

1 AN ACT relating to pharmacy audits.

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

3 ➔Section 1. KRS 304.17A-740 is amended to read as follows:

4 (1) As used in this section, Section 2 of this Act, and Section 3 of this Act~~[KRS~~
5 ~~304.17A-740 to 304.17A-743]~~, unless the context otherwise requires:

6 (a) 1. "Actual overpayment" means the portion of any amount paid for
7 pharmacy or pharmacist services that:

8 a. Is duplicative because the pharmacy or pharmacist has already
9 been paid for the services; or

10 b. Were not rendered in accordance with the prescriber's order, in
11 which case the auditing entity may only seek refund or
12 recoupment for the portion of the prescription that was filled
13 incorrectly or in excess of the prescriber's order. The amount
14 refunded or recouped by an auditing entity shall not include the
15 dispensing fee paid to the pharmacy if the correct medication
16 was dispensed to the patient.

17 2. Unless required by state or federal law, an auditing entity shall not use
18 the accounting practice of extrapolation when calculating the actual
19 overpayment;

20 (b) "Administrator" has the meaning provided in KRS 304.9-051;

21 (c)~~[(b)]~~ "Audit" includes both a desk audit and an on-site audit;

22 (d) "Auditing entity" means an insurer,~~[-or]~~ an administrator, or a pharmacy
23 benefit manager that conducts, or arranges for the performance of, an audit of
24 a pharmacy's records for the purpose of determining compliance with
25 pharmacy benefit requirements;~~[-and]~~

26 (e)~~[(e)]~~ "Insurer":

27 1. Means any of the following persons or entities that offer or provide

1 coverage in this state for pharmacy or pharmacist services, whether
2 such coverage is by direct payment, reimbursement, or otherwise:

3 a. An insurance company;

4 b. A health maintenance organization;

5 c. A limited health service organization;

6 d. A self-insurer, including a governmental plan, church plan, or
7 multiple employer welfare arrangement, not exempt by federal
8 law from regulation under the insurance laws of this state;

9 e. A provider-sponsored integrated health delivery network;

10 f. A self-insured employer-organized association;

11 g. A nonprofit hospital, medical-surgical, dental, and health service
12 corporation; or

13 h. Any other third-party payor that is:

14 i. Authorized to transact health insurance business in this
15 state; or

16 ii. Not exempt by federal law from regulation under the
17 insurance laws of this state; and ~~[has the meaning provided~~
18 ~~in KRS 304.17A-005]~~

19 2. Shall include any person or entity that has contracted with a state or
20 federal agency to provide coverage in this state for pharmacy or
21 pharmacist services;

22 (f) "Master compounding record" means the recipe for the compounded
23 preparation, which may include:

24 1. The official or assigned name;

25 2. Strength and dosage form of the preparation;

26 3. A description of all ingredients and their quantities;

27 4. Equipment needed to prepare the compound; and

1 5. *Mixing instructions beyond use dating and storage requirements;*

2 (g) *"Pharmacy" means a pharmacy located in this state;*

3 (h) *"Pharmacy benefit manager" has the same meaning as in KRS 304.9-020;*

4 and

5 (i) *"Pharmacy or pharmacist services" means any health care procedures,*

6 *treatments within the scope of practice of a pharmacist, or services provided*

7 *by a pharmacy or a pharmacist, including the provision of:*

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

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

10 (2) *Except as provided in subsections (3) and (4) of this section,* a provider agreement
11 or provider contract ~~between a pharmacy and an insurer, an agency of the~~
12 Commonwealth, a pharmacy benefits administrator, or a pharmacy benefits
13 manager~~]~~ that allows an audit of a~~the~~ pharmacy's records by an auditing entity
14 shall comply with KRS 304.17A-741 and 304.17A-743.

