1	AN	ACT relating to the 340B Drug Pricing Program.
2	Be it enac	cted by the General Assembly of the Commonwealth of Kentucky:
3	<b>→</b> S	ECTION 1. A NEW SECTION OF KRS CHAPTER 216 IS CREATED TO
4	READ AS	S FOLLOWS:
5	(1) As u	used in this Section:
6	<u>(a)</u>	"340B drug" means a covered outpatient drug, as defined in 42 U.S.C. sec.
7		1396r-8(k)(2), that has been subject to any offer for reduced prices by a
8		pharmaceutical manufacturer pursuant to 42 U.S.C. sec. 256b(a)(1), and is
9		purchased by a nonprofit hospital;
10	<u>(b)</u>	"340B Drug Pricing Program" means the federal prescription drug pricing
11		program established in accordance with 42 U.S.C. sec. 256b;
12	<u>(c)</u>	"340B profit" means the difference between:
13		1. The aggregate payments received from insurers, third-party payors,
14		and self-paying patients for all 340B drugs; and
15		2. The aggregate acquisition cost paid for all 340B drugs;
16	<u>(d)</u>	"Charity care" means free or discounted health care items and services
17		provided to an individual who meets the hospital's financial assistance
18		criteria and is unable to pay for the items or services, or both, rendered, as
19		reported on line 23 of Worksheet S-10 to the Medicare cost report or any
20		successor form;
21	<u>(e)</u>	"Charity care costs" means the total cost for charity care incurred by a
22		nonprofit hospital, including any offsite outpatient facility associated with
23		the hospital that dispenses 340B drugs purchased by the hospital;
24	<u>(f)</u>	"Contract pharmacy" means a pharmacy with which a nonprofit hospital
25		has contracted to dispense 340B drugs on behalf of the nonprofit hospital to
26		patients of the nonprofit hospital, whether distributed in person, by mail, or
27		any other means of dispensing;

1	(g) "Low-income patient" means a patient with a family income below two
2	hundred percent (200%) of the federal poverty level; and
3	(h) ''Nonprofit hospital'' means a private nonprofit corporation or hospital
4	that:
5	1. Is licensed by the Cabinet for Health and Family Services as a
6	hospital; and
7	2. Meets the definition of covered entity in 42 U.S.C. sec. 256b(a)(4)(L),
8	(M), $(N)$ , $or$ $(O)$ .
9	(2) By July 1, 2026, and each year thereafter, each nonprofit hospital shall report the
10	following information to the Cabinet for Health and Family Services, with
11	respect to the nonprofit hospital and separately for each offsite facility associated
12	with the nonprofit hospital, for the previous calendar year in a form and manner
13	prescribed by the cabinet:
14	(a) Delineated by form of insurance or third-party payor type, including but not
15	limited to Medicare, Medicaid, private insurance, self-pay, and uninsured:
16	1. The aggregate acquisition cost for all 340B drugs dispensed by the
17	nonprofit hospital, an associated facility, or contract pharmacy;
18	2. The aggregate payments received from insurers or third-party payors
19	for all 340B drugs dispensed by the nonprofit hospital, an associated
20	facility, or contract pharmacy;
21	3. The total number of prescriptions and the percentage of the nonprofit
22	hospital's prescriptions that were dispensed or administered with 340B
23	<u>drugs;</u>
24	4. The percentage of patients served on the basis of a sliding fee scale for
25	dispensed or administered 340B drugs at the point of sale;
26	(b) The total operating cost of the nonprofit hospital, including an itemized cost
27	report for the following:

