

1 AN ACT relating to prepayment review of Medicaid claims.

2 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
4 READ AS FOLLOWS:

5 *(1) As used in this section:*

6 *(a) "340B covered entity" means a health care facility that is registered as a*
7 *covered entity under 42 U.S.C. sec. 256b, as amended;*

8 *(b) "340B price" or "340B pricing" means the amount required to be paid to*
9 *the manufacturer of a covered drug as established pursuant to 42 U.S.C.*
10 *sec. 256b, as amended; and*

11 *(c) "Covered drug" has the same meaning as in 42 U.S.C. sec. 256b, as*
12 *amended.*

13 *(2) A manufacturer shall not discriminate, or cause others to discriminate, against a*
14 *340B covered entity by refusing or withholding 340B pricing for a covered drug if*
15 *the manufacturer offers the same drug at a 340B price in any other state.*
16 *Discrimination prohibited under this section includes but is not limited to any*
17 *manufacturer-imposed condition, limitation, or delay on the sale of or purchase*
18 *of a covered drug at a 340B price, unless the condition, limitation, or delay is*
19 *expressly required under federal or state law.*

20 *(3) In addition to any private right of action, any person who believes that a*
21 *manufacturer is in violation of subsection (2) of this section may make a*
22 *complaint to the Attorney General who may, pursuant to KRS 315.235,*
23 *investigate the complaint.*

24 *(4) Nothing in this section shall be construed or interpreted to be less restrictive than,*
25 *or in conflict with, any other federal or state law.*

26 *(5) If at any time after the effective date of this Act, the 340B drug pricing program*
27 *established in accordance with 42 U.S.C. sec. 256b is amended by congressional*

1 action:

2 (a) In a manner that reduces the number of health care facilities that may be
3 eligible for the program, the number of pharmacies with which a 340B
4 covered entity may contract for the purpose of the program, or the discounts
5 offered to 340B covered entities, then the Department for Medicaid Services
6 shall enforce the reductions with regard to covered entities in Kentucky; or

7 (b) In a manner that expands eligibility for the program, or the discounts
8 offered to 340B covered entities, then this section shall be unenforceable
9 unless reauthorized by an act of the General Assembly.

10 (6) This section shall expire on and have no force or effect on or after July 1, 2026,
11 unless extended by an act of the General Assembly.

12 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 216 IS CREATED TO
13 READ AS FOLLOWS:

14 (1) As used in this section:

15 (a) "340B drug" means a covered outpatient drug, as defined in 42 U.S.C. sec.
16 1396r-8(k)(2), that has been subject to any offer for reduced prices by a
17 pharmaceutical manufacturer pursuant to 42 U.S.C. sec. 256b(a)(1) and is
18 purchased by a nonprofit hospital;

19 (b) "340B drug pricing program" means the federal prescription drug pricing
20 program established in accordance with 42 U.S.C. sec. 256b;

21 (c) "340B profit" means the difference between:

22 1. The aggregate payments received from insurers, third-party payors,
23 and self-paying patients for all 340B drugs; and

24 2. The aggregate acquisition cost paid for all 340B drugs;

25 (d) "Charity care" means free or discounted health care items and services
26 provided to an individual who meets a hospital's financial assistance
27 criteria and is unable to pay for the items or services, or both, rendered, as

1 reported on line 23 of Worksheet S-10 to the Medicare cost report or any
2 successor form;

3 (e) "Charity care costs" means the total cost for charity care incurred by a
4 nonprofit hospital, including any offsite outpatient facility associated with
5 the hospital that dispenses 340B drugs purchased by the hospital;

6 (f) "Contract pharmacy" means a pharmacy with which a nonprofit hospital
7 has contracted to dispense 340B drugs on behalf of the nonprofit hospital to
8 patients of the nonprofit hospital, whether distributed in person, by mail, or
9 any other means of dispensing;

10 (g) "Low-income patient" means a patient with a family income below two
11 hundred percent (200%) of the federal poverty level; and

12 (h) "Nonprofit hospital" means a private nonprofit corporation or hospital
13 that:

14 1. Is licensed by the Cabinet for Health and Family Services as a
15 hospital; and

16 2. Meets the definition of covered entity in 42 U.S.C. sec. 256b(a)(4)(L),
17 (M), (N), or (O).

