HOUSE OF REPRESENTATIVES

KENTUCKY GENERAL ASSEMBLY AMENDMENT FORM

2022 REGULAR SESSION

Amend printed copy of **SB 68/HCS 1**

On page 7, lines 26 and 27, and page 8, lines 1 and 2, delete in its entirety and insert the following in lieu thereof:

"➔Section 3. KRS 304.17A-164 is amended to read as follows:

(1) As used in this section:

(a) "Cost sharing"***:***

1. Means the cost to an~~[individual]~~ insured under a health plan***,*** according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirements imposed by the plan~~[, which may be subject to annual limitations on cost sharing, including those imposed under 42 U.S.C. secs. 18022(c) and 300gg-6(b)]~~, in order for ***the insured***~~[an individual]~~ to receive a specific health care service covered by the plan; ***and***

2. May be subject to annual limitations, including those imposed under 42 U.S.C. secs. 18022(c) and 300gg-6(b);

(b) "Generic alternative" means a drug that is designated to be therapeutically equivalent by the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, except that a drug shall not be considered a generic alternative until the drug is nationally available;

(c) "Health plan" ***has the same meaning as in Section 4 of this Act***~~[:~~

Amendment No. HFA Rep. Rep. Steve Sheldon

Committee Amendment Signed:

Floor Amendment LRC Drafter:

Adopted: Date:

Rejected: Doc. ID: XXXX

~~1. Means a policy, contract, certificate, or agreement offered or issued by an insurer to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services; and~~

~~2. Includes a health benefit plan as defined in KRS 304.17A-005]~~;

(d) "Insured" means any individual who is enrolled in a health plan and on whose behalf the insurer is obligated to pay for or provide ***pharmacy or pharmacist***~~[health care]~~ services;

(e) "Insurer"***:***

1. Has the same meaning as in Section 4 of this Act; and

2. Includes~~[:~~

~~1. An insurer offering a health plan providing coverage for pharmacy benefits; or~~

~~2.]~~ any ~~[other]~~administrator of pharmacy benefits under a health plan;

(f) "Person" means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, nonprofit corporation, unincorporated organization, government, or governmental subdivision or agency;

(g) "Pharmacy" includes:

1. A pharmacy, as defined in KRS Chapter 315;
2. A pharmacist, as defined in KRS Chapter 315; ***and***~~[or]~~
3. Any employee of a pharmacy or pharmacist;~~[and]~~

(h) "Pharmacy benefit manager" has the same meaning as in KRS ***304.9-020, except for purposes of this section, the term does not include a pharmacy benefit manager that is contracted by and acting under the direction of any hospital or health system that provides a self-insured plan if the hospital or health system owns a pharmacy; and***~~[304.17A-161]~~

(i) "Pharmacy or pharmacist services" has the same meaning as in Section 4 of this Act.

(2) To the extent permitted under federal law, an insurer ~~[issuing or renewing a health plan on or after January 1, 2022,]~~or a pharmacy benefit manager~~[,]~~ shall not:

(a) Require an insured~~[purchasing a prescription drug]~~ to***:***

1. Pay a cost-sharing amount ***for pharmacy or pharmacist services*** greater than the amount the insured would pay for the ***services***~~[drug]~~ if he or she were to purchase the ***services***~~[drug]~~ without coverage; ***or***

2. a. Use a mail-order pharmaceutical distributor, including a mail-order pharmacy, in order to receive coverage under the plan.

b. Conduct prohibited under this subparagraph includes but is not limited to requiring the use of a mail-order pharmaceutical distributor, including a mail-order pharmacy, to furnish a health care provider a prescription drug by the United States Postal Service or a common carrier for subsequent administration in a hospital, clinic, pharmacy, or infusion center;

(b) ***Impose upon an insured any cost-sharing requirement, fee, or other condition relating to:***

1. Pharmacy or pharmacist services received from a retail pharmacy or pharmacist that is greater, or more restrictive, than what would otherwise be imposed if:

a. The insured used a mail-order pharmaceutical distributor, including a mail-order pharmacy; and

b. The retail pharmacy or pharmacist has agreed to accept reimbursement at no more than the amount that would have been reimbursed to the

mail-order pharmaceutical distributer;

2. Prescription drugs furnished by a health care provider for administration in a hospital, clinic, pharmacy, or infusion center that is greater, or more restrictive, than what would otherwise be imposed if a mail-order pharmaceutical distributor, including a mail-order pharmacy, furnished the prescription drugs to the health care provider; or

