AN ACT relating to prior authorization.

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

➔SECTION 1. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section, "evaluation period" means a six (6) month period of time during which a health care provider's prior authorization experience for a particular health care service is evaluated by an insurer or private review agent for purposes of determining eligibility for an exemption under subsection (3)(a) of this section.

(2) An insurer or its private review agent shall not require a health care provider to obtain prior authorization for a particular health care service if, at the time the health care service was provided, the health care provider qualified for or had an exemption under subsection (3)(a) of this section, or was qualified under the exemption of another health care provider in accordance with subsection (3)(b) of this section, for that health care service.

(3) (a) A health care provider shall qualify for an exemption for a particular health care service if, in the most recent evaluation period, the insurer or its private review agent approved not less than ninety percent (90%) of the prior authorization requests submitted by the health care provider for that health care service.

(b) Subject to the requirements of paragraph (c) of this subsection, a health care provider shall be qualified under the exemption of another health care provider for a particular health care service if:

1. The following requirements are met:

a. The health care provider is an advanced practice registered nurse or physician assistant;

b. The health care provider's collaborating or supervising

physician has an exemption for the health care service under paragraph (a) of this subsection;

c. The health care service is within the scope of practice of an advanced practice registered nurse or physician assistant; and

d. The health care provider submits the claim for the health care service under the collaborating or supervising physician's national provider identifier in a manner consistent with applicable law; or

2. The health care provider is supervising or providing a health care service ordered by a health care provider with an exemption for the health care service under paragraph (a) of this subsection.

(c) 1. For health care services provided under paragraph (b) of this subsection, the health care provider shall include the name and national provider identifier of the collaborating or supervising physician, or the ordering health care provider, on the claim forms for the health care service.

2. The insurer or its private review agent may provide coding guidance to health care providers submitting claim forms under subparagraph 1. of this paragraph to ensure that information is appropriately captured on the claim.

3. If the information required under subparagraph 1. of this paragraph is not included on claim forms submitted for the health care service, the insurer or its private review agent may treat the claim as subject to an otherwise applicable prior authorization requirement.

(4) (a) An insurer or its private review agent shall evaluate, once every six (6) months, whether a health care provider qualifies for an exemption under subsection (3)(a) of this section for each health care service:

1. Provided by the provider during the evaluation period regardless of the number of prior authorization requests submitted for the health care service during the evaluation period; and

2. For which:

a. The insurer or private review agent requires prior authorization; and

b. The provider does not have an exemption under subsection (3)(a) of this section.

(b) An insurer or its private review agent shall not:

1. Include prior authorization requests that have not been finalized in its evaluation under paragraph (a) of this subsection; or

2. Require a health care provider to request an exemption in order to qualify for the exemption.

(5) (a) Except as provided in paragraph (b) of this subsection, not later than five (5) days after conducting an evaluation under subsection (4) of this section, an insurer or its private review agent shall provide a health care provider with a notice, in accordance with Section 4 of this Act, that includes:

1. A statement:

a. Notifying the health care provider that the provider has been granted an exemption under subsection (3)(a) of this section; and

b. Setting forth the duration of the exemption; and

2. A list of the health care services and plans to which the exemption applies.

(b) An insurer or its private review agent may deny an exemption not later than five (5) days after conducting an evaluation under subsection (4) of this section if the insurer or private review agent provides the health care

provider with the following, in accordance with Section 4 of this Act:

1. Actual statistics and data for the relevant evaluation period;

2. Detailed information sufficient to demonstrate that the health care provider does not meet the criteria for an exemption under subsection (3)(a) of this section for the particular health care service; and

3. A plain language explanation of how the health care provider may appeal by seeking an external review of the denial under Section 3 of this Act.

(6) If a health care provider submits a prior authorization request for a health care service for which the health care provider qualifies for an exemption under subsection (3)(a) of this section, the insurer or its private review agent shall promptly provide the health care provider with a notice, in accordance with Section 4 of this Act, that includes:

(a) The information required under subsection (5)(a) of this section; and

(b) The insurer's payment requirements.

