CHAPTER 104

(SB 188)

AN ACT relating to patient access to pharmacy benefits.

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

➔SECTION 1. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 5 of this Act:

(1) "Cost sharing" means the cost to an insured under a health plan according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirements imposed by the plan;

(2) "Health plan":

(a) Except as provided in paragraph (c) of this subsection, means any policy, certificate, contract, or plan that offers or provides coverage in this state for pharmacy or pharmacist services, whether the coverage is by direct payment, reimbursement, or otherwise;

(b) Includes a health benefit plan; and

(c) Does not include:

1. A policy, certificate, contract, or plan that:

a. Offers or provides services under KRS Chapter 205; or

b. Is established by the Teachers' Retirement System pursuant to KRS 161.675 solely for the purpose of providing coverage to Medicare-eligible annuitants and dependents of annuitants;

2. A self-insured health plan provided by a hospital or health system to its employees and dependents of employees if the hospital or health system owns a pharmacy;

3. A prescription drug plan established under Medicare Part D; or

4. Student health insurance offered by a Kentucky-licensed insurer under written contract with a university or college whose students it proposes to insure;

(3) "Insured" means any individual covered under a health plan;

(4) "Insurer":

(a) Means any of the following persons 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;

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 that has contracted with a state or federal agency to provide coverage in this state under a health plan;

(5) "Pharmacy" has the same meaning as in KRS 315.010;

(6) (a) "Pharmacy affiliate" means a pharmacy, including a specialty pharmacy, that owns or controls, is owned or controlled by, or is under common ownership or common control with an insurer, pharmacy benefit manager, or other administrator of pharmacy benefits.

(b) As used in this subsection:

1. "Common control" includes sharing common management or managers and having common members on boards of directors; and

2. "Control" may be direct or indirect through one (1) or more intermediaries;

(7) "Pharmacy benefit manager" has the same meaning as in KRS 304.9-020; and

(8) "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 pharmacist; and

(b) Includes the sale and provision of the following by a pharmacy or pharmacist:

1. Prescription drugs as defined in KRS 315.010; and

2. Home medical equipment as defined in KRS 309.402.

➔SECTION 2. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

To the extent permitted under federal law:

(1) (a) An insurer, a pharmacy benefit manager, or any other administrator of pharmacy benefits that utilizes a network to provide pharmacy or pharmacist services under a health plan shall ensure that the network is reasonably adequate and accessible with respect to the provision of pharmacy or pharmacist services.

(b) A reasonably adequate and accessible network, with respect to the provision of pharmacy or pharmacist services, shall, at a minimum:

1. Offer an adequate number of accessible pharmacies that are not mail-order pharmacies; and

2. Provide convenient access to pharmacies that are not mail-order pharmacies within a reasonable distance from the insured's residence, but in no event shall the distance be more than thirty (30) miles from each insured's residence, to the extent that pharmacy or pharmacist services are available; and

(2) (a) An insurer, a pharmacy benefit manager, and any other administrator of pharmacy benefits conducting business in this state shall file with the commissioner an annual report, in the manner and form prescribed by the commissioner, describing the networks of the insurer, pharmacy benefit manager, or other administrator that are utilized for the provision of pharmacy or pharmacist services under a health plan.

(b) The commissioner shall review each network to ensure that the network complies with this section.

(c) 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.

➔SECTION 3. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Actual overpayment" means the portion of any amount paid for pharmacy or pharmacist services that:

1. Is duplicative because the pharmacy or pharmacist has already been paid for the services; or

2. Was erroneously paid because the services were not rendered in accordance with the prescriber's order, in which case only the amount paid for that portion of the prescription that

was filled incorrectly or in excess of the prescriber's order may be deemed an actual overpayment. The amount denied, refunded, or recouped shall not include the dispensing fee paid to the pharmacy if the correct medication was dispensed to the patient;

(b) "Ambulatory pharmacy" means a pharmacy that:

1. Is open to the general public; and

2. Dispenses outpatient prescription drugs;

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

(d) "Net amount" means the amount paid to the pharmacy or pharmacist by the insurer, pharmacy benefit manager, or other administrator less any fees, price concessions, and all other revenue passing from the pharmacy or pharmacist to the insurer, pharmacy benefit manager, or other administrator; and

(e) "Wholesale acquisition cost" means the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

(2) To the extent permitted under federal law, every contract between a pharmacy or pharmacist and an insurer, a pharmacy benefit manager, or any other administrator of pharmacy benefits for the provision of pharmacy or pharmacist services under a health plan, either directly or through a pharmacy services administration organization or group purchasing organization, shall:

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

(b) Prohibit the insurer, pharmacy benefit manager, or other administrator from:

1. Reducing payment for pharmacy or pharmacist services, directly or indirectly, under a reconciliation process to an effective rate of reimbursement. This prohibition shall include, without limitation, creating, imposing, or establishing direct or indirect remuneration fees, generic effective rates, dispensing effective rates, brand effective rates, any other effective rates, in-network fees, performance fees, point-of-sale fees, retroactive fees, pre-adjudication fees, post-adjudication fees, and any other mechanism that reduces, or aggregately reduces, payment for pharmacy or pharmacist services;