3. Pharmacy or pharmacist services that is not equally imposed upon all insureds in the same benefit category, class, or cost-sharing level under the health plan, unless otherwise required or permitted under this section;

(c) Exclude any cost-sharing amounts paid by an insured**,** or on behalf of an insured by another person**,** for a prescription drug, including any amount paid under paragraph (a)***1.*** of this subsection, when calculating an insured's contribution to any applicable cost-sharing requirement. The requirements of this paragraph shall not apply***:***

1. In the case of a prescription drug for which there is a generic alternative, unless the insured has obtained access to the brand prescription drug through prior authorization, a step therapy protocol, or the insurer's exceptions and appeals process***; or***

2. To any fully insured health benefit plan or self-insured plan provided to an employee under KRS 18A.225;

(d)~~[(c)]~~ Prohibit a pharmacy from discussing any information under subsection (3) of this section; or

(e)~~[(d)]~~ Impose a penalty on a pharmacy for complying with this section.

(3) A pharmacist shall have the right to provide an insured information regarding the applicable limitations on his or her ***cost sharing***~~[cost-sharing]~~ pursuant to this section~~[for a prescription drug]~~.

~~[(4) Subsection (2)(b) of this section shall not apply to any fully insured health benefit plan or self-insured plan provided to an employee under KRS 18A.225.]~~

➔SECTION 4. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

As used in Sections 4 to 6 of this Act:

(1) "Health plan":

(a) Means any policy, certificate, contract, or plan that offers or provides coverage in this state for pharmacy or pharmacist services, whether such coverage is by direct payment, reimbursement, or otherwise;

(b) Includes a health benefit plan; and

(c) Does not include a policy, certificate, contract, or plan that offers or provides Medicaid services under KRS Chapter 205;

(2) "Insurer":

(a) Means any of the following persons or entities that offer or issue a health plan:

1. An insurance company;

2. A health maintenance organization;

3. A limited health service organization;

4. A self-insurer, including a governmental plan, church plan, or multiple employer welfare arrangement, except any hospital or health system that provides a self-insured plan if the hospital or health system owns a pharmacy;

5. A provider-sponsored integrated health delivery network;

6. A self-insured employer-organized association;

7. A nonprofit hospital, medical-surgical, dental, and health service corporation; or

8. Any other third-party payor that is:

a. Authorized to transact health insurance business in this state; or

b. Not exempt by federal law from regulation under the insurance laws of this state; and

(b) Includes any person or entity that has contracted with a state or federal agency to provide coverage in this state for pharmacy or pharmacist services, except persons or entities that have contracted to provide Medicaid services under KRS Chapter 205;

(3) "Pharmacy affiliate" means any pharmacy, including a specialty pharmacy:

(a) With which the pharmacy benefit manager shares common ownership, management, or control;

(b) Which is owned, managed, or controlled by any of the pharmacy benefit manager's management companies, parent companies, subsidiary companies, jointly held companies, or companies otherwise affiliated by a common owner, manager, or holding company;

(c) Which shares any common members on its board of directors with the pharmacy benefit manager; or

(d) Which shares managers in common with the pharmacy benefit manager;

(4) "Pharmacy benefit manager" has the same meaning as in KRS 304.9-020, except for purposes of Sections 5 and 6 of this Act, the term does not include a pharmacy benefit manager that is contracted by and acting under the direction of any hospital or health system that provides a self-insured plan if the hospital or health system owns a pharmacy; and

(5) "Pharmacy or pharmacist services":

(a) Means any health care procedures, treatments within the scope of practice of a pharmacist, or services provided by a pharmacy or a pharmacist; and

(b) Includes the provision of:

1. Prescription drugs, as defined in KRS 315.010; and

2. Home medical equipment, as defined in KRS 309.402.

➔SECTION 5. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

To the extent permitted under federal law:

(1) As used in this section:

(a) "Covered entity" means a covered entity participating in the federal 340B drug pricing program, as described in 42 U.S.C. sec. 256b, as amended; and

(b) "National drug code number" means the unique national drug code number that identifies a specific approved drug, its manufacturer, and its package presentation;

(2) Every contract between a pharmacy or pharmacist and a pharmacy benefit manager for the provision of pharmacy or pharmacist services under a health plan, either directly or through a pharmacy services administration organization, shall comply with subsections (3) and (4) of this section;

(3) A contract referenced in subsection (2) of this section shall:

(a) Outline the terms and conditions for the provision of pharmacy or pharmacist services;

(b) 1. Establish procedures for changing the contract, which shall comply with KRS 304.17A-235.

