| 1 | 1 AN ACT relating to the 34 | 0B Drug Pricing Program. |
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| 2 | 2 Be it enacted by the General As | sembly of the Commonwealth of Kentucky: |
| 3 | 3 → SECTION 1. A NEW | SECTION OF KRS CHAPTER 216 IS CREATED TO |
| 4 | 4 READ AS FOLLOWS: | |
| 5 | 5 (1) As used in this Section: | |
| 6 | 6 <u>(a) "340B drug" means</u> | a covered outpatient drug, as defined in 42 U.S.C. sec. |
| 7 | 7 <u>1396r-8(k)(2), that</u> | has been subject to any offer for reduced prices by a |
| 8 | 8 <u>pharmaceutical man</u> | ufacturer pursuant to 42 U.S.C. sec. 256b(a)(1), and is |
| 9 | 9 <u>purchased by a nonp</u> | <u>profit hospital;</u> |
| 10 | 0 (b) "340B Drug Pricing | Program" means the federal prescription drug pricing |
| 11 | 1 <u>program established</u> | in accordance with 42 U.S.C. sec. 256b; |
| 12 | 2 <u>(c) "340B profit" mean</u> | s the difference between: |
| 13 | 3 <u>1. The aggregate</u> | payments received from insurers, third-party payors, |
| 14 | 4 <u>and self-paying</u> | patients for all 340B drugs; and |
| 15 | 5 <u>2. The aggregate</u> | acquisition cost paid for all 340B drugs; |
| 16 | 6 (d) "Charity care" med | ns free or discounted health care items and services |
| 17 | 7 <u>provided to an ind</u> | ividual who meets the hospital's financial assistance |
| 18 | 8 <u>criteria and is unab</u> | le to pay for the items or services, or both, rendered, as |
| 19 | 9 <u>reported on line 23</u> | of Worksheet S-10 to the Medicare cost report or any |
| 20 | 0 <u>successor form;</u> | |
| 21 | 1 (e) "Charity care costs | " means the total cost for charity care incurred by a |
| 22 | 2 <u>nonprofit hospital, i</u> | ncluding any offsite outpatient facility associated with |
| 23 | 3 <u>the hospital that disp</u> | enses 340B drugs purchased by the hospital; |
| 24 | 4 (f) "Contract pharmac | " means a pharmacy with which a nonprofit hospital |
| 25 | 5 <u>has contracted to dis</u> | pense 340B drugs on behalf of the nonprofit hospital to |
| 26 | 6 patients of the nonp | rofit hospital, whether distributed in person, by mail, or |
| 27 | 7 <u>any other means of a</u> | lispensing; |

| 1 | (g) "Low-income patient" means a patient with a family income below two |
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| 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 |
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| 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 |

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| 1 | 5. The percentage change in total remuneration reported under |
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| 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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23 (c) "Nonprofit hospital" has the same meaning as in Section 1 of this Act.

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