2. Retroactively denying, reducing reimbursement for, or seeking any refunds or recoupments for a claim for pharmacy or pharmacist services, in whole or in part, from the pharmacy or pharmacist after returning a paid claim response as part of the adjudication of the claim, including claims for the cost of a medication or dispensed product and claims for pharmacy or pharmacist services that are deemed ineligible for coverage, unless one (1) or more of the following occurred:

a. The original claim was submitted fraudulently; or

b. The pharmacy or pharmacist received an actual overpayment;

3. Reimbursing the pharmacy or pharmacist for a prescription drug or other service at a net amount that is lower than the amount the insurer, pharmacy benefit manager, or other administrator reimburses itself or a pharmacy affiliate for the same:

a. Prescription drug by national drug code number; or

b. Service;

4. Collecting cost sharing from a pharmacy or pharmacist that was provided to the pharmacy or pharmacist by an insured for the provision of pharmacy or pharmacist services under the health plan; and

5. Designating a prescription drug as a specialty drug unless the drug is a limited distribution drug that:

a. Requires special handling; and

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

(c) Notwithstanding any other law, provide the following minimum reimbursements to the pharmacy or pharmacist for each prescription drug or other service provided by the pharmacy or pharmacist:

1. a. Reimbursement for the cost of the drug or other service at an amount that is not less than:

i. The national average drug acquisition cost for the drug or service at the time the drug or service is administered, dispensed, or provided; or

ii. If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, the wholesale acquisition cost for the drug at the time the drug is administered or dispensed.

b. For purposes of complying with this subparagraph, the insurer, pharmacy benefit manager, or other administrator shall utilize the most recently published monthly national average drug acquisition cost as a point of reference for the ingredient drug product component of a pharmacy's or pharmacist's reimbursement for drugs appearing on the national average drug acquisition cost list; and

2. a. Except as provided in subdivision b. of this subparagraph, for health plan years beginning on or after January 1, 2027, reimbursement for a professional dispensing fee that is not less than the average cost to dispense a prescription drug in an ambulatory pharmacy located in Kentucky, as determined by the commissioner in an administrative regulation promulgated in accordance with KRS Chapter 13A.

b. i. The minimum dispensing fee required under subdivision a. of this subparagraph shall not apply to a mail-order pharmaceutical distributor, including a mail-order pharmacy.

ii. For health plan years beginning prior to January 1, 2027, and for any future health plan years for which a determination under subdivision a. of this subparagraph has not taken effect, the minimum dispensing fee for a pharmacy permitted under KRS Chapter 315 with a designated pharmacy type of "retail independent" on file with the Kentucky Board of Pharmacy, or a pharmacist practicing at such a pharmacy, shall be not less than ten dollars and sixty-four cents ($10.64).

c. In acquiring data for, and making, the determination required under subdivision a. of this subparagraph, the commissioner shall:

i. Promulgate an administrative regulation in accordance with KRS Chapter 13A that establishes the data elements to be collected by the Kentucky Board of Pharmacy under Section 16 of this Act;

ii. Conduct a study of the dispensing data submitted to the commissioner by the Kentucky Board of Pharmacy in accordance with Section 16 of this Act;

iii. Repeat the study every two (2) years to obtain updated information;

iv. Adjust the determination every two (2) years as appropriate based upon the results of each study; and

v. Comply with all requirements of Section 16 of this Act.

d. In carrying out his or her duties under this subparagraph, the commissioner shall cooperate and consult with the Kentucky Board of Pharmacy.

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

To the extent permitted under federal law and except as provided in Section 3 of this Act:

(1) With respect to the provision of pharmacy or pharmacist services under a health plan, an insurer, a pharmacy benefit manager, or any other administrator of pharmacy benefits:

(a) Shall not:

1. a. Require or incentivize an insured to use a mail-order pharmaceutical distributor, including a mail-order pharmacy.

b. Conduct prohibited under this subparagraph includes but is not limited to imposing any cost-sharing requirement, fee, drug supply limitation, or other condition relating to pharmacy or pharmacist services received from a retail pharmacy that is greater, or more restrictive, than what would otherwise be imposed if the insured used a mail-order pharmaceutical distributor, including a mail-order pharmacy;

2. Prohibit a pharmacy or pharmacist from, or impose a penalty on a pharmacy or pharmacist for, the following:

a. Selling a lower cost alternative to an insured, if one is available; or

b. Providing information to an insured under subsection (2) of this section;

3. Discriminate against any pharmacy or pharmacist that is:

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

b. Willing to agree to, or accept, reasonable terms and conditions established for participation in the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network;

4. Impose limits, including quantity limits or refill frequency limits, on an insured's access to medication from a pharmacy that are more restrictive than those existing for a pharmacy affiliate;

5. a. Require or incentivize an insured to receive pharmacy or pharmacist services from a pharmacy affiliate.

b. Conduct prohibited under this subparagraph includes but is not limited to:

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

ii. Charging less cost sharing to insureds that use pharmacy affiliates than what is charged to insureds that use nonaffiliated pharmacies; and

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

c. This subparagraph shall not be construed to prohibit:

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

ii. Requiring an insured to utilize a network that may include pharmacy affiliates in order to receive coverage under the plan, or providing financial incentives for utilizing that network, if the insurer, pharmacy benefit manager, or other administrator complies with this section and Section 2 of this Act; or

6. a. Interfere with an insured's right to choose the insured's network pharmacy of choice.

b. For purposes of this subparagraph, interfering includes inducing, steering, offering financial or other incentives, and imposing a penalty, including but not limited to:

i. Promoting one (1) participating pharmacy over another;

ii. Offering a monetary advantage;

iii. Charging higher cost sharing; and

iv. Reducing an insured's allowable reimbursement for pharmacy or pharmacist services; and

(b) Shall:

1. Provide equal access and incentives to all pharmacies within the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network; and

2. Offer all pharmacies located in the health plan's geographic coverage area eligibility to participate in the insurer's, pharmacy benefit manager's, other administrator's, or health plan's network under identical reimbursement terms for the provision of pharmacy or pharmacist services; and

(2) A pharmacist shall have the right to provide an insured information regarding lower cost alternatives to assist the insured in making informed decisions.

