senate; and

13 (C) One alternate member appointed by the Speaker of the House of Delegates.

14 (3) At least one member of the board shall have expertise in:

15 (i) The 340B Program under the federal Public Health Service Act;

16 (ii) The state's All-Payer Claims Database;

17 (iii) How the program and contract interact; and

18 (iv) How decisions made by the board will affect the model and contract.

19 (4) A member or an alternate member may not be an employee of, a board member of, or a
20 consultant to a manufacturer, pharmacy benefits manager, health insurance carrier, health
21 maintenance organization, managed care organization, or wholesale distributor or related trade
22 association.

23 (5) Any conflict of interest, including whether the individual has an association, including a
24 financial or personal association, that has the potential to bias or has the appearance of biasing an
25 individual's decision in matters related to the board or the conduct of the board's activities, shall be
26 considered and disclosed when appointing members and alternate members to the board.

27 (6) To the extent practicable and consistent with federal and state law, the membership of
28 the board shall reflect the racial, ethnic, and gender diversity of the state.

29 (b)(1) The term of a member or an alternate member is five years.

30 (2) The terms of the members and alternate members are staggered and will be
31 implemented as follows:

32 (A) The first term of the member appointed by the Governor shall begin in 2024 and end in
33 2026, with every other term being five years in length;

34 (B) The first terms of the members appointed by the President of the Senate and the
35 Speaker of the House shall begin in 2024 and end in 2027, with every subsequent term being five
36 years in length;

37 (C) The first term of the member appointed by the Attorney General shall begin in 2024 and
38 end in 2028, with every other term being five years in length;

39 (D) The first term of the member appointed by the Insurance Commissioner shall begin in
40 2024 and shall be five years in length, as shall all subsequent terms.

41 (E) The first terms of the alternates shall match those of the primary members appointed by
42 the same government official.

43 (c)(1) The chair shall hire an executive director and staff for the board.

44 (2) The chair shall develop a five-year budget and staffing plan and submit it to the board
45 for approval.

46 (3) Staff of the board shall receive a salary as provided in the budget of the board.

47 (d) A member of the board:

48 (1) May receive compensation as a member of the board in accordance with the state
49 budget; and

50 (2) Is entitled to reimbursement for expenses under the reimbursement plans in effect at
51 the Department of Health at that time.

52 (e)(1) The board shall meet in open session at least four times a year.

53 (A) At the chair's discretion, the chair may cancel or postpone a meeting.

54 (B) The following actions by the board shall be made in open session:

55 (i) The study required under §16-8C-7 of this code;

56 (ii) Deliberations on whether to subject a prescription drug product to a cost review under §
57 16-8C-8;

58 (iii) Any vote on whether to impose an upper payment limit on purchases and payor
59 reimbursements of prescription drug products in the state; and

60 (iv) Any decision by the board.

61 (2) Notwithstanding the Open Meetings Act, the board may meet in closed session to
62 discuss trade secrets or confidential and proprietary data and information. The board shall provide
63 public notice of each board meeting in compliance with the Open Meetings Act, including notice of
64 whether this is a public meeting.

65 (3) Materials for each board meeting shall be made available to the public at least three
66 days in advance of the meeting. Materials containing trade secrets or confidential and proprietary
67 data or information that is not otherwise available to the public may not be made available to the
68 public.

69 (4) The board shall provide an opportunity for public comment at each open meeting of the
70 board.

71 (5) The board shall provide the public with the opportunity to provide written comments on
72 pending decisions of the board.

73 (6) The board may allow expert testimony at board meetings, including when the board
74 meets in closed session.

75 (7) To the extent practicable, the board shall access pricing information for prescription
76 drug products by:

77 (A) Entering into a memorandum of understanding with another state to which
78 manufacturers already report pricing information; and

79 (B) Accessing other available pricing information.

80 (8) A majority of the members of the board constitutes a quorum.

81 (9) Members of the board shall recuse themselves from decisions related to a prescription
82 drug product if the member, or an immediate family member of the member, has received or could
83 receive any of the following:

84 (A) A direct financial benefit of any amount deriving from the result or finding of a study or
85 determination by or for the board; or

86 (B) A financial benefit from any person that owns, manufactures, or provides prescription
87 drug products, services, or items to be studied by the board that in the aggregate exceeds \$5,000
88 per year.