2. For purposes of implementing this paragraph, any changes to procedures set forth in the contract for dispute resolution, verification of drugs included on a formulary, or contract termination shall be considered material;

(c) Except as may otherwise be required under state or federal law, provide the pharmacy or pharmacist:

1. A thirty (30) day right to cure any violations of the terms and conditions of the contract prior to termination or nonrenewal of the contract on the basis of those violations;

2. At least ninety (90) days' prior written notice of a nonrenewal of the contract, sent in accordance with the notice required for proposed material changes under KRS 304.17A-235, which shall include the following:

a. The proposed effective date of the nonrenewal;

b. The name, business address, telephone number, and electronic mail address of a representative of the pharmacy benefit manager that can discuss the proposed nonrenewal; and

c. An opportunity for a meeting using real-time communication to discuss the proposed nonrenewal; and

3. At least thirty (30) days' prior written notice of any notices to insureds covered under the health plan that the pharmacy has been or will be removed from the plan's provider network; and

(d) 1. Prohibit the pharmacy benefit manager from reducing payment for pharmacy or pharmacist services, directly or indirectly, under a reconciliation process to an effective rate of reimbursement.

2. Conduct prohibited under subparagraph 1. of this paragraph shall include, without limitation, creating, imposing, or establishing:

a. Direct or indirect remuneration fees;

b. Any effective rate, including but not limited to:

i. Generic effective rates;

ii. Dispensing effective rates; and

iii. Brand effective rates;

c. In-network fees;

d. Performance fees;

e. Pre-adjudication fees;

f. Post-adjudication fees; and

g. Any other mechanism that reduces, or aggregately reduces, payment for pharmacy or pharmacist services;

(4) A contract referenced in subsection (2) of this section shall not:

(a) Designate a prescription drug as a "specialty drug" unless the drug is a limited distribution prescription drug that:

1. Requires special handling; and

2. Is not commonly carried at retail pharmacies or oncology clinics or practices;

(b) Establish a standard or formula containing one (1) or more variables for reimbursement of pharmacy or pharmacist services that permits the pharmacy benefit manager, at its sole discretion, to change or determine the value of any variable;

(c) Prohibit a pharmacy or pharmacist from utilizing the United States Postal Service or a common carrier to deliver prescription drugs to patients; or

(d) Require a pharmacy or pharmacist to enter a separate mail-order agreement in order to allow delivery of prescription drugs by the United States Postal Service or a common carrier;

(5) A pharmacy benefit manager providing pharmacy benefit management services on behalf of a health plan shall not:

(a) Discriminate against any pharmacy, including a pharmacy owned by or contracted with a covered entity; or

(b) Create, modify, implement, or establish, directly or indirectly, any fee not otherwise

prohibited under this section relating to pharmacy or pharmacist services on the pharmacy, pharmacist, or an insured without first seeking and obtaining written approval from the commissioner to do so; and

(6) Conduct prohibited by subsection (5)(a) of this section includes but is not limited to:

(a) Discriminating against any pharmacy or pharmacist that is:

1. Located within the geographic coverage area of the health plan; and

2. Willing to agree to, or accept, reasonable terms and conditions established by the pharmacy benefit manager for network participation;

(b) Reimbursing a covered entity, including any pharmacy owned by or contracted with the covered entity, for a pharmacy-dispensed drug at an amount that is lower than the amount paid for the same drug by national drug code number to an entity that is not a covered entity or a pharmacy that is not owned by or contracted with a covered entity;

(c) Assessing any pharmacy-related fee, chargeback, or other adjustment, including any fee, chargeback, or adjustment relating to pharmacy-dispensed drugs, upon a covered entity, including any pharmacy owned by or contracted with a covered entity, that is not equally assessed on an entity that is not a covered entity or a pharmacy that is not owned by or contracted with a covered entity;

(d) Imposing limits, including quantity limits or refill frequency limits, on a pharmacy's access to medication that differ from those existing for a pharmacy affiliate;

(e) 1. Requiring, or incentivizing, an insured to receive pharmacy or pharmacist services from a pharmacy affiliate.