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

(1) Any insured, pharmacy, or pharmacist impacted by an alleged violation of Section 2, 3, or 4 of this Act may file a complaint with the commissioner.

(2) The commissioner shall:

(a) Review and investigate all complaints filed under this section;

(b) Issue, in writing, a determination to the insured, pharmacy, or pharmacist as to whether a violation occurred;

(c) For alleged violations of subsection (2)(b)5. of Section 3 of this Act, consult with the Kentucky Board of Pharmacy in making the determination of whether a violation occurred; and

(d) Otherwise comply with KRS 304.2-160 and 304.2-165.

(3) An insurer, a pharmacy benefit manager, or any other administrator of pharmacy benefits shall comply with KRS 304.2-165 and otherwise respond to, and comply with, any requests made by the commissioner under this section.

➔SECTION 6. 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 2, 3, 4, or 5 of this Act.

➔Section 7. KRS 304.9-053 is amended to read as follows:

(1) (a) In order to conduct business in this state, a pharmacy benefit manager shall first obtain a license from the commissioner. The license shall be in lieu of an administrator's license as required by KRS 304.9-052.

(b) A licensed pharmacy benefit manager performing utilization review, as defined in KRS 304.17A-600, shall be registered as a private review agent in accordance with KRS 304.17A-607.

(2) ***(a)*** ***A person seeking*** a pharmacy benefit manager~~[seeking a]~~ license shall apply to the commissioner in writing on a form provided by the department.

(b) The application~~[form]~~ shall ***include:***~~[state]~~

1. The name, address, official position, and professional qualifications of each individual responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, and any other person who exercises control or influence over the affairs of the pharmacy benefit manager***;***~~[,]~~ and

2. The name and address of the applicant's agent for service of process in this state.

(3) Each application for a license***,*** and subsequent renewal for a license***,*** shall be accompanied by***:***

(a) A nonrefundable fee of one thousand dollars ($1,000)***;***~~[and]~~

(b) Evidence of financial responsibility in an amount of one million dollars ($1,000,000)***; and***

(c) ***Any methodologies utilized, or to be utilized, by the pharmacy benefit manager in connection with reimbursement, which shall:***

1. ***Comply with subsection (2)(c) of Section 3 of this Act; and***

2. ***Be used in determining all appeals under KRS 304.17A-162***.

(4) ***(a)*** ~~[Any person acting as a pharmacy benefit manager on July 15, 2016, and who is required to obtain a license under subsection (1) of this section, shall obtain a license from the commissioner not later than January 1, 2017, in order to continue to do business in this state. If the license fee required in subsection (3) of this section is submitted after January 1, 2017, a penalty fee of five hundred dollars ($500) shall be paid.~~

~~(5) ~~]All licenses issued under this section shall be renewed annually in accordance with KRS 304.9-260.

(b) If the renewal fee required ***by***~~[in]~~ subsection (3) of this section is paid after the renewal date, a penalty fee of five hundred dollars ($500) shall be paid.

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

(1) ***(a)*** Upon receipt of a completed application,~~[evidence of financial responsibility, and]~~ fee, ***and other documentation and information required under Section 7 of this Act,*** the commissioner shall make a review of each applicant ***for a pharmacy benefit manager license.***~~[and]~~

(b) ***The commissioner*** shall issue a license if***:***

1. The applicant is qualified in accordance with this section and KRS 304.9-053***; and***

2. ***The commissioner determines, after reasonable investigation, that the applicant, upon licensure, is likely to be in compliance with Sections 1 to 5 of this Act***.

(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 ***comply with this section and*** verify the information contained in the application.

(2)~~[(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***, except that a license shall not be renewed if the licensee is not in compliance with Sections 1 to 5 of this Act***.

(b)~~[(4)]~~ The commissioner may make determinations on the length of suspension for ***a license***~~[an applicant]~~, not to exceed twenty-four (24) months.

(c) ~~[However, the licensee may have the alternative, subject to the approval of the commissioner, to pay]~~In lieu of ***serving*** part or all of the days of any suspension period ***determined under paragraph (b) of this subsection, the commissioner may permit a licensee to pay*** a sum of one thousand dollars ($1,000) per day not to exceed two hundred fifty thousand dollars ($250,000).

(d)~~[(5)]~~ If ***a pharmacy benefit manager license is denied or revoked***~~[the commissioner's denial or revocation is sustained after a hearing in accordance with KRS Chapter 13B]~~, ***the previous***~~[an]~~ applicant ***or licensee*** may make a new application not earlier than one (1) full year after the date on which ***the***~~[a]~~ denial or revocation ***became final***~~[was sustained]~~.

(3)~~[(6)]~~ ~~[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.]~~The ***commissioner shall promulgate*** administrative regulations ***in accordance with KRS Chapter 13A that***~~[shall]~~ specify the contents ***and format*** of***:***

(a) The application ***submitted under subsection (2) of Section 7 of this Act;***~~[form]~~ and

(b) Any other form***, disclosure,*** or report required ***or permitted under this section or Section 2 or 7 of this Act***.