(7) An exemption that a health care provider qualifies for or has under subsection (3)(a) of this section shall remain in effect until it is rescinded under Section 2 of this Act.

(8) When a health care provider's exemption has been denied under subsection (5)(b) of this section or rescinded under Section 2 of this Act, the health care provider may qualify for or have an exemption under subsection (3)(a) of this section for the same health care service beginning six (6) months after the effective date of the rescission or denial.

➔SECTION 2. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section, "evaluation period" means a six (6) month period of time during which a health care provider's claims experience for a particular health

care service is evaluated by an insurer or private review agent for purposes of determining whether an exemption may be rescinded under this section.

(2) (a) Subject to this section and except as provided in subsection (6) of Section 3 of this Act, an insurer or its private review agent may, during the months of January and July of each year, rescind an exemption granted in accordance with subsection (3)(a) of Section 1 of this Act, if the insurer or private review agent:

1. Makes a determination, based on a retrospective review of a random sample of not less than five (5) and not more than twenty (20) claims submitted by the health care provider for the particular health care service during the most recent evaluation period, that less than ninety percent (90%) of the claims met the medical necessity criteria that would have been used during the relevant evaluation period by the insurer or private review agent when conducting a prior authorization review for that health care service; and

2. Notifies the health care provider of the rescission in accordance with Section 4 of this Act and paragraph (b) of this subsection.

(b) The notification required under paragraph (a) of this subsection shall include:

1. An identification of the health care services and plans for which the exemption is being rescinded;

2. The date the notification was issued;

3. The date the rescission is effective under subsection (3)(c)2. of this section;

4. A statement that includes:

a. The total number of payable claims submitted by or in connection with the health care provider during the most recent

evaluation period that were eligible to be evaluated for each health care service subject to the rescission;

b. Identification of each claim included in the random sample;

c. The insurer's or private review agent's determination of whether each claim met the insurer's or private review agent's medical necessity criteria; and

d. For any claim determined to not have met the insurer's or private review agent's medical necessity criteria:

i. The principal reasons for the determination, including, if applicable, a statement that the determination was based on a failure to submit specified medical records;

ii. The clinical basis for the determination;

iii. A description of the medical necessity criteria sources that were used as guidelines in making the determination; and

iv. The professional specialty of the health care provider who made the determination;

5. A plain language explanation of how the health care provider may appeal by seeking an external review of the rescission under Section 3 of this Act;

6. A form, prescribed by the commissioner under Section 7 of this Act, to be filled out by the health care provider to request an external review of the rescission under Section 3 of this Act that includes:

a. The name, address, contact information, and national provider identifier of the health care provider;

b. An indication of whether the health care provider is requesting the independent review entity to review the same random sample of claims or an additional random sample of claims, as provided

in subsection (4)(a) of Section 3 of this Act;

c. The date the appeal is being requested; and

d. An instruction for the health care provider to:

i. Return the form to the insurer or private review agent before the date the rescission becomes effective under subsection (3)(c)2. of this section; and

ii. Include applicable medical records for any determination that was based on a failure to provide medical records; and

7. The address and contact information for returning, by mail or electronic means, the form referenced in subparagraph 6. of this paragraph.

(c) An insurer or its private review agent shall not rescind an exemption of a health care provider that has less than five (5) claims subject to review under paragraph (a) of this subsection.

(3) (a) 1. Except as provided in subparagraph 2. of this paragraph, the review periods under subsection (2)(a) of this section shall be January through June and July through December of each year.

2. If six (6) months has not elapsed since the date of the notification under subsection (5)(a) or (6) of Section 1 of this Act, whichever is earlier, the review period shall be extended to include the next full review period set forth in subparagraph 1. of this paragraph.

(b) An insurer or private review agent shall not include claims that have not been finalized in its review under subsection (2)(a) of this section.

(c) A rescission determination under subsection (2) of this section shall:

1. Be made by an individual:

a. Licensed to practice medicine in this state; and

b. When relating to a physician, who has the same or similar

specialty as the physician, when possible; and

2. Take effect:

a. Except as provided in subdivision b. of this subparagraph, on the thirtieth day after the date the insurer or its private review agent notifies the health care provider of the rescission; or

b. If the health care provider timely requests an external review of the rescission under subsection (2)(a)1. of Section 3 of this Act, on the fifth day after the date the independent review entity affirms the rescission.