15 (3) *Sections 2 and 3 of this Act shall not apply to any audit conducted:*

16 (a) *By or on behalf of a state agency pursuant to KRS Chapter 205; or*

17 (b) *In which an allegation of fraud, willful misrepresentation, or abuse is made*
18 *by the auditing entity regarding the audited pharmacy and the auditing*
19 *entity has evidence, from its review of claims data, statements, or physical*
20 *evidence or its use of other investigative methods, to support the allegation.*

21 (4) (a) *The provisions of this section, Section 2 of this Act, and Section 3 of this*
22 *Act shall be subject to all applicable federal law and regulations. To the*
23 *extent that any provision of this section, Section 2 of this Act, or Section 3*
24 *of this Act conflicts with an applicable federal law or regulation, the*
25 *applicable federal law or regulation shall control.*

26 (b) *In instances where the enforcement of a provision of this section, Section 2*
27 *of this Act, or Section 3 of this Act would result in the loss of federal funds*

1 that may be available for medical assistance provided under KRS Chapter
2 205, the provision shall not be enforceable to the extent necessary to qualify
3 for receipt of the federal funds.

4 (c) The Cabinet for Health and Family Services, or any of its departments,
5 shall take any steps necessary to effectuate the provisions of this section,
6 Section 2 of this Act, and Section 3 of this Act for audits conducted by or on
7 behalf of a managed care organization providing services under KRS
8 Chapter 205, including but not limited to:

9 1. Requesting an amendment to the State Medicaid Plan;

10 2. Filing an application for a waiver or waiver amendment; or

11 3. Making any other submissions necessary to obtain approval or
12 authorization for managed care organizations providing services
13 under KRS Chapter 205 to comply with this section, Section 2 of this
14 Act, and Section 3 of this Act.

15 ➔ Section 2. KRS 304.17A-741 is amended to read as follows:

16 Except as provided in Section 1 of this Act,~~[When]~~ an audit of a pharmacy's records~~[the~~
17 ~~records of a pharmacy is conducted]~~ by an auditing entity~~[, it]~~ shall comply with~~[be~~
18 ~~subject to]~~ the following conditions:

19 (1) (a) The auditing entity shall give the following~~[at least thirty (30) days]~~ written
20 notice to the pharmacy prior to conducting the audit for each audit to be
21 conducted:

22 1. At least thirty (30) days for a desk audit; and

23 2. At least ninety (90) days for an on-site audit.

24 (b) The notice shall provide detailed information about each claim being
25 audited, including prescription numbers and date of service;

26 (2) An audit performed by the auditing entity that involves clinical or professional
27 judgment shall be conducted in consultation with a pharmacist licensed in this

1 state. For audits involving a compounded medication, the audit shall be
2 conducted in consultation with a pharmacist licensed in this state who is trained
3 to compound in compliance with state and federal law and regulations;

4 (3) A pharmacy may use the records of a hospital, physician, or other practitioner as
5 defined in KRS 217.015(35), ~~as~~ transmitted to the pharmacy by any means of
6 communication, for purposes of validating pharmacy records with respect to orders
7 or refills of a drug;

8 (4) An auditing entity shall not require a pharmacy to keep records for a period of time
9 longer than:

10 (a) Two (2) years; ~~or~~

11 (b) As required by state or federal law or regulation;

12 (5) (a) An auditing entity may request the following information from a pharmacy
13 regarding a claim being audited by the entity:

14 1. A copy of the original prescription order;

15 2. A copy of proof of receipt or shipment of the prescription order;

16 3. A copy or reprint of the prescription label;

17 4. The prescriber's information, such as address, phone number,
18 National Provider Identifier (NPI), and United States Drug
19 Enforcement Administration (DEA) registration number;

20 5. The vaccine administration record;

21 6. Any annotation made by a pharmacist or pharmacy personnel that
22 applies to the fulfillment of the prescription order; and

23 7. For a compounded medication:

24 a. A list of ingredients;

25 b. National Drug Code (NDC), manufacturer, lot number, and
26 expiration date for each ingredient; and

27 c. The quantities used in the compounded preparation.

1 (b) An auditing entity shall not request, obtain, or use the following during an
2 audit:

3 1. Any information that is not relevant to the claim in question;

4 2. Information relating to the pharmacy's compliance with United States
5 Pharmacopeia and the National Formulary (USP-NF) standards;

6 3. The pharmacy's:

7 a. Standard operating procedures;

8 b. Employee training documentation;

9 c. Collaborative care agreements; or

10 d. Master compounding records; or

11 4. Any other information relating to the pharmacy's compliance with any
12 state or federal laws or regulations under the jurisdiction of the
13 Kentucky Board of Pharmacy or another state or federal regulatory
14 body;

15 (6) Notwithstanding Sections 6, 7, and 8 of this Act, during any auditing period, an
16 auditing entity shall not seek a~~[The]~~ recoupment or refund for the following:

17 (a) Errors identified as a result of an audit request unless the auditing entity
18 confirms the pharmacy's receipt of the audit request;

19 (b) Reoccurring errors on the same or a linked prescription, including but not
20 limited to errors in reporting fields for quantity, days supply, or "dispense
21 as written/do not substitute (DAW/DNS)", more than thirty (30) days after
22 the date of the first error, unless the auditing entity:

23 1. Provides notice of the errors to the pharmacy within thirty (30) days of
24 the date of the first error; and

25 2. Confirms the pharmacy's receipt of the notice;

26 (c) Absent an actual overpayment, any error identified as being a clerical or
27 recordkeeping error if the pharmacy corrects the error by submitting an

1 amended claim within thirty (30) days of being notified of the auditing
2 entity's discovery of the error. An auditing entity shall notify the pharmacy
3 of its right to submit an amended claim under this paragraph at the time it
4 notifies the pharmacy of the error; and

5 (d) Any amount paid or reimbursed to a pharmacy, including amounts
6 reimbursed for the cost of a medication or dispensed product or amounts
7 reimbursed or paid for pharmacy or pharmacist services that are
8 retroactively denied or deemed ineligible for coverage, unless one (1) or
9 more of the following occurred:

10 1. The original claim was submitted fraudulently; or

11 2. The pharmacy received an actual overpayment~~[of claims shall be based~~
12 ~~on the actual overpayment or underpayment of claims unless the~~
13 ~~pharmacy agrees to a settlement to the contrary];~~

14 ~~(7)[(6)]~~ A pharmacy shall be audited under the same standards and parameters as other
15 similarly situated pharmacies audited by the auditing entity;

16 ~~(8)[(7)]~~ The period covered by the audit shall not exceed two (2) years from the date
17 the claim was submitted for payment except if a longer period is allowed by federal
18 law or if there is evidence of fraud;

19 ~~(9)[(8)]~~ An audit shall not be scheduled during the first seven (7) calendar days of any
20 month, unless consented to by the pharmacy;

21 ~~(10)[(9)]~~ A preliminary audit report shall be delivered to the pharmacy as follows:

22 (a) For an on-site audit,~~[shall be delivered to the pharmacy]~~ within one hundred
23 twenty (120) days after the exit interview; and

24 (b) For a desk audit, within ninety (90) days after conclusion of the audit;

25 ~~(11)[(10)]~~ A final audit report shall be delivered to the pharmacy within six (6) months
26 after receipt of the preliminary audit report~~[or after all appeals have been~~
27 ~~exhausted, whichever is later];~~

1 ~~(12)~~~~(11)~~ The auditing entity shall allow a pharmacy at least thirty (30) days following
2 receipt of the preliminary audit report to produce documentation to address any
3 discrepancies found during an audit;

4 ~~(13)~~~~(12)~~ The final audit report shall provide claim-level detail of the amounts and
5 reasons for each claim recovery found due. If no amounts have been found due, the
6 final audit report shall so state;

7 ~~(14)~~~~(13)~~ The auditing entity shall not:

8 (a) Receive payment based on the amount recovered in an audit; or

9 (b) *Charge a pharmacy any fees for or relating to an audit;*

10 ~~(15)~~~~(14)~~ The auditing entity shall conduct an exit interview at the close of each on-
11 site~~the~~ audit. The exit interview shall be conducted at a time agreed to by the
12 audited pharmacy. The interview shall provide the audited pharmacy an opportunity
13 to:

14 (a) Respond to questions from the auditing entity;

15 (b) Review and comment on the initial findings of the auditing entity; and

16 (c) Provide additional documentation to clarify the initial findings of the auditing
17 entity;

18 ~~{(15) If an audit results in the identification of any clerical or recordkeeping errors such as~~
19 ~~typographical errors, scrivener's errors, omissions, or computer errors, the pharmacy~~
20 ~~shall not be subject to recoupment of funds by the auditing entity unless the auditing~~
21 ~~entity can provide proof of intent to commit fraud or the error results in an actual~~
22 ~~overpayment to the pharmacy or the wrong medication being dispensed to the~~
23 ~~patient. The pharmacy shall have the right to submit amended claims within thirty~~
24 ~~(30) days of the discovery of an error to correct clerical or recordkeeping errors in~~
25 ~~lieu of recoupment if the prescription was dispensed according to requirements set~~
26 ~~forth in state or federal law;}~~