(4)~~[(7)]~~ ***(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. KRS 304.9-055 is amended to read as follows:

(1) Pharmacy benefit managers shall be subject to this subtitle and to the provisions of Subtitles 1, 2, 3, 4, 12, 14, 17, 17A, 17C, 18, 25, 32, 38, 47, and 99 of KRS Chapter 304 to the extent applicable and not in conflict with the expressed provisions of this subtitle.

(2) ***The commissioner shall promulgate any administrative regulations in accordance with KRS Chapter 13A that are necessary to implement, enforce, or aid in the effectuation of any provision of this chapter applicable to pharmacy benefit managers, including but not limited to administrative regulations that establish:***

(a) ***Prohibited practices, including market conduct practices, of pharmacy benefit managers;***

(b) ***Data reporting requirements; and***

(c) ***Specifications for the sharing of information with pharmacy affiliates.***

➔Section 10. KRS 304.14-120 is amended to read as follows:

(1) ***(a)*** ***Except as otherwise provided in this section, a***~~[No]~~ basic insurance policy or annuity contract form, or application form where written application is required and is to be made a part of the policy or contract, or printed rider or indorsement form or form of renewal certificate, shall ***not*** be delivered, or issued for delivery in this state, unless the form has been filed with and approved by the commissioner.

(b) This ***subsection***~~[provision]~~ shall not apply to***:***

1. Any rates filed under Subtitle 17A of this chapter***;***~~[,]~~

2. Surety bonds***;***~~[, or to]~~

3. Specially rated inland marine risks***;***~~[,]~~ or~~[to]~~

4. Policies, riders, indorsements, or forms of unique character***:***

a. Designed for and used with relation to insurance upon a particular subject***;***~~[,]~~ or

b. Which relate to the manner or distribution of benefits or to the reservation of rights and benefits under life or health insurance policies and are used at the request of the individual policyholder, contract holder, or certificate holder.

(c) As to group insurance policies issued and delivered to an association outside this state but covering persons resident in this state, all or substantially all of the premiums for which are payable by the insured members, the group certificates to be delivered or issued for delivery in this state shall be filed with and approved by the commissioner.

(d)~~[(a)]~~ ***1.*** As to forms for use in property, marine (other than wet marine and transportation insurance), casualty***,*** and surety insurance coverages (other than accident and health)***,*** the filing required by this subsection may be made by advisory organizations or form providers on behalf of their members and subscribers***.***~~[; but this provision]~~

2. ***This paragraph*** shall not be ***construed***~~[deemed]~~ to prohibit any~~[such]~~ member or subscriber ***of an advisory organization or form provider*** from filing any~~[such]~~ forms on its own behalf.

(e)~~[(b)]~~ Every advisory organization and form provider shall file with the commissioner for approval every property and casualty policy form and endorsement before distribution to members, subscribers, customers, or others.

(f)~~[(c)]~~ Every property and casualty insurer shall file with the commissioner notice of adoption before use of any approved form filed by an advisory organization or form provider or filed by the insurer pursuant to paragraph ***(d)***~~[(a)]~~ of this subsection.

(2) ***(a)*** Every~~[such]~~ filing ***required under this section*** shall be made not less than sixty (60) days in advance of any~~[such]~~ delivery ***of the form in this state***.

(b) At the expiration of~~[such]~~ sixty (60) days***,*** the form so filed shall be deemed approved unless prior thereto it has been affirmatively approved or disapproved by order of the commissioner.

(c) Approval of any ***filing***~~[such form]~~ by the commissioner ***under this section*** shall constitute a waiver of any unexpired portion of ***the***~~[such]~~ waiting period ***established under this subsection***.

(d) The commissioner may extend ***the waiting period established under paragraph (a) of this subsection*** by not more than a thirty (30) day period***,*** within which ***time*** he or she may~~[so]~~ affirmatively approve or disapprove any ***filing***~~[such form]~~, by giving notice to the insurer of ***the***~~[such]~~ extension before expiration of the initial sixty (60) day period.

(e) At the expiration of any~~[such]~~ period~~[as so]~~ extended ***under paragraph (d) of this subsection***, and in the absence of ***a***~~[such]~~ prior affirmative approval or disapproval, ***the filing***~~[any such form]~~ shall be deemed approved.

(f) The commissioner may at any time, after notice and for cause shown, withdraw~~[any such]~~ approval ***of any filing***.

(3) ***(a)*** Any order of the commissioner disapproving any ***filing,***~~[such form]~~ or any notice of the commissioner withdrawing a previous approval***,*** shall state the grounds therefor and the particulars thereof in such detail as reasonably to inform the insurer~~[thereof]~~.

(b) Any~~[such]~~ withdrawal of a previously approved ***filing***~~[form]~~ shall be effective~~[at expiration of such period,]~~ not less than thirty (30) days after the ***insurer receives***~~[giving of the]~~ notice of ***the*** withdrawal, as the commissioner shall in such notice prescribe.

(4) ***Except as provided in subsection (6) of this section,*** the commissioner may, by order, exempt from the requirements of this section***,*** for so long as he or she deems proper***,*** any insurance document or form or type thereof***,*** as specified in ***the commissioner's***~~[such]~~ order***,*** to which, in his or her opinion***:***~~[,]~~

(a) This section may not practicably be applied***;***~~[,]~~ or

(b) The filing and approval of~~[which]~~ are~~[, in his or her opinion,]~~ not desirable or necessary for the protection of the public.