89 (C) For the purposes of this section, a financial benefit includes honoraria, fees, stock, the
90 value of the member's or immediate family member's stock holdings, and any direct financial
91 benefit deriving from the finding of a review conducted under this subtitle.

92 (f) In addition to the powers set forth elsewhere in this subtitle, the board may:

93 (1) Adopt regulations to carry out the provisions of this subtitle; and

94 (2) Enter into a contract with a qualified, independent third party for any service necessary
95 to carry out the powers and duties of the board.

96 (g) Unless permission is granted by the board, a third party hired by the board in
97 accordance with subsection (f)(2) of this section may not release, publish, or otherwise use any
98 information to which the third party has access under its contract.

99 (h) The board is subject to the rules and policies of the Purchasing Division.

100 (i) The Attorney General is the legal adviser to the board.

101 (1) The Attorney General shall designate an assistant attorney general as counsel to the
102 board.

103 (2) As needed, the Attorney General may assign additional assistant attorneys general to
104 the board to give effective legal advice and counsel.

105 (3) The counsel to the board may not have a duty other than to:

106 (i) Give the legal aid, advice, and counsel required by the board;

107 (ii) Supervise the other assistant attorneys general assigned to the board, if any; and

108 (iii) Perform for the board the duties that the Attorney General assigns.

109 (4) The counsel shall perform these duties subject to the control and supervision of the

110 Attorney General.

111 (5) After the Attorney General designates the counsel to the board, the Attorney General
112 may not reassign the counsel without consulting the board.

§16-8C-4. Prescription Drug Affordability Stakeholder Council.

1 (a) There is a Prescription Drug Affordability Stakeholder Council.

2 (b) The purpose of the Stakeholder Council is to provide stakeholder input to assist the
3 board in making decisions as required under this subtitle.

4 (c) The Stakeholder Council consists of 26 members appointed in accordance with this
5 subsection.

6 (1) The Speaker of the House of Delegates shall appoint:

7 (A) One representative of generic drug corporations;

8 (B) One representative of nonprofit insurance carriers;

9 (C) One representative of a statewide health care advocacy coalition;

10 (D) One representative of a statewide advocacy organization for seniors;

11 (E) One representative of a statewide organization for diverse communities;

12 (F) One representative of a labor union;

13 (G) One health services researcher specializing in prescription drugs; and

14 (H) One public member at the discretion of the Speaker of the House of Delegates.

15 (2) The President of the Senate shall appoint:

16 (A) One representative of brand name drug corporations;

17 (B) One representative of physicians;

18 (C) One representative of nurses;

19 (D) One representative of hospitals;

20 (E) One representative of dentists;

21 (F) One representative of managed care organizations;

22 (G) One representative of pharmacists;

- 23 (H) One clinical researcher; and
- 24 (I) One public member at the discretion of the President of the Senate.
- 25 (3) The Governor shall appoint:
- 26 (A) One representative of brand name drug corporations;
- 27 (B) One representative of generic drug corporations;
- 28 (C) One representative of biotechnology companies;
- 29 (D) One representative of for-profit health insurance carriers;
- 30 (E) One representative of employers;
- 31 (F) One representative of pharmacy benefits managers;
- 32 (G) One representative of the State Budget Office;
- 33 (H) One pharmacologist; and
- 34 (I) One public member at the discretion of the Governor.
- 35 (4) Collectively, the members of the Stakeholder Council shall have knowledge of the
- 36 following:
- 37 (i) The pharmaceutical business model;
- 38 (ii) Supply chain business models;
- 39 (iii) The practice of medicine or clinical training;
- 40 (iv) Consumer or patient perspectives;
- 41 (v) Health care costs trends and drivers;
- 42 (vi) Clinical and health services research; or
- 43 (vii) The state's health care marketplace.
- 44 (5) To the extent practicable and consistent with federal and state law, the membership of
- 45 the Stakeholder Council shall reflect the racial, ethnic, and gender diversity of the state.
- 46 (6) From among the membership of the Stakeholder Council, the board chair shall appoint
- 47 two members to be cochairs of the Stakeholder Council.
- 48 (d)(1) The term of a member is 3 years.