2. Conduct prohibited under this paragraph includes the offer or implementation of a plan design that requires or incentivizes insureds to use

pharmacy affiliates, including but not limited to:

a. Requiring or incentivizing an insured to obtain a specialty drug from a pharmacy affiliate;

b. Charging less cost sharing to insureds that use pharmacy affiliates than the pharmacy benefit manager charges to insureds that use nonaffiliated pharmacies; and

c. Providing any incentives for insureds that use pharmacy affiliates that are not provided for insureds that use nonaffiliated pharmacies.

3. This paragraph shall not be construed to prohibit:

a. Communications to insureds regarding pharmacy networks and prices if the communication is accurate and includes information about all eligible nonaffiliated pharmacies; or

b. Requiring an insured to utilize a pharmacy network that may include pharmacy affiliates in order to receive coverage under the plan, or providing financial incentives for utilizing that network, if the pharmacy benefit manager complies with subsection (5)(a) of this section; and

(f) 1. Not providing equal access and incentives to all pharmacies within the pharmacy benefit manager's network.

2. Conduct prohibited under this paragraph includes but is not limited to interfering with an insured's right to choose the insured's network pharmacy of choice. For purposes of this subparagraph, interfering includes inducement, steering, offering financial or other incentives, or imposing a penalty.

➔SECTION 6. A NEW SECTION OF SUBTITLE 17A KRS CHAPTER 304 IS

CREATED TO READ AS FOLLOWS:

To the extent permitted under federal law, for contracts between an insurer or its administrator and a pharmacy benefit manager for the provision of pharmacy benefit management services on behalf of a health plan:

(1) Prior to entering into the contract, the pharmacy benefit manager shall disclose to the insurer any activity, policy, practice, contract, including any national pharmacy contract, or agreement that may directly or indirectly present a conflict of interest in the pharmacy benefit manager's relationship with the insurer;

(2) The insurer shall monitor the activities carried out in this state on its behalf by the pharmacy benefit manager to ensure compliance with the requirements of this chapter; and

(3) The contract shall require the pharmacy benefit manager to:

(a) Owe a fiduciary duty to the insurer; and

(b) Comply with the requirements of this chapter.

➔SECTION 7. A NEW SECTION OF SUBTITLE 99 OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

In addition to any other remedies, penalties, or damages available under common law or statute, the commissioner may order reimbursement to any person who has incurred a monetary loss as a result of a violation of Section 3, 5, or 6 of this Act.

➔Section 8. KRS 304.9-054 is amended to read as follows:

(1) ***As used in this section, "rebate":***

(a) Means a discount, price concession, or payment that is:

1. Based on utilization of a prescription drug; and

2. Paid after a claim for pharmacy or pharmacist services has been adjudicated at a pharmacy; and

(b) Includes, without limitation, incentives, disbursements, and reasonable estimates of a volume-based discount.

(2) (a) Upon receipt of a completed application, evidence of financial responsibility, and fee, the commissioner shall make a review of each applicant ***for a pharmacy benefit manager license.***~~[and]~~

(b) The commissioner shall issue a license if the applicant is qualified in accordance with this section and KRS 304.9-053.

(c)~~[(2)]~~ The commissioner may require ***and obtain*** additional information or submissions from applicants~~[and may obtain any documents or information]~~***, as*** reasonably necessary to verify the information contained in the application.

(3) ***(a)*** The commissioner may suspend, revoke, or refuse to issue or renew any ***pharmacy benefit manager*** license in accordance with KRS 304.9-440.

(b)~~[(4)]~~ The commissioner may make determinations on the length of suspension for an applicant, not to exceed twenty-four (24) months. However, the licensee may have the alternative, subject to the approval of the commissioner, to pay in lieu of part or all of the days of any suspension period a sum of one thousand dollars ($1,000) per day not to exceed two hundred fifty thousand dollars ($250,000).

(c)~~[(5)]~~ If the commissioner's denial or revocation is sustained after a hearing in accordance with KRS Chapter 13B, an applicant may make a new application not earlier than one (1) full year after the date on which a denial or revocation was sustained.