(5) Appeals from orders of the commissioner disapproving any ***filing***~~[such form]~~ or withdrawing a previous approval shall be taken as provided in Subtitle 2 of this chapter.

(6) ***The commissioner shall:***

(a) ***Review every filing relating to a health plan, as defined in Section 1 of this Act, for compliance with Sections 1 to 5 of this Act; and***

(b) ***Not approve any filing referenced in paragraph (a) of this subsection that does not comply with Sections 1 to 5 of this Act.***

(7) ***As used in***~~[For the purposes of]~~ this section, unless the context requires otherwise:

(a) "Advisory organization" has the ***same*** meaning ***as***~~[provided]~~ in KRS 304.13-011; and

(b) "Form provider" has the ***same*** meaning ***as***~~[provided]~~ in KRS 304.13-011.

➔Section 11. KRS 304.17A-712 is amended to read as follows:

(1) ***Except as provided in subsection (2) of this section,*** if an insurer determines that payment was made for services rendered to an individual who was not eligible for coverage or that payment was made for services not covered by a covered person's health benefit plan, the insurer shall give written notice to the provider and:

(a)~~[(1)]~~ Request a refund from the provider; or

(b)~~[(2)]~~ Make a recoupment of the overpayment from the provider in accordance with KRS 304.17A-714.

(2) An insurer, a pharmacy benefit manager, or any other administrator of pharmacy benefits shall not request a refund or make a recoupment in violation of Section 3 of this Act.

➔Section 12. KRS 304.17C-125 (Effective January 1, 2025) is amended to read as follows:

The following ~~[KRS 304.17A-262]~~ shall apply to limited health service benefit plans, including any limited health service contract, as defined in KRS 304.38A-010***:***

(1) KRS 304.17A-262; and

(2) Sections 1 to 5 of this Act.

➔Section 13. KRS 304.38A-115 (Effective January 1, 2025) is amended to read as follows:

Limited health service organizations shall comply with***:***

(1) KRS 304.17A-262***;***

(2) KRS 304.17A-265; and

(3) Sections 1 to 5 of this Act.

➔Section 14. KRS 18A.2254 is amended to read as follows:

(1) Based on the recommendation of the secretary of the Personnel Cabinet, the secretary of the Finance and Administration Cabinet, in lieu of contracting with one (1) or more insurers licensed to do business in this state, shall procure, in compliance with KRS 45A.080, 45A.085, and 45A.090, and reviewed by the Government Contract Review Committee pursuant to KRS 45A.705, a contract with one (1) or more third-party administrators licensed to do business in the Commonwealth pursuant to KRS 304.9-052 to administer a self-insured plan offered to the Public Employee Health Insurance Program for public employees. The requirements for the self-insured plan shall be as follows:

(a) 1. The secretary of the Personnel Cabinet shall incorporate by reference in an administrative regulation, pursuant to KRS 13A.2251, the plan year handbook distributed by the Department of Employee Insurance in the Personnel Cabinet to public employees covered under the self-insured plan. The plan year handbook shall contain, at a minimum, the premiums, employee contributions, employer contributions, and a summary of benefits, copays, coinsurance, and deductibles for each plan provided to public employees covered under the self-insured plan;

2. Notwithstanding any other provision of KRS Chapter 18A to the contrary, the administrative regulation shall not be subject to review by the Personnel Board prior to filing the administrative regulation with the Legislative Research Commission; and

3. The secretary of the Personnel Cabinet shall file the administrative regulation for the self-insured plan with the Legislative Research Commission on or before September 15 of the year before each new plan year begins;

(b) The self-insured plan offered by the program shall cover hospice care at least equal to the Medicare benefit;

(c) The Personnel Cabinet shall provide written notice of any formulary change to employees covered under the self-insured plan who are directly impacted by the formulary change and to the Kentucky Group Health Insurance Board fifteen (15) days before implementation of any formulary change. If, after consulting with his or her physician, the employee still disagrees with the formulary change, the employee shall have the right to appeal the change. The employee shall have sixty (60) days from the date of the notice of the formulary change to file an appeal with the Personnel Cabinet. The cabinet shall render a decision within thirty (30) days from the receipt of the request for an appeal. After a final decision is rendered by the Personnel Cabinet, the employee shall have a right to file an appeal pursuant to the utilization review statutes in KRS 304.17A-600 to 304.17A-633. During the appeal process, the employee shall have the right to continue to take any drug prescribed by his or her physician that is the subject of the formulary changes;

(d) The Personnel Cabinet shall develop the necessary capabilities to ensure that an independent review of each formulary change is conducted and includes but is not limited to an evaluation of the fiscal impact and therapeutic benefit of the formulary change. The independent review shall be conducted by knowledgeable medical professionals and the results of the independent review shall be posted on the Web sites of the Personnel Cabinet and the Cabinet for Health and Family Services and made available

to the public upon request within thirty (30) days of the notice from the Personnel Cabinet required in paragraph (c) of this subsection;

(e) If the self-insured plan restricts pharmacy benefits to a drug formulary, the plan shall comply with and have an exceptions policy in accordance with KRS 304.17A-535;

(f) Premiums for all plans offered by the Public Employee Health Insurance Program to employees shall be based on the experience of the entire group;~~[and]~~

(g) The plan year for the Public Employee Health Insurance Program, whether for fully insured or self-insured benefits, shall be on a calendar year basis***; and***

(h) The self-insured plan shall comply with subsection (4) of this section.