27 (16) ~~{In the case of overpayment, the auditing entity may seek a refund or recoupment of~~

1 the overpayment in accordance with KRS 304.17A-712. The amount refunded or
2 recouped shall be limited to the amount paid to the pharmacy minus the amount that
3 should have been paid to the pharmacy absent the overpayment and shall not
4 include the dispensing fee if the correct medication was dispensed to the patient;
5 and

6 ~~(17)~~ Claims shall be paid in accordance with ~~[pursuant to]~~ KRS 304.17A-702;

7 (17) Appeals shall be conducted in accordance with Section 3 of this Act; and

8 (18) Whenever a pharmacy's receipt of notice or a request is required to be confirmed
9 under this section, the auditing entity may comply with this requirement by
10 providing the notice or request through electronic mail that is confirmed
11 through:

12 (a) A reply from the pharmacy acknowledging receipt; or

13 (b) An automatic receipt that is generated when the pharmacy accesses the
14 electronic mail.

15 ➔ Section 3. KRS 304.17A-743 is amended to read as follows:

16 Except as provided in Section 1 of this Act:

17 (1) ~~An~~~~The~~ auditing entity conducting an audit shall establish the following:

18 (a) ~~[Establish]~~ An internal appeals process, under which a pharmacy may appeal
19 a final audit report. Upon completion of the internal appeal, the auditing
20 entity shall provide to the pharmacy a written final internal appeal
21 disposition ~~[The auditing entity shall provide to the pharmacy, prior to or at~~
22 ~~the time of the delivery of the preliminary audit report, a written explanation~~
23 ~~of the appeals process, including the name, address, and phone number of the~~
24 ~~person to whom the appeal should be addressed].~~ The appeal disposition shall
25 strike or correct all or any portion of the final audit report that is
26 determined by the auditing entity to be unsubstantiated. If no portion of the
27 final audit report is found to be unsubstantiated, the appeal disposition

1 shall so state; and

2 (b) An external appeals process, under which a pharmacy may appeal a final
3 internal appeal disposition issued under paragraph (a) of this subsection.

4 The appeal shall be:

5 1. For audits other than those conducted by or on behalf of a managed
6 care organization providing services under KRS Chapter 205, to an
7 independent review entity certified in accordance with Section 4 of this
8 Act; and

9 2. For audits conducted by or on behalf of a managed care organization
10 providing services under KRS Chapter 205, an external independent
11 third-party review performed by an independent third party outside of
12 the managed care organization's internal appeal process pursuant to
13 administrative regulations promulgated by the Cabinet for Health and
14 Family Services, Department for Medicaid Services.

15 ~~(2) Following the appeal if it is determined that an audit report or any portion thereof is~~
16 ~~unsubstantiated, the audit report or unsubstantiated portion shall be dismissed~~
17 ~~without the necessity of further proceedings.~~

18 ~~(3)~~ In establishing the appeals processes required under subsection (1) of this
19 section, the auditing entity shall:

20 (a) Provide each pharmacy a written explanation of the appeal process
21 established by the auditing entity, including the name, address, and phone
22 number of the person to whom an appeal should be addressed, prior to or at
23 the time of delivery of the following:

24 1. For internal appeals, the preliminary audit report; and

25 2. For external appeals, the final internal appeal disposition;

26 (b) Within five (5) days of receipt, transmit all requests for an external appeal
27 to:

- 1 1. For audits other than those conducted by or on behalf of a managed
2 care organization providing services under KRS Chapter 205, the
3 department for assignment to a certified independent review entity in
4 accordance with subsection (4) of this section; and
- 5 2. For audits conducted by or on behalf of a managed care organization
6 providing services under KRS Chapter 205, the Cabinet for Health
7 and Family Services, Department for Medicaid Services for processing
8 in accordance with administrative regulations promulgated under
9 subsection (5) of this section; and
- 10 (c) ~~[The auditing entity shall.]~~ Not do the following until all appeals authorized
11 under this section are final:
- 12 1. Recoup disputed funds; or
13 2. Charge or collect interest on disputed funds~~[until the final internal~~
14 ~~disposition of the audit, including the appeals process set forth in~~
15 ~~subsection (1) of this section].~~
- 16 (3) (a) A pharmacy shall submit a request for appeal to the auditing entity within
17 thirty (30) days of receiving:
- 18 1. For internal appeals, the final audit report; and
19 2. For external appeals, the final internal appeal disposition.
- 20 (b) If requested, the pharmacy shall provide written consent authorizing the
21 auditing entity or independent review entity or third party, as applicable, to
22 obtain all necessary records regarding the appeal.
- 23 (4) For external appeals of audits other than those conducted by or on behalf of a
24 managed care organization providing services under KRS Chapter 205:
- 25 (a) The pharmacy shall be assessed a one (1) time filing fee of twenty-five
26 dollars (\$25) to be paid to the independent review entity. The auditing entity
27 shall reimburse the pharmacy for the cost of this fee if the independent