(4) If a notice under subsection (2) of this section is sent in a manner inconsistent with the requirements of Section 4 of this Act, the notice shall be defective and any exemption referenced in the defective notice shall remain in effect.

➔SECTION 3. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section, "evaluation period" has the same meaning as in Section 2 of this Act.

(2) (a) 1. Except as provided in paragraph (b) of this subsection, a health care provider may, within thirty (30) days of receiving an exemption denial under Section 1 of this Act or an exemption rescission under Section 2 of this Act, submit a request for an external review of the rescission or denial to the insurer or its private review agent. An external review requested under this subparagraph shall be conducted by an independent review entity.

2. Requests for an external review under subparagraph 1. of this paragraph shall be forwarded by the insurer or its private review agent to the independent review entity within twenty-four (24) hours of receipt by the insurer or private review agent.

3. The department shall establish a system for each insurer or its private review agent to be assigned an independent review entity for external reviews conducted under subparagraph 1. of this paragraph.

4. The system established under subparagraph 3. of this paragraph shall:

a. Be prospective; and

b. Require insurers and private review agents to utilize independent review entities on a rotating basis so that an insurer or private review agent does not have the same independent review entity for two (2) consecutive external reviews.

5. For purposes of the system established under subparagraph 3. of this paragraph, the department shall contract with not less than two (2) independent review entities.

(b) 1. A health care provider may submit a request for an external review of any rescission notice alleged to have been sent in a manner inconsistent with Section 4 of this Act. An external review requested under this subparagraph shall be conducted by the department.

2. The commissioner shall promulgate an administrative regulation to establish procedures for an external review requested under subparagraph 1. of this paragraph.

(c) An insurer or its private review agent shall:

1. Not require a health care provider to engage in an internal appeal before requesting an external review under this subsection; and

2. Provide options for a health care provider to submit a request for an external review under paragraph (a)1. of this subsection by mail, electronic mail, or other electronic methods.

(3) For an external review of an exemption denial under Section 1 of this Act, the independent review entity shall base its decision on the criteria established under

subsection (3)(a) of Section 1 of this Act.

(4) For an external review of an exemption rescission under Section 2 of this Act:

(a) A health care provider may request that the independent review entity, as part of its review, consider, if available, another random sample of not less than five (5) and not more than twenty (20) claims submitted to the insurer or its private review agent by the health care provider during the relevant evaluation period for the relevant health care service;

(b) The independent review entity shall base its decision on the criteria established under subsection (2)(a) of Section 2 of this Act as determined by the medical necessity of the following sample of claims:

1. The claims reviewed by the insurer or its private review agent under subsection (2)(a) of Section 2 of this Act; and

2. If the health care provider makes a request under paragraph (a) of this subsection, the additional claims submitted for review under this subsection; and

(c) In making its decision, the independent review entity shall take into account all of the following:

1. Information submitted by the insurer or its private review agent and the health care provider, including:

a. The relevant medical records for the claims being reviewed;

b. The standards, criteria, and clinical rationale used by the insurer or private review agent to make its determination; and

c. The insurer's health plan;

2. Findings, studies, research, and other relevant documents of government agencies and nationally recognized organizations, including the National Institutes of Health, the National Cancer Institute, the National Academy of Sciences, the United States Food

and Drug Administration, the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services, and the Agency for Health Care Research and Quality; and

3. Relevant findings in peer-reviewed medical or scientific literature, published opinions of nationally recognized medical specialists, and clinical guidelines adopted by relevant national medical societies.

(5) (a) The independent review entity shall issue an external review decision to the health care provider, insurer or its private review agent, and department not later than thirty (30) days after the date the health care provider files a request under subsection (2)(a)1. of this section.

(b) The external review decision issued under this subsection shall include:

1. The findings for either the health care provider or the insurer or its private review agent regarding each exemption under review;

2. The relevant provisions of the insurer's health plan and how the provisions applied; and

3. The relevant provisions of any nationally recognized and peer-reviewed medical or scientific documents used in the external review.