(4)~~[(6)]~~ ***(a) The commissioner may promulgate administrative regulations to implement, enforce, or aid in the effectuation of any provision of this chapter applicable to pharmacy benefit managers.***

(b) The administrative regulations permitted under paragraph (a) of this subsection

include but are not limited to administrative regulations that establish:

1. Prohibited practices, including market conduct practices, of pharmacy benefit managers;

2. Data reporting requirements; and

3. Specifications for the sharing of information with pharmacy affiliates. ~~[The department shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement and enforce the provisions of this section and KRS 205.647, 304.9-053, 304.9-055, and 304.17A-162.]~~

(c) The ***commissioner shall promulgate*** administrative regulations ***that*** ~~[shall]~~ specify the contents ***and format*** of the application form and any other form***, disclosure,*** or report required ***or permitted under this section***.

(5) ~~[(7)]~~ ***(a) For contracts referenced in Section 6 of this Act, a pharmacy benefit manager shall report to the commissioner, on a quarterly basis, for each insurer:***

1. The aggregate amount of rebates received by the pharmacy benefit manager;

2. The aggregate amount of rebates distributed to the insurer;

3. The aggregate amount of rebates passed on to insureds of the insurer at the point of sale that reduced the insured's applicable deductible, copayment, coinsurance, or other cost-sharing amount;

4. The individual and aggregate amount paid by the insurer to the pharmacy benefit manager for pharmacy or pharmacist services, which shall be itemized by pharmacy, product, and goods and services; and

5. The individual and aggregate amount a pharmacy benefit manager paid for pharmacy or pharmacist services, which shall be itemized by pharmacy, product, and goods and services.

(b) In addition to the reporting required under paragraph (a) of this subsection,

pharmacy benefit managers providing pharmacy benefit management services on behalf of a health plan shall submit an annual report to the commissioner.

(c) To the extent permitted under federal law, the annual report required under paragraph (b) of this subsection shall include but not be limited to:

1. A list of the health plans that are administered by the pharmacy benefit manager; and

2. For health plan contracts entered during the immediately preceding calendar year, the aggregate amount of rebates that the pharmacy benefit manager received for all insurers.

(d) All information and data acquired by the department under this subsection that is generally recognized as confidential or proprietary shall not be subject to disclosure under KRS 61.870 to 61.884, except the department may publicly disclose aggregated information not descriptive of any readily identifiable person or entity.

(6) (a) The department may impose a fee upon pharmacy benefit managers**,** in addition to a license fee**,** to cover the costs of implementation and enforcement of ***KRS 205.647 and any provision of this chapter applicable to pharmacy benefit managers, including but not limited to*** this section and KRS ~~[205.647,]~~304.9-053, 304.9-055, and 304.17A-162**.**

(b) The fees permitted under paragraph (a) of this subsection shall include~~[, including]~~ fees to cover the cost of:

1.~~[(a)]~~ Salaries and benefits paid to the personnel of the department engaged in the enforcement;

2.~~[(b)]~~ Reasonable technology costs related to the enforcement process. Technology costs shall include the actual cost of software and hardware utilized

in the enforcement process and the cost of training personnel in the proper use of the software or hardware; and

3.~~[(c)]~~ Reasonable education and training costs incurred by the state to maintain the proficiency and competence of the enforcing personnel.

➔SECTION 9. A NEW SECTION OF SUBTITLE 17C OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

Sections 3, 4, 5, and 6 of this Act shall apply to limited health service benefit plans, including limited health service contracts as defined in KRS 304.38A-010.

➔SECTION 10. A NEW SECTION OF SUBTITLE 38A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

A limited health service organization shall comply with Sections 3 and 6 of this Act.

➔Section 11. Section 3 of this Act applies to health plans issued or renewed on or after January 1, 2023.

➔Section 12. Sections 5 and 6 of this Act applies to contracts issued, delivered, entered, renewed, extended, or amended on or after January 1, 2023.

➔Section 13. If any provision of this Act, or this Act's application to any person or circumstance, is held invalid, the invalidity shall not affect other provisions or applications of the Act, which shall be given effect without the invalid provision or application, and to this end the provisions and applications of this Act are severable.

➔Section 14. The commissioner of insurance shall promulgate administrative regulations to implement the provisions of Sections 3 to 13 of this Act on or before January 1, 2023.

➔Section 15. Sections 3 to 12 of this Act take effect on January 1, 2023.

➔Section 16. Whereas there is urgent need to improve the administration and provision of pharmacy benefits, an emergency is declared to exist, and Sections 1 and 2 of this Act take effect upon its passage and approval by the Governor or upon its otherwise becoming law."