18 (2) By December 15, 2025, and each year thereafter, each nonprofit hospital shall
19 report the following information to the Cabinet for Health and Family Services,
20 with respect to the nonprofit hospital and separately for each offsite facility
21 associated with the nonprofit hospital, for the previous calendar year in a form
22 and manner prescribed by the cabinet:

23 (a) Delineated by form of insurance or third-party payor type, including but not
24 limited to Medicare, Medicaid, private insurance, self-pay, and uninsured:

25 1. The aggregate acquisition cost for all 340B drugs dispensed by the
26 nonprofit hospital, an associated facility, or contract pharmacy;

27 2. The aggregate payments received from insurers or third-party payors

1 for all 340B drugs dispensed by the nonprofit hospital, an associated
2 facility, or contract pharmacy;

3 3. The total number of prescriptions and the percentage of the nonprofit
4 hospital's prescriptions that were dispensed or administered with 340B
5 drugs; and

6 4. The percentage of patients served on the basis of a sliding fee scale for
7 dispensed or administered 340B drugs at the point of sale;

8 (b) The total operating cost of the nonprofit hospital, including an itemized cost
9 report for the following:

10 1. Implementing direct pass through of 340B profits to patients in the
11 form of lower cost sharing for dispensed or administered 340B drugs
12 at the point of sale;

13 2. Implementing a sliding fee scale for dispensed or administered 340B
14 drugs at the point of sale for low-income patients; and

15 3. Charity care costs;

16 (c) Total payments made to:

17 1. Contract pharmacies for 340B drug pricing program-related services
18 and other functions;

19 2. Third-party administrators for managing any aspect of the nonprofit
20 hospital's 340B drug pricing program; and

21 3. Any other party or entity in connection with 340B drug pricing
22 program-related compliance, legal services, education, or
23 administrative costs;

24 (d) Information regarding contract pharmacies, including:

25 1. The total number of contract pharmacies;

26 2. The number of contract pharmacies located outside the
27 Commonwealth of Kentucky and the states in which those pharmacies

1 are located;

2 3. The total number of prescriptions written by the hospital or its staff
 3 that were filled at a contract pharmacy and the percentage of all
 4 prescriptions written by the hospital or its staff that were filled by
 5 contract pharmacies, delineated by in-state and out-of-state contract
 6 pharmacies;

7 4. The total remuneration paid to or retained by contract pharmacies or
 8 their affiliates for any 340B drug pricing program-related services
 9 performed on behalf of the nonprofit hospital; and

10 5. The percentage change in total remuneration reported under
 11 subparagraph 4. of this paragraph as compared to the previous
 12 calendar year;

13 (e) A detailed and itemized accounting of expenditures associated with 340B
 14 profits, including an itemized report of all programs, services, equipment
 15 purchases, staffing, and any other expenditures financed, in part or in
 16 whole, by 340B profits; and

17 (f) Any additional information that the Legislative Research Commission may
 18 request be included in the report.

19 (3) An officer of the nonprofit hospital shall certify that the report submitted
 20 pursuant to this section is complete and accurate.

21 (4) The Cabinet for Health and Family Services shall post all reports submitted
 22 pursuant to this section on its website.

23 ➔Section 3. KRS 205.5514 is amended to read as follows:

24 (1) The department shall:

25 (a) Establish a single preferred drug list to be used by the state pharmacy benefit
 26 manager for each managed care organization with whom the department
 27 contracts for the delivery of Medicaid services; and

- 1 (b) Promulgate administrative regulations that establish:
- 2 1. Reimbursement methodologies; and
- 3 2. Dispensing fees which may take into account applicable guidance by the
- 4 Centers for Medicare and Medicaid Services and which may, to the
- 5 extent permitted under federal law, vary by pharmacy type, including
- 6 rural and independently owned pharmacies, chain pharmacies, and
- 7 pharmacies owned or contracted by a health care facility that is
- 8 registered as a covered entity pursuant to 42 U.S.C. sec. 256b.

9 Except as provided in subsection (5) of this section, reimbursement

10 methodologies established by administrative regulations shall not discriminate

11 against pharmacies owned or contracted by a health care facility that is

12 registered as a covered entity pursuant to 42 U.S.C. sec. 256b, to the extent

13 allowable by the Centers for Medicare and Medicaid Services.

14 (2) The reimbursement methodologies and dispensing fees established by the

15 department pursuant to subsection (1) of this section shall be used by the state

16 pharmacy benefit manager for each managed care organization with whom the

17 department contracts for the delivery of Medicaid services.