1 review entity finds in favor of the pharmacy;

2 (b) The auditing entity shall be responsible for the remainder of the cost of the
3 independent review entity;

4 (c) The department shall establish a system for each auditing entity to be
5 assigned a certified independent review entity for external appeals. The
6 system established shall require auditing entities to utilize certified
7 independent review entities on a rotating basis so that the auditing entity
8 does not have the same independent review entity for two (2) consecutive
9 external appeals;

10 (d) Upon assignment, the independent review entity shall notify the parties of
11 its assignment and set a deadline for the auditing entity and the pharmacy
12 to submit information for the entity's consideration;

13 (e) An independent review entity shall make a determination on an external
14 appeal within twenty-one (21) calendar days from the deadline established
15 by the entity under paragraph (d) of this subsection; and

16 (f) The auditing entity or pharmacy may submit written complaints to the
17 department regarding any independent review entity's actions believed to be
18 an inappropriate application of this section. The department shall promptly
19 review the complaint, and if the department determines that the actions of
20 the independent review entity were inappropriate, the department shall take
21 corrective measures, including decertification or suspension of the
22 independent review entity from further participation in external appeals.

23 (5) For external appeals of audits conducted by or on behalf of a managed care
24 organization providing services under KRS Chapter 205, the Cabinet for Health
25 and Family Services, Department for Medicaid Services shall, on or before the
26 effective date of this Act, promulgate administrative regulations to implement the
27 external independent third-party review required by subsection (1)(b)2. of this

1 section.

2 (6) In making an external appeal determination, an independent review entity or
3 third party shall consider all relevant information submitted by the auditing entity
4 and the pharmacy, including the following:

5 (a) The information referenced in subsection 5(a) of Section 2 of this Act;

6 (b) The standards, criteria, and rationale used by the auditing entity to make its
7 final internal appeal disposition;

8 (c) The pharmacy's provider agreement or contract;

9 (d) Standards, criteria, and requirements imposed by the Kentucky Board of
10 Pharmacy or another state or federal regulatory body;

11 (e) Relevant findings in peer-reviewed professional or scientific literature,
12 published opinions of nationally recognized specialists, and guidelines
13 adopted by relevant national professional societies; and

14 (f) Any other findings, studies, research, or other relevant documents of
15 government agencies and nationally recognized organizations.

16 (7) The independent review entity or third party shall base its external appeal
17 determination on:

18 (a) The information submitted under subsection (6) of this section; and

19 (b) The requirements of the pharmacy's provider agreement or contract, to the
20 extent consistent with state and federal law.

21 (8) (a) The independent review entity or third party shall provide to the auditing
22 entity and the pharmacy a written external appeal determination that includes:

23 1. Findings for either the auditing entity or the pharmacy regarding each
24 issue appealed by the pharmacy; and

25 2. The relevant provisions of the following that were relied upon by the
26 independent review entity or third party to make its determination and
27 how those provisions were applied to support the findings made;

- 1 a. The pharmacy's provider agreement or contract;
2 b. State law;
3 c. Federal law; and
4 d. Professional, clinical, or scientific standards, criteria, literature,
5 or authority.

6 (b) The written external appeal determination shall also be provided to the
7 department or the Cabinet for Health and Family Services, Department for
8 Medicaid Services, as applicable.

9 (9) (a) For external appeals of audits other than those conducted by or on behalf of
10 a managed care organization providing services under KRS Chapter 205,
11 the determination of the independent review entity shall be binding on the
12 auditing entity.