1		1. Implementing direct pass through of 340B profits to patients in the
2		form of lower cost sharing for dispensed or administered 340B drugs
3		at the point of sale;
4		2. Implementing a sliding fee scale for dispensed or administered 340B
5		drugs at the point of sale for low-income patients; and
6		3. Charity care costs;
7	<u>(c)</u>	Total payments made to:
8		1. Contract pharmacies for 340B Drug Pricing Program-related services
9		and other functions;
10		2. Third-party administrators for managing any aspect of the nonprofit
11		hospital's 340B Drug Pricing Program; and
12		3. Any other party or entity in connection with 340B Drug Pricing
13		Program-related compliance, legal services, education, or
14		administrative costs;
15	<u>(d)</u>	Information regarding contract pharmacies, including:
16		1. The total number of contract pharmacies;
17		2. The number of contract pharmacies located outside the
18		Commonwealth of Kentucky and the states in which those pharmacies
19		are located;
20		3. The total number of prescriptions written by the hospital or its staff
21		that were filled at a contract pharmacy and the percentage of all
22		prescriptions written by the hospital or its staff that were filled by
23		contract pharmacies, delineated by in-state and out-of-state contract
24		pharmacies;
25		4. The total remuneration paid to or retained by contract pharmacies or
26		their affiliates for any 340B Drug Pricing Program-related services
27		performed on behalf of the nonprofit hospital; and

1	5. The percentage change in total remuneration reported under
2	subparagraph 4. of this paragraph as compared to the previous
3	calendar year; and
4	(e) A detailed and itemized accounting of expenditures associated with 340B
5	profits, including an itemized report of all programs, services, equipment
6	purchases, staffing, and any other expenditures financed, in part or in
7	whole, by 340B profits.
8	(3) An officer of the nonprofit hospital shall certify that the report submitted
9	pursuant to this section is complete and accurate.
10	(4) The Cabinet for Health and Family Services shall post all reports submitted
11	pursuant to this section to its website.
12	→ Section 2. (1) The Personnel Cabinet is hereby directed to study the impact
13	of nonprofit hospital purchases, contract pharmacy arrangements, and general practices
14	related to dispensing and administering 340B drugs on the Kentucky Employee Health
15	Plan. The study shall include but not be limited to an analysis of foregone rebates, the
16	effect on plan premiums, and the impact of the 340B Drug Pricing Program on state
17	employee's out-of-pocket healthcare expenses. The Personnel Cabinet shall submit a
18	report containing the findings of the study required under this section to the Legislative
19	Research Commission for referral to the Interim Joint Committee on Health Services and
20	the Interim Joint Committee on State Government no later than December 1, 2025.
21	(2) As used in this section:
22	(a) "340B drugs" has the same meaning as in Section 1 of this Act;
23	(b) "Contract pharmacy" has the same meaning as in Section 1 of this Act; and
24	(c) "Nonprofit hospital" has the same meaning as in Section 1 of this Act.
25	→ Section 3. (1) The Cabinet for Health and Family Services shall submit a
26	report on the 340B Drug Pricing Program established in accordance with 42 U.S.C. sec.
27	256b to the Legislative Research Commission for referral to the Interim Joint Committee

on Appropriations and Revenue and the Interim Joint Committee on Health Services no

- 2 later than December 1, 2025. The report shall include the following for total aggregated
- 3 Medicaid cover outpatient drug units dispensed or administered in the state during the
- 4 prior calendar year separately for the Department for Medicaid Services fee for service
- 5 population and for each managed care organization with whom the department has
- 6 contracted for the delivery of Medicaid services:
- 7 (a) The number of dispensed or administered covered outpatient drug units;
- 8 (b) The number of dispensed or administered covered outpatient drug units that 9 were subject to a rebate under 42 U.S.C. sec. 1396r-8;
- 10 (c) The number of dispensed or administered covered outpatient drug units where 11 340B pricing was obtained by the nonprofit hospital, and the number of units billed by 12 contract pharmacies; and
- 13 (d) A reasonable estimate of net costs or savings to the Medicaid program due to 14 nonprofit hospital purchases of covered outpatient drug units at 340B pricing.
  - (2) To the extent that the Cabinet for Health and Family Services lacks information to provide a data element required under subsection (1)(d) of this section, it shall provide a reasonable estimate based on all available information and an explanation of the information that it lacks.
- 19 (3) As used in this section:
- 20 (a) "Contract pharmacy" has the same meaning as in Section 1 of this Act;
- 21 (b) "Covered outpatient drug" has the same meaning as in 42 U.S.C. sec. 1396r-
- 8(k)(2); and

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(c) "Nonprofit hospital" has the same meaning as in Section 1 of this Act.

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