(6) If an insurer's or its private review agent's denial or rescission is overturned by an independent review entity under this section, the insurer or private review agent:

(a) Shall be bound by the decision;

(b) Shall not attempt to rescind the exemption reviewed by the independent review entity before the end of the next evaluation period that occurs; and

(c) May only deny or rescind the exemption reviewed by the independent review entity after the insurer or private review agent complies with this section and Sections 1 and 2 of this Act.

(7) An insurer or its private review agent shall pay:

(a) For any external review requested under this section; and

(b) A reasonable fee determined by the Kentucky Board of Medical Licensure for any copies of medical records or other documents requested from a health care provider during an external review requested under this section.

(8) The external review process shall be confidential and shall not be subject to KRS 61.805 to 61.850 or KRS 61.870 to 61.884.

(9) (a) The insurer, private review agent, or health care provider involved in an external review under subsection (2)(a)1. of this section may submit a written complaint to the department regarding any independent review entity's actions believed to be an inappropriate application of this section.

(b) 1. The department shall promptly review the complaint, and if the department determines that the actions of the independent review entity were inappropriate, the department shall take corrective measures, including decertification or suspension of the independent review entity from further participation in external reviews.

2. The department's actions under subparagraph 1. of this paragraph shall be subject to the powers and administrative procedures set forth in this subtitle.

➔SECTION 4. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

(1) For purposes of sending forms and notices to a health care provider under Sections 1 to 7 of this Act, an insurer or its private review agent shall solicit from each health care provider the provider's preferred:

(a) Method of contact; and

(b) Contact information.

(2) An insurer or its private review agent shall:

(a) Send all forms and notices required to be sent to a health care provider

under Sections 1 to 7 of this Act, or administrative regulations promulgated pursuant thereto, in the manner designated by the health care provider under subsection (1) of this section; and

(b) Provide a process for health care providers to update the preferences designated under subsection (1) of this section.

➔SECTION 5. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

(1) An insurer or its private review agent shall not retrospectively:

(a) Except as provided in subsection (2) of this section, deny, or reduce payment to a health care provider for a health care service for which the health care provider:

1. Qualified or had an exemption under subsection (3)(a) of Section 1 of this Act based on medical necessity or appropriateness of care; or

2. Qualified under the exemption of another health care provider under subsection (3)(b) of Section 1 of this Act based on medical necessity or appropriateness of care; or

(b) Deny a health care service on the basis of a rescission under Section 2 of this Act, regardless of whether an independent review entity affirms the insurer's or private review agent's determination.

(2) The prohibition under subsection (1)(a) of this section shall not apply if the health care provider:

(a) Knowingly and materially misrepresented the health care service in a request for payment submitted to the insurer or private review agent with the specific intent to deceive and obtain an unlawful payment from the insurer or private review agent; or

(b) Failed to substantially perform the health care service.

(3) Notwithstanding any other law to the contrary, an insurer or its private review

agent shall not conduct a retrospective review of a health care service for which the health care provider qualified or had an exemption under subsection (3)(a) of Section 1 of this Act, or qualified under the exemption of another health care provider under subsection (3)(b) of Section 1 of this Act, except:

(a) To determine if the health care provider continues to qualify for an exemption; or

(b) When the insurer or private review agent has reasonable cause to suspect a basis for denial exists under subsection (1)(a) of this section.

➔SECTION 6. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

Nothing in Sections 1 to 7 of this Act shall be construed to:

(1) Authorize a health care provider to provide a health care service outside the scope of the provider's applicable license; or

(2) Require an insurer or its private review agent to pay for a health care service described in subsection (1) of this section that is performed in violation of the laws of this state.

➔SECTION 7. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

For every process relating to an exemption from prior authorization requirements under Sections 1 to 7 of this Act, the commissioner shall, by administrative regulation, establish standardized forms that shall be used by insurers and private review agents.