49 (2) The initial members of the Stakeholder Council shall serve staggered terms as follows:

50 (A) The first term of the member appointed by the Governor shall begin in 2024 and end in
51 2026, with every other term being five years in length;

52 (B) The first terms of the members appointed by the President of the Senate shall begin in
53 2024 and end in 2026, with every subsequent term being three years in length;

54 (C) The first terms of the members appointed by the President of the Senate shall begin in
55 2024 and end in 2026, with every subsequent term being three years in length;

56 (D) The first terms of the members appointed by the Speaker of the House shall begin in
57 2024 and end in 2025, with every subsequent term being three years in length;

58 (e) A member of the Stakeholder Council:

59 (1) May not receive compensation as a member of the Stakeholder Council; but

60 (2) Is entitled to reimbursement travel in accordance with the state budget.

§16-8C-5. Disclosure of conflicts of interest.

1 (a)(1) A conflict of interest shall be disclosed:

2 (A) By the board when hiring board staff;

3 (B) By the appointing authority when appointing members and alternate members to the
4 board and members to the Stakeholder Council; and

5 (C) By the board, when a member of the board is recused in any final decision resulting
6 from a review of a prescription drug product.

7 (2) A conflict of interest shall be disclosed:

8 (A) In advance of the first open meeting after the conflict is identified; or

9 (B) Within five days after the conflict is identified.

10 (b)(1) A conflict of interest disclosed under this section shall be posted on the website of
11 the board unless the chair of the board recuses the member from any final decision resulting from
12 a review of a prescription drug product.

13 (2) A posting of the conflict of interest on the board's website shall include the type, nature,

14 and magnitude of the interests of the member involved.

§16-8C-6. Ethics of board members, staff, and third-party contractors.

1 The board members, staff, and third-party contractors must adhere the West Virginia
2 Public Employees' Ethics Act.

§16-8C-7. Study and report.

1 On or before December 31, 2027, the board, in consultation with the Stakeholder Council,
2 shall:

3 (1) Study the entire pharmaceutical distribution and payment system in the state and policy
4 options being used in other states and countries to lower the list price of pharmaceuticals,
5 including:

- 6 (A) Setting upper payment limits;
- 7 (B) Using a reverse auction marketplace; and
- 8 (C) Implementing a bulk purchasing process; and

9 (2) Report its findings and recommendations and any legislation required to implement the
10 recommendations, to the Governor and the Legislative Joint Committee on Government on
11 Finance.

§16-8C-8. Collection, review, and use of transparency data for prescription drug products.

1 (a) On or before December 31, 2027, the board shall:

2 (1) Collect and review publicly available information regarding prescription drug product
3 manufacturers, health insurance carriers, health maintenance organizations, managed care
4 organizations, wholesale distributors, and pharmacy benefits managers; and

5 (2) Identify states that require reporting on the cost of prescription drug products; and

6 (3) Initiate a process of entering into memoranda of understanding with the states identified
7 under §16-8C-8(a)(2) of this code to aid in the collection of transparency data for prescription drug
8 products.

9 (b) Based on the information collected under this section and obtained through

10 memoranda of understanding under this section, the board, in consultation with the stakeholder
11 council, shall adopt regulations to:

12 (1) Establish methods for collecting additional data necessary to carry out its duties under
13 this subtitle; and

14 (2) Identify circumstances under which the cost of a prescription drug product may create
15 or has created affordability challenges for the state health care system and patients.

16 (c) The board shall use the information collected under this section and obtained through
17 memoranda of understanding under this section to identify prescription drug products that are:

18 (1) Brand name drugs or biologics that, as adjusted annually for inflation in accordance
19 with the Consumer Price Index, have:

20 (A) A launch wholesale acquisition cost of \$30,000 or more per year or course of treatment;
21 or

22 (B) A wholesale acquisition cost increase of \$3,000 or more in any 12-month period, or
23 course of treatment if less than 12 months;

24 (2) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15%
25 lower than the referenced brand biologic at the time the biosimilars are launched;

26 (3) Generic drugs that, as adjusted annually for inflation in accordance with the Consumer
27 Price Index, have a wholesale acquisition cost:

28 (A) Of \$100 or more for:

29 (i) A 30-day supply lasting a patient for a period of 30 consecutive days based on the
30 recommended dosage approved for labeling by the United States Food and Drug Administration;

31 (ii) A supply lasting a patient for fewer than 30 days based on the recommended dosage
32 approved for labeling by the United States Food and Drug Administration; or

33 (iii) One unit of the drug if the labeling approved by the United States Food and Drug
34 Administration does not recommend a finite dosage; and

35 (B) That increased by 200% or more during the immediately preceding 12-month period,

36 as determined by the difference between the resulting wholesale acquisition cost and the average
37 of the wholesale acquisition cost reported over the immediately preceding 12 months; and

38 (4) Other prescription drug products that may create affordability challenges for the state
39 health care system and patients, in consultation with the Stakeholder Council.