(2) (a) 1. In addition to any fully insured health benefit plans or self-insured plans, beginning January 1, 2015, the Personnel Cabinet shall offer a health reimbursement account or health flexible spending account for public employees insured under the Public Employee Health Insurance Program.

2. The Personnel Cabinet may offer a health savings account in conjunction with a high deductible health plan option as defined by 26 U.S.C. sec. 223(c)(2) or as an optional account to which the Personnel Cabinet may deposit funds of an employee who waives coverage in accordance with paragraph (b) of this subsection, provided the employee who waives coverage is eligible to contribute to a health savings account.

(b) If a public employee waives coverage provided by his or her employer under the Public Employee Health Insurance Program, the employer shall forward a monthly amount to be determined by the secretary of the Personnel Cabinet for that employee as an employer contribution to the health reimbursement account or health flexible spending account, but not less than one hundred seventy-five dollars ($175) per month, subject to any conditions or limitations imposed by the secretary to comply with applicable federal law.

(c) The administrative fees associated with the employee's health savings account, health reimbursement account, or health flexible spending account shall be an authorized expense to be charged to the public employee health insurance trust fund.

(3) (a) The public employee health insurance trust fund is established in the Personnel Cabinet. The purpose of the public employee health insurance trust fund is to provide funds to pay medical claims and other costs associated with the administration of the Public Employee Health Insurance Program self-insured plan under a competitively bid contract as provided by KRS Chapter 45A and reviewed by the Government Contract Review Committee pursuant to KRS 45A.705. Unless authorized by the General Assembly, the trust fund shall not utilize funds for any other purpose and the trust fund receipts from prior plan years shall not be used to pay claims and expenses for current or subsequent plan years, except as provided by paragraph (b) of this subsection.

(b) In the event of a projected deficit in the trust fund balance of a prior plan year, the secretary of the Finance and Administration Cabinet may declare an emergency and transfer up to twenty-five percent (25%) of another prior plan year's balance to that plan year, provided the Governor, all members of the General Assembly, and Legislative Research Commission are notified at least thirty (30) days prior to the transfer. The Legislative Research Commission shall refer the notice to appropriate committees of jurisdiction for their review.

(c) The following moneys shall be directly deposited into the trust fund:

1. Employer and employee premiums collected under the self-insured plan;

2. Interest and investment returns earned by the self-insured plan;

3. Rebates and refunds attributed to the self-insured plan; and

4. All other receipts attributed to the self-insured plan.

(d) Any balance remaining in the public employee health insurance trust fund at the end of a fiscal year shall not lapse. Any balance remaining at the end of a fiscal year shall be carried forward to the next fiscal year and be used solely for the purpose established in paragraphs (a) and (b) of this subsection. The balance of funds in the public employee health insurance trust fund shall be invested by the Office

of Financial Management consistent with the provisions of KRS Chapter 42, and interest income shall be credited to the trust fund. Any balance for a specific plan year and any subsequent interest income for that specific plan year shall be accounted for separately.

(e) The Auditor of Public Accounts shall be responsible for a financial audit of the books and records of the trust fund. The audit shall be conducted in accordance with generally accepted accounting principles and shall be completed within ninety (90) days of the close of the fiscal year. All audit reports shall be filed with the Governor, the President of the Senate, the Speaker of the House of Representatives, and the secretary of the Personnel Cabinet.

(f) The secretary of the Personnel Cabinet shall file a quarterly report on the status of the trust fund with the Governor, the Interim Joint Committee on Appropriations and Revenue, the Kentucky Group Health Insurance Board, and the Advisory Committee of State Health Insurance Subscribers. The first status report shall be submitted no later than July 30, 2006, and subsequent reports shall be submitted no later than sixty (60) days following the end of each calendar quarter. The report shall include the following:

1. The current balance of the trust fund and the amount of the balance associated with each plan year;

2. A detailed description of all income to the trust fund since the last report;

3. A detailed description of any receipts due to the trust fund;

4. A total amount of payments made for medical and pharmacy claims from the trust fund by plan year;

5. A detailed description of all payments made to the third-party administrator of the self-insured plan by the trust fund;

6. Current enrollment data, including monthly enrollment since the last report, of the Public Employee Health Insurance Program self-insured plan;

7. Any other information the secretary may include;

8. Any other information requested by the Interim Joint Committee on Appropriations and Revenue concerning the operation of the Public Employee Health Insurance Program self-funded plan or the trust fund; and

9. In addition to the information required under subparagraphs 1. to 8. of this paragraph, the quarterly report filed in July and January shall also include the following:

   a. A projection of the medical claims incurred but not yet reported that are considered liabilities to the trust fund;

   b. A statement of any other trust fund liabilities;

   c. A detailed calculation outlining proposed premium rates for the next plan year, including base claims, trend assumptions, administrative fees, and any proposed plan or benefit changes;

   d. A detailed description of the current in-state and out-of-state networks provided under the plan, any changes to the networks since the last report, and any proposed changes to the in-state or out-of-state networks during the next six (6) months; and

   e. Specific data regarding the third-party administrator's performance under the contract. The data shall include the following:

      i. Any results or outcomes of disease management and wellness programs;

      ii. Results of case management audits and educational and communication efforts; and

      iii. Comparison of actual measurable results to contract performance guarantees.