➔Section 8. KRS 304.17A-600 is amended to read as follows:

As used in KRS 304.17A-600 to 304.17A-633:

(1) (a) "Adverse determination" means a determination by an insurer or its designee that the health care services furnished or proposed to be furnished to a covered person are:

1. Not medically necessary, as determined by the insurer, or its designee or

experimental or investigational, as determined by the insurer, or its designee; and

2. Benefit coverage is therefore denied, reduced, or terminated.

(b) "Adverse determination" does not mean a determination by an insurer or its designee that the health care services furnished or proposed to be furnished to a covered person are specifically limited or excluded in the covered person's health benefit plan;

(2) "Authorized person" means a parent, guardian, or other person authorized to act on behalf of a covered person with respect to health care decisions;

(3) "Concurrent review" means utilization review conducted during a covered person's course of treatment or hospital stay;

(4) "Covered person" means a person covered under a health benefit plan;

(5) "External review" means a review that is conducted by an independent review entity~~[which meets specified criteria as established in KRS 304.17A-623, 304.17A-625, and 304.17A-627]~~;

(6) "Health benefit plan" has the same meaning as in KRS 304.17A-005, except that for purposes of KRS 304.17A-600 to 304.17A-633, the term includes short-term coverage policies;

(7) "Health care provider" or "provider" has the same meaning as in KRS 304.17A-005 except that, for purposes of Sections 1 to 7 of this Act, the term includes, if practicing independently, any:

(a) Licensed clinical alcohol and drug counselor licensed under KRS Chapter 309;

(b) Licensed psychologist, licensed psychological practitioner, or certified psychologist with autonomous functioning licensed or certified under the provisions of KRS Chapter 319;

(c) Licensed professional clinical counselor licensed under KRS Chapter 335;

(d) Licensed marriage and family therapist licensed under KRS Chapter 335;

(e) Licensed professional art therapist licensed under KRS Chapter 309; and

(f) Licensed clinical social worker licensed under KRS Chapter 335;

(8) ~~[(7)]~~ "Independent review entity" means an individual or organization certified by the department to perform external reviews~~[under KRS 304.17A-623, 304.17A-625, and 304.17A-627]~~;

(9) ~~[(8)]~~ "Insurer" means any of the following entities authorized to issue health benefit plans~~[as defined in subsection (6) of this section]~~:

(a) An insurance company***;*** ~~[,]~~

(b) A health maintenance organization;

(c) A self-insurer or multiple employer welfare arrangement not exempt from state regulation by ERISA;

(d) A provider-sponsored integrated health delivery network;

(e) A self-insured employer-organized association;

(f) A nonprofit hospital, medical-surgical, or health service corporation; or

(g) Any other entity authorized to transact health insurance business in Kentucky;

(10) ~~[(9)]~~ "Internal appeals process" means a formal process, as set forth in KRS 304.17A-617, established and maintained by the insurer, its designee, or agent whereby the covered person, an authorized person, or a provider may contest an adverse determination rendered by the insurer, its designee, or private review agent;

(11) ~~[(10)]~~ "Nationally recognized accreditation organization":

(a) Means a private nonprofit entity that:

1. Sets national utilization review and internal appeal standards; and

2. Conducts review of insurers, agents, or independent review entities for the purpose of accreditation or certification; and

(b) Shall include the Accreditation Association for Ambulatory Health Care (AAAHC), the National Committee for Quality Assurance (NCQA), the

American Accreditation Health Care Commission (URAC), the Joint Commission, or any other organization identified by the department;

(12)~~[(11)]~~ "Private review agent" or "agent":

(a) Means a person or entity performing utilization review that is either affiliated with, under contract with, or acting on behalf of any insurer or other person providing or administering health benefits to citizens of this Commonwealth; and

(b) Does not include an independent review entity ***that***~~[which]~~ performs external ***reviews***~~[review]~~ of adverse determinations;

(13)~~[(12)]~~ "Prospective review"***:***

(a) Means a utilization review that is conducted prior to the provision of health care services***; and***~~[. "Prospective review" also]~~

(b) Includes any insurer's or agent's requirement that a covered person or provider notify the insurer or agent prior to providing a health care service, including but not limited to prior authorization, step therapy protocol, preadmission review, pretreatment review, utilization, and case management;

