# WEST VIRGINIA LEGISLATURE 2025 REGULAR SESSION

### Introduced

## House Bill 2831

By Delegates Young and Lewis

[Introduced February 24, 2025; referred to the Committee on Health and Human Resources then Finance]

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A BILL to amend the Code of West Virginia, 1931, as amended, by adding a new article, designated §16-8C-1, §16-8C-2, §16-8C-3, §16-8C-4, §16-8C-5, §16-8C-6, §16-8C-7, §16-8C-8, §16-8C-9, §16-8C-10, §16-8C-11, §16-8C-12, §16-8C-13, §16-8C-14, §16-8C-15, and §16-8C-16, relating to establishing the West Virginia Prescription Drug Affordability Board; providing definitions; providing for the creation of a Board and the composition, compensation, and duties associated with the Board; providing for the creation of a stakeholder council and the composition, and duties associated with the Council; providing disclosures of conflicts of interest and requiring adherence to the Ethics Act; requiring a study and report on transparency data on prescription drug products; providing a cost review of prescription drug products with affordability challenges; requiring confidentiality; establishing a fund; providing for enforcement; clarifying drug products eligible; providing 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.

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

#### §16-8C-2. Definitions.

- 1 For purposes of this article the following words have the meanings indicated.
- 2 "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 "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 <u>"Board" means the West Virginia Prescription Drug Affordability Board.</u>

7	"Brand name drug" means a drug that is produced or distributed in accordance with an
8	original new drug application approved under 21 U.S.C. § 355(c). "Brand name drug" does not
9	include an authorized generic as defined by 42 C.F.R. § 447.502.
10	"Generic drug" means:
11	(1) A retail drug that is marketed or distributed in accordance with an abbreviated new drug
12	application, approved under 21 U.S.C. § 355(j);
13	(2) An authorized generic as defined by 42 C.F.R. § 447.502; or
14	(3) A drug that entered the market before 1962 that was not originally marketed under a
15	new drug application.
16	"Manufacturer" means an entity that:
17	(1)(A) Engages in the manufacture of a prescription drug product; or
18	(B) Enters into a lease with another manufacturer to market and distribute a prescription
19	drug product under the entity's own name; and
20	(2) Sets or changes the wholesale acquisition cost of the prescription drug product it
21	manufactures or markets.
22	"Prescription drug product" means a brand name drug, a generic drug, a biologic, or a
23	biosimilar.
24	"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	(A) The 340B Program under the federal Public Health Service Act;
16	(B) The state's All-Payer Claims Database;
17	(C) How the program and contract interact; and
18	(D) 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 2025 and end in
33	2027 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 2025 and end in 2028, 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 2025 and
38	end in 2029, 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	2025 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;
56	(ii) Deliberations on whether to subject a prescription drug product to a cost review under §
57	<u>16-8C-8;</u>
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

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; (E) One representative of a statewide organization for diverse communities; 11 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 2025 and end in

51	2027, 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	2025 and end in 2027, 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	2025 and end in 2027, 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	2025 and end in 2027, 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, 2028, 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, 2028, 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) to aid in the collection of transparency data for prescription drug products.
8	(b) Based on the information collected under this section and obtained through
9	memoranda of understanding under this section, the board, in consultation with the stakeholder
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10	council, shall adopt regulations to:

12	this subtitle; and
13	(2) Identify circumstances under which the cost of a prescription drug product may create
14	or has created affordability challenges for the state health care system and patients.
15	(c) The board shall use the information collected under this section and obtained through
16	memoranda of understanding under this section to identify prescription drug products that are:
17	(1) Brand name drugs or biologics that, as adjusted annually for inflation in accordance
18	with the Consumer Price Index, have:
19	(A) A launch wholesale acquisition cost of \$30,000 or more per year or course of treatment;
20	<u>or</u>
21	(B) A wholesale acquisition cost increase of \$3,000 or more in any 12-month period, or
22	course of treatment if less than 12 months;
23	(2) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15%
24	lower than the referenced brand biologic at the time the biosimilars are launched;
25	(3) Generic drugs that, as adjusted annually for inflation in accordance with the Consumer
26	Price Index, have a wholesale acquisition cost:
27	(A) Of \$100 or more for:
28	(i) A 30-day supply lasting a patient for a period of 30 consecutive days based on the
29	recommended dosage approved for labeling by the United States Food and Drug Administration;
30	(ii) A supply lasting a patient for fewer than 30 days based on the recommended dosage
31	approved for labeling by the United States Food and Drug Administration; or
32	(iii) One unit of the drug if the labeling approved by the United States Food and Drug
33	Administration does not recommend a finite dosage; and
34	(B) That increased by 200% or more during the immediately preceding 12-month period,
35	as determined by the difference between the resulting wholesale acquisition cost and the average
36	of the wholesale acquisition cost reported over the immediately preceding 12 months; and
37	(4) Other prescription drug products that may create affordability challenges for the state

38 <u>health care system and patients, in consultation with the Stakeholder Council.</u>

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

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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 has led or will lead to an affordability challenge, the board shall consider the
28	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
31	treatment in the most recent tax year that are specific to the prescription drug product under review
52	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,
88	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, 2026, 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;
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, that sell or offer for sale prescription
9	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	<u>manner.</u>
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	<u>fund.</u>
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, non-lapsing 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, 2026.
	§16-8C-12. Enforcement.
1	The Office of the Attorney General may pursue any available remedy under state law when
2	enforcing this subtitle.
2	enforcing this subtitle.  §16-8C-13. Process for setting upper payment limits for prescription drug products.
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	§16-8C-13. Process for setting upper payment limits for prescription drug products.
1	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a
1 2	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led
1 2 3	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council,
1 2 3 4	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the board shall
1 2 3 4 5	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the board shall use to set upper payment limits.
1 2 3 4 5	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the board shall use to set upper payment limits.  (b) The criteria for setting upper payment limits shall include consideration of:
1 2 3 4 5 6 7	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the board shall use to set upper payment limits.  (b) The criteria for setting upper payment limits shall include consideration of:  (1) The cost of administering the prescription drug product;
1 2 3 4 5 6 7 8	§16-8C-13. Process for setting upper payment limits for prescription drug products.  (a) If, under §16-8C-7, the board finds that it is in the best interest of the state to establish a process for setting upper payment limits for prescription drug products that it determines have led or will lead to an affordability challenge, the board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process that includes the criteria the board shall use to set upper payment limits.  (b) The criteria for setting upper payment limits shall include consideration of:  (1) The cost of administering the prescription drug product;  (2) The cost of delivering the prescription drug product to consumers; and

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), the board may set upper payment
2	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	<u>and</u>
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.

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On or before December 1, 2028, the board, in consultation with the stakeholder council,

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- 2 shall report to the Legislative Oversight Commission on Health and Human Resources
- 3 Accountability:
- 4 (a) The legality, obstacles, and benefits of setting upper payment limits on all purchases
- 5 and payor reimbursements of prescription drug products in the state; and
- 6 (b) Recommendations regarding whether the Legislature should pass legislation to expand
- 7 the authority of the board to set upper payment limits to all purchases and payor reimbursements
- 8 of prescription drug products in the state.

NOTE: The purpose of this bill is to establish the West Virginia Prescription Drug Affordability Board; provide definitions; provide for the creation of a Board and the composition, compensation, and duties associated with the Board; provide for the creation of a stakeholder council and the composition, and duties associated with the Council; provide disclosures of conflicts of interest and requiring adherence to the Ethics Act; require a study and report on transparency data on prescription drug products; provide a cost review of prescription drug products with affordability challenges; require confidentiality; establish a fund; provide for enforcement; clarify drug products eligible; provide remedies; and list all report requirements.

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

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