(4) (a) Any fully insured health benefit plan, self-insured plan, or other health plan, as defined in Section 1 of this Act, offered, issued, or renewed to public employees under this section or KRS 18A.225 shall comply with Sections 1 to 5 of this Act, including any state cabinet, agency, or official that contracts with a third-party administrator to administer any self-insured plan offered, issued, or renewed to public employees under this section or KRS 18A.225.

(b) The plan or plans referred to in paragraph (a) of this subsection shall be filed with the commissioner of the Department of Insurance, and the commissioner shall review the plan or plans in accordance with subsection (6) of Section 10 of this Act.

➔Section 15. KRS 367.828 is amended to read as follows:

(1) As used in this section, "health discount plan" means any card, program, device, or mechanism that is not insurance that purports to offer discounts or access to discounts from a health care provider without recourse to the health discount plan.

(2) No person shall sell, market, promote, advertise, or otherwise distribute a health discount plan unless:

(a) The health discount plan clearly states in bold and prominent type on all cards or other purchasing devices, promotional materials, and advertising that the discounts are not insurance;

(b) The discounts are specifically authorized by an individual and separate contract with each health care provider listed in conjunction with the health discount plan;~~[and]~~

(c) The discounts or the range of discounts advertised or offered by the plan are clearly and conspicuously disclosed to the consumer***; and***

(d) For health discount plans that purport to offer discounts or access to discounts on prescription drugs:

1. The plan does not utilize the same identifying information used by an insurer under a health insurance policy, certificate, plan, or contract, including but not limited to policy numbers, group numbers, or member identifications; and

2. The person or plan does not seek, or contract for, the payment of any refunds, recoupments, or fees from a pharmacy or pharmacist.

(3) The provisions of subsection (2) of this section do not apply to the following:

(a) A customer discount or membership card issued by a retailer for use in its own facility; or

(b) Any card, program, device, or mechanism that***:***

1. Is not insurance***;***~~[and which]~~

2. Is administered by a health insurer authorized to transact the business of insurance in this state***; and***

3. Does not purport to offer discounts or access to discounts on prescription drugs.

(4) ***(a)*** A violation of this section shall be deemed an unfair, false, misleading, or deceptive act or practice in the conduct of trade or commerce in violation of KRS 367.170.

(b) All of the remedies, powers, and duties delegated to the Attorney General by KRS 367.190 to 367.300 and penalties pertaining to acts and practices declared unlawful under KRS 367.170 shall be applied to acts and practices in violation of this section.

➔SECTION 16. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Ambulatory pharmacy" has the same meaning as in Section 3 of this Act; and

(b) "Commissioner" means the commissioner of the Department of Insurance.

(2) An ambulatory pharmacy located in Kentucky and permitted under this chapter shall, by March 1, 2026, and by March 1 every other year thereafter, provide data to the board, in accordance with the requirements of Section 3 of this Act and subsection (3) of this section, relating to the pharmacy's dispensing costs for the previous calendar year.

(3) The board shall promulgate an administrative regulation in accordance with KRS Chapter 13A to implement and effectuate subsection (2) of this section, which shall include:

(a) Incorporating the data elements to be collected from each pharmacy, as determined by the commissioner under subsection (2)(c)2.c.i. of Section 3 of this Act; and

(b) Establishing the reporting format, and the manner, of the data submission.

(4) The data collected by the board under this section shall, within thirty (30) days of receipt, be shared with the commissioner for the purposes set forth in subsection (2)(c)2. of Section 3 of this Act.

(5) In carrying out its duties under this section, the board shall cooperate and consult with the commissioner.

(6) All information and data acquired by the board or the commissioner under this section or Section 3 of this Act shall:

(a) Be deemed, and protected as, confidential and proprietary; and

(b) Not be subject to disclosure under KRS 61.870 to 61.884.

(7) The board or the commissioner may retain or contract with one (1) or more third-party vendors or contractors to collect or process the data required under this section, or provide any other expertise, service, or function necessary to carry out the board's or commissioner's duties under this section or Section 3 of this Act, if the vendor or contractor:

(a) Agrees in a written or electronic record to maintain the confidential and proprietary status of the data and all information relating to the data; and

(b) Is not owned by or affiliated with a pharmacy benefit manager, as defined in KRS 304.9-020.

➔Section 17. KRS 315.191 is amended to read as follows:

(1) The board is authorized to:

(a) Promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters set forth in this chapter relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers, to the extent that regulation and control of same have not been delegated to some other agency of the Commonwealth, but administrative regulations relating to drugs shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order. However, ***except as provided in Section 16 of this Act,*** nothing contained in this chapter shall be construed as authorizing the board to promulgate any administrative regulations relating to prices or fees or to advertising or the promotion of the sales or use of commodities or services;

(b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to schedule and conduct hearings on behalf of the board on any matter under the jurisdiction of the board;

(c) Prescribe the time, place, method, manner, scope, and subjects of examinations, with at least two (2) examinations to be held annually;

(d) Issue and renew all licenses, certificates, and permits for all pharmacists, pharmacist interns, pharmacies, pharmacy technicians, wholesale distributors, and manufacturers engaged in the manufacture, distribution, or dispensation of drugs;