(14)~~[(13)]~~ "Qualified personnel" means ***a*** licensed physician, registered nurse, licensed practical nurse, medical records technician, or other licensed medical personnel who***,*** through training and experience***,*** shall render consistent decisions based on the review criteria;

(15)~~[(14)]~~ "Registration" means an authorization issued by the department to an insurer or a private review agent to conduct utilization review;

(16)~~[(15)]~~ "Retrospective review":

(a) Means utilization review that is conducted after health care services have been provided to a covered person; and

(b) Does not include the review of a claim that is limited to an evaluation of reimbursement levels~~[,]~~ or adjudication of payment;

(17)~~[(16) (a)]~~ "Urgent health care services"***:***

(a) Means health care or treatment with respect to which the application of the time periods for making nonurgent determination:

1. Could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or
2. In the opinion of a physician with knowledge of the covered person's medical condition, would subject the covered person to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review***; and***~~[.]~~

(b) ***Includes***~~[Urgent health care services include]~~ all requests for hospitalization and outpatient surgery;

(18)~~[(17)]~~ ***(a)*** "Utilization review" means a review of the medical necessity and appropriateness of hospital resources and medical services given or proposed to be given to a covered person for purposes of determining the availability of payment.

(b) Areas of review include concurrent, prospective, and retrospective review; and

(19)~~[(18)]~~ "Utilization review plan" means a description of the procedures governing utilization review activities performed by an insurer or a private review agent.

➔Section 9. KRS 304.17A-605 is amended to read as follows:

(1) ***Sections 1 to 7 of this Act and*** KRS 304.17A-600, 304.17A-603, 304.17A-605, 304.17A-607, 304.17A-609, 304.17A-611, 304.17A-613, and 304.17A-615 set forth the requirements and procedures regarding utilization review and shall apply to:

(a) Any insurer or its private review agent that provides or performs utilization review in connection with a health benefit plan or a limited health service benefit plan; and

(b) Any private review agent that performs utilization review functions on behalf of any person providing or administering health benefit plans or limited health service benefit plans.

(2) Where an insurer or its agent provides or performs utilization review, and in all instances where internal appeals as set forth in KRS 304.17A-617 are involved, the insurer or its agent shall be responsible for:

(a) Monitoring all utilization reviews and internal appeals carried out by or on behalf of the insurer;

(b) Ensuring that all requirements of KRS 304.17A-600 to 304.17A-633 are met;

(c) Ensuring that all administrative regulations promulgated in accordance with KRS 304.17A-609, 304.17A-613, and 304.17A-629 are complied with; and

(d) Ensuring that appropriate personnel have operational responsibility for the performance of the insurer's utilization review plan.

(3) A private review agent that operates solely under contract with the federal government for utilization review or patients eligible for hospital services under Title XVIII of the Social Security Act shall not be subject to the registration requirements set forth in KRS 304.17A-607, 304.17A-609, and 304.17A-613.

➔Section 10. KRS 304.17A-607 is amended to read as follows:

(1) An insurer or private review agent shall not provide or perform utilization reviews without being registered with the department. A registered insurer or private review agent shall:

(a) Have available the services of sufficient numbers of registered nurses, medical records technicians, or similarly qualified persons supported by licensed physicians with access to consultation with other appropriate physicians to carry out its utilization review activities;

(b) Ensure that~~[, for any contract entered into on or after January 1, 2020,]~~**:**

1. For the provision of utilization review services, only licensed

physicians, who are of the same or similar specialty and subspecialty, when possible, as the ordering provider, shall:

a.~~[1.]~~Make a utilization review decision to deny, reduce, limit, or terminate a health care benefit or to deny, or reduce payment for**,** a health care service because that service is not medically necessary, experimental, or investigational except***:***

i. In the case of a health care service rendered by a chiropractor or optometrist**,**~~[where]~~ the denial shall be made respectively by a chiropractor or optometrist duly licensed in Kentucky; and

ii. For the provision of utilization review services relating to prior authorization, only physicians licensed in this state shall make the utilization review decision; and

b.~~[2.]~~Supervise qualified personnel conducting case reviews; ***and***

2. For the provision of utilization review services relating to prior authorization for any prescription drug, the drug shall be the basis for the prior authorization decision regardless of the dosage;