13 (b) 1. For external appeals of audits conducted by or on behalf of a
14 managed care organization providing services under KRS Chapter
15 205, the pharmacy shall be entitled to appeal a final decision of the
16 external independent third-party review to the administrative hearing
17 tribunal within the Cabinet for Health and Family Services for an
18 administrative hearing to be held in accordance with KRS Chapter
19 13B.

20 2. An appeal shall be filed within thirty (30) days from the pharmacy's
21 receipt of the final decision of the external independent third-party
22 review.

23 3. A decision of the administrative hearing tribunal shall be final for
24 purposes of judicial review.

25 4. The Cabinet for Health and Family Services, Department for
26 Medicaid Services may promulgate administrative regulations to
27 establish reasonable fees, not to exceed one thousand dollars (\$1,000),

1 to defray expenses associated with an administrative hearing that shall
2 be paid by the party who does not prevail in the administrative
3 hearing.

4 (c) Within thirty (30) days of a final determination in favor of a pharmacy, the
5 auditing entity shall provide written notification to the department or the
6 Cabinet for Health and Family Services, Department for Medicaid Services,
7 as applicable, that the determination has been implemented in accordance
8 with this section.

9 (d) Failure to comply with a final determination issued in accordance with this
10 section shall be a violation of the insurance code of a nature sufficient to
11 warrant the commissioner to revoke or suspend the auditing entity's license
12 or certificate of authority.

13 (e) Any pharmacy damaged as a result of an auditing entity's violation of this
14 subsection shall have a cause of action against the auditing entity to recover
15 compensatory damages, plus all reasonable investigation and litigation
16 expenses, including attorneys' fees, at the trial and appellate courts.

17 (10) An independent review entity or third party and any specialist the entity or third
18 party utilizes shall not be liable for damages in a civil action or be subject to
19 professional disciplinary action for making, in good faith, any finding,
20 conclusion, or determination required under this section.

21 (11) Appeals subject to this section shall be confidential and shall not be subject to
22 KRS 61.800 to 61.850 or KRS 61.870 to 61.884.

23 ➔Section 4. KRS 304.17A-627 is amended to read as follows:

24 (1) To be certified as an independent review entity under this chapter, an organization
25 shall submit to the department an application on a form required by the department.
26 The application shall include the following:

27 (a) The name of each stockholder or owner of more than five percent (5%) of any

- 1 stock or options for an applicant;
- 2 (b) The name of any holder of bonds or notes of the applicant that exceeds one
3 hundred thousand dollars (\$100,000);
- 4 (c) The name and type of business of each corporation or other organization that
5 the applicant controls or with which it is affiliated and the nature and extent of
6 the affiliation or control;
- 7 (d) The name and a biographical sketch of each director, officer, and executive of
8 the applicant and any entity listed under paragraph (c) of this subsection and a
9 description of any relationship the named individual has with an insurer~~—as~~
10 ~~defined in KRS 304.17A-600~~ or a provider of health care services;
- 11 (e) The percentage of the applicant's revenues that are anticipated to be derived
12 from independent reviews;
- 13 (f) A description of the minimum qualifications employed by the independent
14 review entity to select health care professionals to perform external review,
15 their areas of expertise, and the medical credentials of the health care
16 professionals currently available to perform external reviews; and
- 17 (g) The procedures to be used by the independent review entity in making review
18 determinations.
- 19 (2) If at any time there is a material change in the information included in the
20 application, provided for in subsection (1) of this section, the independent review
21 entity shall submit updated information to the department.
- 22 (3) An independent review entity shall not be a subsidiary of, or in any way affiliated
23 with, or owned, or controlled by an insurer or a trade or professional association of
24 payors.
- 25 (4) An independent review entity shall not be a subsidiary of, or in any way affiliated
26 with, or owned, or controlled by a trade or professional association of providers.
- 27 (5) Health care professionals who are acting as reviewers for the independent review

1 entity shall hold in good standing a nonrestricted license in a state of the United
2 States.

3 (6) Health care professionals who are acting as reviewers for the independent review
4 entity shall hold a current certification by a recognized American medical specialty
5 board or other recognized health care professional boards in the area appropriate to
6 the subject of the review, be a specialist in the treatment of the covered person's
7 medical condition under review, and have actual clinical experience in that medical
8 condition.