§16-8C-9. Cost review of prescription drug products with affordability challenges.

1 (a)(1) After identifying prescription drug products as required by §16-8C-8 of this subtitle,
2 the board shall determine whether to conduct a cost review as described in subsection (b) of this
3 section for each identified prescription drug product by:

4 (A) Seeking Stakeholder Council input about the prescription drug product; and

5 (B) Considering the average cost share of the prescription drug product.

6 (2)(A) To the extent there is no publicly available information to conduct a cost review as
7 described in subsection (b) of this section, the board shall request the information from:

8 (i) The manufacturer of the prescription drug product; and

9 (ii) As appropriate, a wholesale distributor, pharmacy benefits manager, health insurance
10 carrier, health maintenance organization, or managed care organization with relevant information
11 on setting the cost of the prescription drug product in the state.

12 (B) The information to conduct a cost review may include any document and research
13 related to the manufacturer's selection of the introductory price or price increase of the prescription
14 drug product, including life cycle management, net average price in the state, market competition
15 and context, projected revenue, and the estimated value or cost-effectiveness of the prescription
16 drug product.

17 (C) Failure of a manufacturer, wholesale distributor, pharmacy benefits manager, health
18 insurance carrier, health maintenance organization, or managed care organization to provide the
19 board with the information requested under this paragraph does not affect the authority of the
20 board to conduct a review as described in subsection (b) of this section.

21 (b)(1) If the board conducts a review of the cost of a prescription drug product, the review

22 shall determine whether use of the prescription drug product that is fully consistent with the
23 labeling approved by the United States Food and Drug Administration or standard medical
24 practice has led or will lead to affordability challenges for the state health care system or high out-
25 of-pocket costs for patients.

26 (2) To the extent practicable, in determining whether a prescription drug product identified
27 under §16-8C-8 of this code has led or will lead to an affordability challenge, the board shall
28 consider the following factors:

29 (A) The wholesale acquisition cost and any other relevant prescription drug cost index for
30 the prescription drug product sold in the state;

31 (B) The average monetary price concession, discount, or rebate the manufacturer
32 provides to health plans in the state or is expected to provide to health plans in the state as
33 reported by manufacturers and health plans, expressed as a percent of the wholesale acquisition
34 cost for the prescription drug product under review;

35 (C) The total amount of the price concession, discount, or rebate the manufacturer
36 provides to each pharmacy benefits manager operating in the state for the prescription drug
37 product under review, as reported by manufacturers and pharmacy benefits managers, expressed
38 as a percent of the wholesale acquisition costs;

39 (D) The price at which therapeutic alternatives have been sold in the state;

40 (E) The average monetary concession, discount, or rebate the manufacturer provides or is
41 expected to provide to health plan payors and pharmacy benefits managers in the state for
42 therapeutic alternatives;

43 (F) The costs to health plans based on patient access consistent with United States Food
44 and Drug Administration labeled indications;

45 (G) The impact on patient access resulting from the cost of the prescription drug product
46 relative to insurance benefit design;

47 (H) The current or expected dollar value of drug-specific patient access programs that are

48 supported by the manufacturer;

49 (I) The relative financial impacts to health, medical, or social services costs as can be
50 quantified and compared to baseline effects of existing therapeutic alternatives;

51 (J) The average patient copay or other cost-sharing for the prescription drug product in the
52 state; and

53 (K) Any other factors as determined by the board in regulations adopted by the board.

54 (3) If the board is unable to determine whether a prescription drug product will produce or
55 has produced challenges to the affordability of the drug for the state health care system, using the
56 factors listed in paragraph (2) of this subsection, the board may consider the following factors:

57 (A) The manufacturer's research and development costs, as indicated on the
58 manufacturer's federal tax filing or information filed with the Federal Securities and Exchange
59 Commission for the most recent tax year in proportion to the manufacturer's sales in the state;

60 (B) The portion of direct-to-consumer marketing costs eligible for favorable federal tax
61 treatment in the most recent tax year that are specific to the prescription drug product under review
62 and that are multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales
63 in the United States for the product under review;

64 (C) Gross and net manufacturer, pharmacy benefits manager, and wholesale distributor
65 revenues for the prescription drug product under review for the most recent tax year;

66 (D) Any additional factors proposed by the manufacturer and appropriate health insurance
67 carriers, health maintenance organizations, managed care organizations, wholesale distributors,
68 and pharmacy benefits managers that the board considers relevant; and

69 (E) Any additional factors as established by the board in regulations.