(c) Have available the services of sufficient numbers of practicing physicians in appropriate specialty areas to assure the adequate review of medical and surgical specialty and subspecialty cases;

(d) Not disclose or publish individual medical records or any other confidential medical information in the performance of utilization review activities except as provided in the Health Insurance Portability and Accountability Act, Subtitle F, secs. 261 to 264 and 45 C.F.R. ***parts***~~[secs.]~~ 160 to 164 and other applicable laws and administrative regulations;

(e) Provide a toll free telephone line for covered persons, authorized persons, and providers to contact the insurer or private review agent and be accessible to

covered persons, authorized persons, and providers for forty (40) hours a week during normal business hours in this state;

(f) Where an insurer, its agent, or private review agent provides or performs utilization review, be available to conduct utilization review during normal business hours and extended hours in this state on Monday and Friday through 6:00 p.m., including federal holidays;

(g) Provide decisions to covered persons, authorized persons, and all providers on appeals of adverse determinations and coverage denials of the insurer or private review agent, in accordance with this section and administrative regulations promulgated in accordance with KRS 304.17A-609;

(h) Except for retrospective review of an emergency admission where the covered person remains hospitalized at the time the review request is made, which shall be considered a concurrent review, or as otherwise provided in this subtitle, provide a utilization review decision in accordance with the timeframes in paragraph (i) of this subsection and 29 C.F.R. part 2560, including written notice of the decision;

(i) 1. Render a utilization review decision concerning urgent health care services, and notify the covered person, authorized person, or provider of that decision ***not***~~[no]~~ later than twenty-four (24) hours after obtaining all necessary information to make the utilization review decision; and

2. If the insurer or agent requires a utilization review decision of nonurgent health care services, render a utilization review decision and notify the covered person, authorized person, or provider of the decision within five (5) days of obtaining all necessary information to make the utilization review decision.

For purposes of this paragraph, "necessary information" is limited to:

a. The results of any face-to-face clinical evaluation;

b. Any second opinion that may be required; and

c. Any other information determined by the department to be necessary to making a utilization review determination;

(j) Provide written notice of review decisions to the covered person, authorized person, and providers. The written notice may be provided in an electronic format, including e-mail or facsimile, if the covered person, authorized person, or provider has agreed in advance in writing to receive the notices electronically. An insurer or agent that denies a step therapy exception, as defined in KRS 304.17A-163, or denies coverage or reduces payment for a treatment, procedure, drug that requires prior approval, or device shall include in the written notice:

1. A statement of the specific medical and scientific reasons for denial or reduction of payment or identifying that provision of the schedule of benefits or exclusions that demonstrates that coverage is not available;

2. The medical license number and the title of the reviewer making the decision;

3. Except for retrospective review, a description of alternative benefits, services, or supplies covered by the health benefit plan, if any; and

4. Instructions for initiating or complying with the insurer's internal appeal procedure, as set forth in KRS 304.17A-617, stating, at a minimum, whether the appeal shall be in writing, and any specific filing procedures, including any applicable time limitations or schedules, and the position and phone number of a contact person who can provide additional information;

(k) Afford participating physicians an opportunity to review and comment on all medical and surgical and emergency room protocols, respectively, of the insurer and afford other participating providers an opportunity to review and

comment on all of the insurer's protocols that are within the provider's legally authorized scope of practice; and

(l) Comply with its own policies and procedures on file with the department or, if accredited or certified by a nationally recognized accrediting entity, comply with the utilization review standards of that accrediting entity where they are comparable and do not conflict with state law.

(2) ***(a)*** The insurer's or private review agent's failure to make a determination and provide written notice within the time frames set forth in this section shall be deemed to be a prior authorization for the health care services or benefits subject to the review.

(b) This ***subsection***~~[provision]~~ shall not apply where the failure to make the determination or provide the notice results from circumstances which are documented to be beyond the insurer's control.