9 (7) The independent review entity shall have a quality assurance mechanism to ensure
10 the timeliness and quality of the review, the qualifications and independence of the
11 physician reviewer, and the confidentiality of medical records and review material.

12 (8) Neither the independent review entity nor any reviewers of the entity, shall have any
13 material, professional, familial, or financial conflict of interest with any of the
14 following:

15 (a) *For external reviews conducted in accordance with KRS 304.17A-621,*
16 *304.17A-623, and 304.17A-625:*

17 1. The insurer involved in the review;

18 2.~~1(b)}~~ Any officer, director, or management employee of the insurer;

19 3.~~1(e)}~~ The provider proposing the service or treatment or any associated
20 independent practice association;

21 4.~~1(d)}~~ The institution at which the service or treatment would be
22 provided;

23 5.~~1(e)}~~ The development or manufacture of the principal drug, device,
24 procedure, or other therapy proposed for the covered person whose
25 treatment is under review; or

26 6.~~1(f)}~~ The covered person; and

27 *(b) For external appeals conducted in accordance with Section 3 of this Act:*

1 1. The auditing entity or pharmacy involved in the appeal; or

2 2. Any officer, director, or management employee of the auditing entity
 3 or pharmacy.

4 (9) As used in this section, "conflict of interest" shall not be interpreted to include:

- 5 (a) A contract under which an academic medical center or other similar medical
 6 center provides health care services to covered persons, except for academic
 7 medical centers that may provide the service under review;
- 8 (b) Provider affiliations which are limited to staff privileges; or
- 9 (c) A specialist reviewer's relationship with an insurer as a contracting health care
 10 provider, except for a specialist reviewer proposing to provide the service
 11 under review.

12 (10) On an annual basis, the independent review entity shall report to the department the
 13 following information:

14 (a) For external reviews conducted under KRS 304.17A-621, 304.17A-623, and
 15 304.17A-625:

16 1. The number of independent review decisions in favor of covered
 17 persons;

18 2.~~1(b)}~~ The number of independent review decisions in favor of insurers;

19 3.~~1(c)}~~ The average turnaround time for an independent review decision;

20 4.~~1(d)}~~ The number of cases in which the independent review entity did
 21 not reach a decision in the time specified in statute or administrative
 22 regulation; and

23 5.~~1(e)}~~ The reasons for any delay; and

24 (b) For external appeals conducted under Section 3 of this Act:

25 1. The number of external appeal determinations in favor of
 26 pharmacies;

27 2. The number of external appeal determinations in favor of auditing

1 entities;

2 3. The average turnaround time for an external appeal determination;

3 4. The number of cases in which the independent review entity did not
4 reach a determination in the time specified in Section 3 of this Act;

5 and

6 5. The reasons for any delay.

7 ➔Section 5. KRS 304.17A-633 is amended to read as follows:

8 The commissioner shall report every six (6) months to the Interim Joint Committee on
9 Banking and Insurance~~[,]~~ and to the Governor on the state of the Independent External
10 Review Program and external appeals under Section 3 of this Act. The Cabinet for
11 Health and Family Services, Department for Medicaid Services shall provide the
12 commissioner all information necessary relating to external appeals involving
13 managed care organizations providing services under KRS Chapter 205 for the report.

14 The report shall include a summary of the number of reviews conducted, medical
15 specialties affected, and a summary of the findings and recommendations made~~by the~~
16 ~~independent external review entity].~~

17 ➔Section 6. KRS 304.17A-708 is amended to read as follows:

18 (1) An insurer shall not require a provider to appeal errors in payment where the insurer
19 has not paid the claim according to the contracted rate. Miscalculations in payments
20 made by the insurer shall be corrected and paid within thirty (30) calendar days
21 upon the insurer's receipt of documentation from the provider verifying the error.

22 (2) An insurer shall not be required to correct a payment error to a provider if the
23 provider's request for a payment correction is filed more than twenty-four (24)
24 months after the date that the provider received payment for the claim from the
25 insurer.

26 (3) (a) Except in cases of fraud, an insurer may only retroactively deny
27 reimbursement to a provider during the twenty-four (24) month period after

1 the date that the insurer paid the claim submitted by the provider.

2 (b) An insurer that retroactively denies reimbursement to a provider under this
3 section shall give the provider a written or electronic statement specifying the
4 basis for the retroactive denial.