(e) Investigate all complaints or violations of the state pharmacy laws and the administrative regulations promulgated by the board, and bring all these cases to the notice of the proper law enforcement authorities;

(f) Promulgate administrative regulations, pursuant to KRS Chapter 13A, that are necessary and to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between pharmacists and pharmacies licensed or issued a permit by it;

(g) Perform all other functions necessary to carry out the provisions of law and the administrative regulations promulgated by the board relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers;

(h) Establish or approve programs for training, qualifications, and registration of pharmacist interns;

(i) Assess reasonable fees, in addition to the fees specifically provided for in this chapter and consistent with KRS 61.870 to 61.884, for services rendered to perform its duties and responsibilities, including, but not limited to, the following:

1. Issuance of duplicate certificates;

2. Mailing lists or reports of data maintained by the board;

3. Copies of documents; or

4. Notices of meetings;

(j) Seize any drug or device found by the board to constitute an imminent danger to public health and welfare;

(k) 1. Establish an advisory council to advise the board on statutes, administrative regulations, and other matters within the discretion of the board pertinent to the practice of pharmacy and regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug distribution, and drug manufacturing. The council shall provide recommendations for updating policies and procedures, including administrative regulations relating to the practice of pharmacy.

2. The council shall consist of nine (9) pharmacists broadly representative of the profession of pharmacy. For purposes of this subparagraph, "broadly representative" means the following:

a. Two (2) pharmacists appointed by the Kentucky Pharmacists Association;

b. Two (2) pharmacists appointed by the Kentucky Independent Pharmacy Alliance;

c. One (1) pharmacist who practices or specializes primarily in a mail order pharmacy appointed by the Kentucky Pharmacists Association;

d. One (1) pharmacist who practices or specializes primarily in a long-term care pharmacy appointed by Kentucky Association of Health Care Facilities;

e. One (1) pharmacist who practices or specializes primarily in a veterinary pharmacy appointed by the Kentucky Pharmacists Association;

f. One (1) pharmacist who practices or specializes primarily in a hospital pharmacy appointed by the Kentucky Society of Health-System Pharmacists; and

g. One (1) pharmacist who practices in a specialized pharmacy that solely or mostly provides medication to persons living with serious health conditions requiring complex therapies, appointed by the Kentucky Pharmacists Association.

3. Each pharmacist member shall be licensed by the board, a resident of Kentucky, and employed for at least two (2) consecutive years in the practice area he or she represents.

4. Members shall serve terms of up to four (4) years and may serve two (2) consecutive terms, but shall not serve on the council for more than two (2) consecutive terms. Members may continue to serve until their successors are appointed.

5. Members shall be confirmed by roll call vote of the board at a meeting conducted in accordance with the Open Meetings Act, KRS 61.805 to 61.850; and

(l) Promulgate administrative regulations establishing the qualifications that pharmacy technicians are required to attain prior to engaging in pharmacy practice activities outside the immediate supervision of a pharmacist.

(2) The board shall have other authority as may be necessary to enforce pharmacy laws and administrative regulations of the board including, but not limited to:

(a) Joining or participating in professional organizations and associations organized exclusively to promote improvement of the standards of practice of pharmacy for the protection of public health and welfare or facilitate the activities of the board; and

(b) Receiving and expending funds, in addition to its biennial appropriation, received from parties other than the state, if:

1. The funds are awarded for the pursuit of a specific objective which the board is authorized to enforce through this chapter, or which the board is qualified to pursue by reason of its jurisdiction or professional expertise;

2. The funds are expended for the objective for which they were awarded;

3. The activities connected with or occasioned by the expenditure of the funds do not interfere with the performance of the board's responsibilities and do not conflict with the exercise of its statutory powers;

4. The funds are kept in a separate account and not commingled with funds received from the state; and

5. Periodic accountings of the funds are maintained at the board office for inspection or review.

(3) In addition to the sanctions provided in KRS 315.121, the board or its hearing officer may direct any licensee, permit holder, or certificate holder found guilty of a charge involving pharmacy or drug laws, rules, or administrative regulations of the state, any other state, or federal government, to pay to the board a sum not to exceed the reasonable costs of investigation and prosecution of the case, not to exceed twenty-five thousand dollars ($25,000).

(4) In an action for recovery of costs, proof of the board's order shall be conclusive proof of the validity of the order of payment and any terms for payment.

➔Section 18. The following KRS section is repealed:

304.38A-120 Compliance with KRS 304.17A-265.

➔Section 19. Sections 2, 3, and 4 of this Act apply to contracts issued, delivered, entered, renewed, extended, or amended on or after January 1, 2025.

➔Section 20. 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 21. (1) Except as provided in subsection (2) of this section, on or before January 1, 2025, the commissioner of the Department of Insurance shall promulgate any emergency and ordinary administrative regulations necessary to implement the provisions of this Act, including but not limited to the administrative regulation required under subsection (2)(c)2.c.i. of Section 3 of this Act.

(2) On or before June 1, 2026, the commissioner of insurance shall promulgate any emergency and ordinary administrative regulations required under subsection (2)(c)2.a. of Section 3 of this Act.

➔Section 22. On or before January 1, 2025, the Kentucky Board of Pharmacy shall promulgate any emergency and ordinary administrative regulations required under Section 16 of this Act.

➔Section 23. Sections 1 to 15, 18, and 19 of this Act take effect January 1, 2025.

Signed by Governor April 5, 2024.