70 (c) On or before December 31, 2025, and each December 31 thereafter, the board shall
71 submit to the Governor and the Legislative Joint Committee on Government a report that includes:

72 (1) Price trends for prescription drug products;

73 (2) The number of prescription drug products that were subject to board review and the

74 results of the review; and

75 (3) Any recommendations the board may have on further legislation needed to make
76 prescription drug products more affordable in the state.

§16-8C-10. Confidentiality.

1 (a) All information and data obtained by the board under this subtitle, that is not otherwise
2 publicly available:

3 (1) Is considered to be a trade secret and confidential and proprietary information; and

4 (2) Is not subject to disclosure under the West Virginia Freedom of Information Act, §29B-
5 1-1 et seq. of this code.

6 (b) Only board members and staff may access trade secrets and confidential and
7 proprietary data and information obtained under this subtitle that is not otherwise publicly
8 available.

9 (c) The provisions of §47-22-1, et seq. of this code shall apply to any trade secrets and
10 confidential and proprietary data and information obtained under this subtitle that is not otherwise
11 publicly available.

§16-8C-11. Funding source.

1 (a) In this section, “fund” means the Prescription Drug Affordability Fund.

2 (b)(1) The board shall assess and collect an annual fee on:

3 (A) Manufacturers that sell or offer for sale prescription drug products to persons in the
4 state;

5 (B) Pharmacy benefits managers, as defined in §33-51-3 this code;

6 (C) Insurers and private insurance carriers, as defined in §23-1-1, et seq. and §33-1-1, et
7 seq. of this code; and

8 (D) Wholesale distributors, as defined in §12-6C-01 of this code, that sell or offer for sale
9 prescription drug products to persons in the state.

10 (2) The board shall:

11 (A) Assess and collect the annual fee under paragraph (1) of this subsection in accordance
12 with criteria established in regulations adopted by the board; and

13 (B) Calculate the annual fee under paragraph (1) of this subsection in a fair and equitable
14 manner.

15 (3)(i) On or before October 1 each year, each entity assessed a fee under this subsection
16 shall pay the fee assessed by the board.

17 (ii) The board shall allow entities to make partial payments when paying the fee assessed
18 under this subsection.

19 (iii) Any fee not paid within 30 days after the payment due date may be subject to an
20 interest penalty to be determined and collected by the board.

21 (4) The total amount of fees that the board collects in each calendar year under paragraph
22 (1) of this subsection may not exceed \$2,000,000.

23 (5) The board shall pay all fees collected under paragraph (1) of this subsection into the
24 fund.

25 (c)(1) There is a Prescription Drug Affordability Fund.

26 (2) The purpose of the fund is to provide funding for the board and to carry out the purpose
27 of this subtitle.

28 (3) The board shall administer the fund.

29 (4)(A) The fund is a special, nonlapsing fund that shall not revert to the general fund.

30 (B) The state Treasurer shall hold the fund separately.

31 (5) The fund consists of:

32 (A) Revenue distributed to the fund under subsection (b) of this section;

33 (B) Money appropriated in the state budget to the fund;

34 (C) Interest earnings; and

35 (D) Any other money from any other source accepted for the benefit of the fund.

36 (6) The fund may be used only to provide funding for the board and for the purposes

37 authorized under this subtitle, including administrative expenses and any costs expended by any
38 state agency to implement this subtitle.

39 (7)(A) The State Treasurer shall invest the money of the fund in the same manner as other
40 state money may be invested.

41 (B) Any interest earnings of the fund shall be credited to the fund.

42 (8) Expenditures from the fund may be made only in accordance with the state budget.

43 (9) The fund is subject to audit by the Legislative Auditor.

44 (10) This subsection may not be construed to prohibit the fund from receiving funds from
45 any other source.

46 (d)(1) The board shall be established using special or general funds, which shall be repaid
47 to the state with the funds from the fund.

48 (2) If the board receives funding from the West Virginia Department of Health under
49 paragraph (1) of this subsection, the board shall repay the funds to the commission from the fund
50 over a three-year period beginning June 1, 2025.

§16-8C-12.

Enforcement.