5 (c) If the retroactive denial of reimbursement results from coordination of
6 benefits, the written statement shall specify the name and address of the entity
7 acknowledging responsibility for payment of the denied claim.

8 (d) If an insurer retroactively denies reimbursement for services as a result of
9 coordination of benefits with another insurer, the provider shall have twelve
10 (12) months from the date that the provider received notice of the denial,
11 unless the insurer that retroactively denied reimbursement permits a longer
12 period, to submit a claim for reimbursement for the service to the insurer, the
13 medical assistance program, or the Medicare program responsible for
14 payment.

15 (e) Notwithstanding the provisions of this subsection, an insurer shall not
16 request a refund or recoup funds from a pharmacy or pharmacist in
17 violation of Section 2 of this Act.

18 ➔Section 7. KRS 304.17A-712 is amended to read as follows:

19 Except as provided in Section 2 of this Act, if an insurer determines that payment was
20 made for services rendered to an individual who was not eligible for coverage or that
21 payment was made for services not covered by a covered person's health benefit plan, the
22 insurer shall give written notice to the provider and:

23 (1) Request a refund from the provider; or

24 (2) Make a recoupment of the overpayment from the provider in accordance with KRS
25 304.17A-714.

26 ➔Section 8. KRS 304.17A-714 is amended to read as follows:

27 Except as provided in Section 2 of this Act:

- 1 (1) Except for overpayments which are a result of an error in the payment rate or
2 method, an insurer that determines that a provider was overpaid shall, within
3 twenty-four (24) months from the date that the insurer paid the claim, provide
4 written or electronic notice to the provider of the amount of the overpayment, the
5 covered person's name, patient identification number, date of service to which the
6 overpayment applies, insurer reference number for the claim, and the basis for
7 determining that an overpayment exists. Electronic notice includes e-mail or
8 facsimile where the provider agreed in advance in writing to receive such notices.
9 The insurer shall either:
- 10 (a) Request a refund from the provider; or
11 (b) Indicate on the notice that, within thirty (30) calendar days from the postmark
12 date or electronic delivery date of the insurer's notice, if the insurer does not
13 receive a notice of provider dispute in accordance with subsection (2) of this
14 section, the amount of the overpayment will be recouped from future
15 payments.
- 16 (2) If a provider disagrees with the amount of the overpayment, the provider shall
17 within thirty (30) calendar days from the postmark date or the electronic delivery
18 date of the insurer's written notice dispute the amount of the overpayment by
19 submitting additional information to the insurer.
- 20 (3) If a provider files a dispute in accordance with subsection (2) of this section, no
21 recoupment shall be made until the dispute is resolved. If a provider does not
22 dispute the amount of the overpayment and does not provide a refund as required in
23 subsection (2) of this section, the insurer may recoup the amount due from future
24 payments.
- 25 (4) All disputes submitted by providers pursuant to subsection (2) of this section shall
26 be processed in accordance and completed within thirty (30) days with the insurer's
27 provider appeals process.

(5) An insurer may recover an overpayment resulting from an error in the payment rate or method by requesting a refund from the provider or making a recoupment of the overpayment from the provider, subject to the provisions of subsection (6) of this section. A provider may dispute such recoupment in accordance with the provisions contained in KRS 304.17A-708.

(6) If an insurer chooses to collect an overpayment made to a provider through a recoupment against future provider payments, the insurer shall, within twenty-four (24) months from the date that the insurer paid the claim, and at the actual time of recoupment give the provider written or electronic documentation that specifies:

- (a) The amount of the recoupment;
- (b) The covered person's name to whom the recoupment applies;
- (c) Patient identification number; and
- (d) Date of service.

➔SECTION 9. 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 1, 2, and 3 of this Act.

➔Section 10. The following KRS sections are repealed:

304.17A-745 KRS 304.17A-740 to 304.17A-743 not applicable to audits conducted by state agency pursuant to KRS Chapter 205.

304.17A-747 KRS 304.17A-740 to 304.17A-743 not applicable when fraud, willful misrepresentation, or abuse alleged.

➔Section 11. This Act applies to provider agreements or contracts issued, delivered, entered, renewed, extended, or amended on or after the effective date of this Act.

➔Section 12. 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

- 1 application, and to this end the provisions and applications of this Act are severable.
- 2 ➔Section 13. This Act takes effect on January 1, 2021.