18 (3) The state pharmacy benefit manager shall administer, adjudicate, and reimburse

19 pharmacy benefit claims submitted by pharmacies to the state pharmacy benefit

20 manager in accordance with:

21 (a) The terms of any contract between a health care facility that is registered as a

22 covered entity pursuant to 42 U.S.C. sec. 256b and a Medicaid managed care

23 organization;

24 (b) The terms and conditions of the contract between the state pharmacy benefit

25 manager and the Commonwealth; and

26 (c) The reimbursement methodologies and dispensing fees established by the

27 department, pursuant to subsection (1) of this section.

- 1 (4) The following shall apply to the state pharmacy benefit manager, the contract
2 between the state pharmacy benefit manager and the department, and, where
3 applicable, any contract between the state pharmacy benefit manager and a
4 pharmacy:
- 5 (a) The department shall be responsible for reviewing and shall approve or deny:
- 6 1. Any contract, any change in the terms of a contract, or suspension or
7 termination of a contract between the state pharmacy benefit manager
8 and a pharmacy licensed under KRS Chapter 315; and
- 9 2. Any contract, any change in the terms of a contract, or suspension or
10 termination of a contract between the state pharmacy benefit manager
11 and an entity that contracts on behalf of a pharmacy licensed under KRS
12 Chapter 315;
- 13 (b) The state pharmacy benefit manager shall comply with KRS 304.9-053,
14 304.9-054, and 304.9-055;
- 15 (c) After December 1, 2020, the state pharmacy benefit manager shall not enter
16 into, renew, extend, or amend a national contract with any pharmacy that is
17 inconsistent with:
- 18 1. The terms and conditions of the contract between the state pharmacy
19 benefit manager and the Commonwealth; or
- 20 2. The reimbursement methodologies and dispensing fees established by
21 the department, pursuant to subsection (1) of this section;
- 22 (d) 1. When creating or establishing a pharmacy network for a managed care
23 organization with whom the department contracts for the delivery of
24 Medicaid services, the state pharmacy benefit manager shall not
25 discriminate against any pharmacy or pharmacist that is:
- 26 a. Located within the geographic coverage area of the managed care
27 organization; and

- 1 b. Willing to agree to or accept reasonable terms and conditions
2 established by the state pharmacy benefit manager, or other
3 administrator for network participation, including obtaining
4 preferred participation status.
- 5 2. Discrimination prohibited by this paragraph shall include denying a
6 pharmacy the opportunity to participate in a pharmacy network at
7 preferred participation status; and
- 8 (e) A contract between the state pharmacy benefit manager and a pharmacy shall
9 not release the state pharmacy benefit manager from the obligation to make
10 any payments owed to the pharmacy for services rendered prior to the
11 termination of the contract between the state pharmacy benefit manager and
12 the pharmacy or removal of the pharmacy from the pharmacy network.

13 **(5) (a) Notwithstanding subsection (1)(b) of this section:**

- 14 **1. a. A 340B covered entity that purchases a Medicaid-covered drug**
15 **through the 340B program and bills Kentucky Medicaid for that**
16 **drug shall submit the 340B price on the claim and identify the**
17 **drug as being purchased through the 340B program;**
- 18 **b. 340B covered entities may not utilize contract pharmacies to bill**
19 **Kentucky Medicaid unless the covered entity, contract pharmacy,**
20 **and the Department for Medicaid Services have a written**
21 **agreement in place to prevent duplicate discounts; and**
- 22 **c. Any claim that does not comply with subdivision a. of this**
23 **subparagraph may be denied by the Department for Medicaid**
24 **Services or a managed care organization.**
- 25 **2. A hospital that fails to fully comply with the reporting requirements**
26 **established in subsection (2) of Section 2 of this Act shall be ineligible**
27 **for reimbursement by Kentucky Medicaid for 340B drugs during the**

1 following calendar year.

2 **(b) As used in this subsection:**

3 **1. "340B covered entity" means a health care facility that is registered as**
4 **a covered entity under 42 U.S.C. sec. 256b, as amended;**

5 **2. "340B price" means the amount required to be paid to the**
6 **manufacturer of a covered drug as established pursuant to 42 U.S.C.**
7 **sec. 256b, as amended;**

8 **3. "340 program" means the federal drug discount program established**
9 **in accordance with 42 U.S.C. sec. 256b; and**

10 **4. "Contract pharmacy" means a pharmacy contracted with a 340B**
11 **covered entity to provide pharmacy services and 340B covered drugs to**
12 **authorized patients.**