1 The Office of the Attorney General may pursue any available remedy under state law when
2 enforcing this subtitle.

§16-8C-13. Process for setting upper payment limits for prescription drug products.

1 (a) If, under §16-8C-7 of this code, the board finds that it is in the best interest of the state to
2 establish a process for setting upper payment limits for prescription drug products that it
3 determines have led or will lead to an affordability challenge, the board, in conjunction with the
4 Stakeholder Council, shall draft a plan of action for implementing the process that includes the
5 criteria the board shall use to set upper payment limits.

6 (b) The criteria for setting upper payment limits shall include consideration of:

7 (1) The cost of administering the prescription drug product;

8 (2) The cost of delivering the prescription drug product to consumers; and

9 (3) Other relevant administrative costs related to the prescription drug product.

10 (c) The process for setting upper payment limits shall:

11 (1) Prohibit the application of an upper payment limit for a prescription drug product that is
12 on the federal Food and Drug Administration prescription drug shortage list; and

13 (2) Require the board to:

14 (A) Monitor the availability of any prescription drug product for which it sets an upper
15 payment limit; and

16 (B) If there becomes a shortage of the prescription drug product in the state, reconsider or
17 suspend the upper payment limit.

18 (d)(1) If a plan of action is drafted under subsection (a) of this section, the board shall
19 submit the plan of action to the Legislative Oversight Commission on Health and Human
20 Resources.

21 (2) The Legislative Oversight Commission on Health and Human Resources shall have 45
22 days to approve the plan of action.

23 (3) If the Legislative Oversight Commission on Health and Human Resources does not
24 approve the plan of action, the board shall submit the plan to the Governor and the Attorney
25 General for approval.

26 (4) The Governor and the Attorney General shall have 45 days to approve the plan of
27 action.

28 (5) The board may not set upper payment limits unless the plan is approved, in accordance
29 with this subsection, by:

30 (A) The Legislative Oversight Commission on Health and Human Resources; or

31 (B) The Governor and Attorney General.

§16-8C-14. Eligible drug products; limit amount; drug product availability.

1 (a) If a plan of action is approved under §16-8C-13(d) of this code, the board may set upper
2 payment limits for prescription drug products that are:

3 (1) Purchased or paid for by a unit of state or local government or an organization on behalf
4 of a unit of state or local government, including:

5 (A) State or county correctional facilities;

6 (B) State hospitals; and

7 (C) Health clinics at state institutions of higher education;

8 (2) Paid for through a health benefit plan on behalf of a unit of state or local government,
9 including a county, or municipal employee health benefit plan; or

10 (3) Purchased for or paid for by the West Virginia Department of Health.

11 (b) The upper payment limits set under subsection (a) of this section shall:

12 (1) Be for prescription drug products that have led or will lead to an affordability challenge;
13 and

14 (2) Be set in accordance with the criteria established in regulations adopted by the board.

15 (c)(1) The board shall:

16 (A) Monitor the availability of any prescription drug product for which it sets an upper
17 payment limit; and

18 (B) If there becomes a shortage of the prescription drug product in the state, reconsider
19 whether the upper payment limit should be suspended or altered.

20 (2) An upper payment limit set under subsection (a) of this section may not be applied to a
21 prescription drug product while the prescription drug product is on the federal Food and Drug
22 Administration prescription drug shortage list.

§16-8C-15.

Remedies.

1 (a) A person aggrieved by an upper payment limit set by the board may request an appeal
2 within 30 days after the board makes the decision to set the limit.

3 (b) The board shall hear the appeal and make a final decision within 60 days after the
4 appeal is requested.

5 (c) Any person aggrieved by a final decision of the board issued under subsection (b) of

6 this section may petition for judicial review.

§16-8C-16.

Report.

1 On or before December 1, 2027, the board, in consultation with the stakeholder council,
2 shall report to the Legislative Oversight Commission on Health and Human Resources:

3 (a) The legality, obstacles, and benefits of setting upper payment limits on all purchases
4 and payor reimbursements of prescription drug products in the state; and

5 (b) Recommendations regarding whether the Legislature should pass legislation to
6 expand the authority of the board to set upper payment limits to all purchases and payor
7 reimbursements of prescription drug products in the state.

NOTE: The purpose of this bill is to establish the Prescription Drug Affordability Board and Prescription Drug Affordability Stakeholder Council and establishing the Prescription Drug Affordability Fund, and commissioning studies and reports from the board and council.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.