(3) ***(a)*** An insurer or private review agent shall submit a copy of any changes to its utilization review policies or procedures to the department.

(b) No change to ***utilization review*** policies and procedures shall be effective or used until after it has been filed with and approved by the commissioner.

(4) ***(a)*** A private review agent shall provide to the department the names of the entities for which the private review agent is performing utilization review in this state.

(b) Notice shall be provided ***to the department*** within thirty (30) days of any change.

➔Section 11. KRS 304.17A-621 is amended to read as follows:

The Independent External Review Program is hereby established in the department. The program shall provide covered persons with a formal, independent review to address disagreements between the covered person and the covered person's insurer regarding an adverse determination made by the insurer, its designee, or a private review agent. This

section and KRS 304.17A-623 and 304.17A-625 establish requirements and procedures governing ***the program*** ~~[external review and independent review entities]~~.

➔Section 12. KRS 304.17A-627 is amended to read as follows:

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

(a) The name of each stockholder or owner of more than five percent (5%) of any stock or options for an applicant;

(b) The name of any holder of bonds or notes of the applicant that exceeds one hundred thousand dollars ($100,000);

(c) The name and type of business of each corporation or other organization that the applicant controls or with which it is affiliated and the nature and extent of the affiliation or control;

(d) The name and a biographical sketch of each director, officer, and executive of the applicant and any entity listed under paragraph (c) of this subsection and a description of any relationship the named individual has with an insurer as defined in KRS 304.17A-600 or a provider of health care services;

(e) The percentage of the applicant's revenues that are anticipated to be derived from independent reviews;

(f) A description of the minimum qualifications employed by the independent review entity to select health care professionals to perform external review, their areas of expertise, and the medical credentials of the health care professionals currently available to perform external reviews; and

(g) The procedures to be used by the independent review entity in making review determinations.

(2) If at any time there is a material change in the information included in the application~~[,]~~ ***required under*** ~~[provided for in]~~ subsection (1) of this section, the

independent review entity shall submit updated information to the department.

(3) An independent review entity shall not be a subsidiary of,~~[or]~~ in any way affiliated with, or owned~~[,]~~ or controlled by an insurer or a trade or professional association of payors.

(4) An independent review entity shall not be a subsidiary of,~~[or]~~ in any way affiliated with, or owned~~[,]~~ or controlled by a trade or professional association of providers.

(5) Health care professionals who are acting as reviewers for the independent review entity shall hold in good standing a nonrestricted license in a state of the United States.

(6) Health care professionals who are acting as reviewers for the independent review entity shall***:***

(a) Hold a current certification by a recognized American medical specialty board or other recognized health care professional boards in the area appropriate to the subject of the review***;***~~[,]~~

(b) Be a specialist in the treatment of the covered person's medical condition under review***;***~~[,]~~ and

(c) Have actual clinical experience in that medical condition.

(7) The independent review entity shall***:***

(a) Have a quality assurance mechanism to ensure the timeliness and quality of the review***;***~~[,]~~

(b) The qualifications and independence of the physician reviewer***;***~~[,]~~ and

(c) The confidentiality of medical records and review material.

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

(a) ***For external reviews conducted in accordance with Section 11 of this Act and KRS 304.17A-623 and 304.17A-625:***

1. The insurer involved in the review;

2.~~[(b)]~~ Any officer, director, or management employee of the insurer;

3.~~[(c)]~~ The provider proposing the service or treatment or any associated independent practice association;

4.~~[(d)]~~ The institution at which the service or treatment would be provided;

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

6.~~[(f)]~~ The covered person***; and***

(b) For external reviews conducted in accordance with subsection (2)(a)1. of Section 3 of this Act:

1. The requesting health care provider;

2. The insurer or private review agent involved in the review;

3. Any officer, director, or management employee of the insurer or private review agent; or

4. The development or manufacture of the principal drug, device, procedure, or other therapy involved in the health care service that is the subject of the exemption determination being reviewed.

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

(a) A contract under which an academic medical center or other similar medical center provides health care services to covered persons, except for academic medical centers that may provide the service under review;

(b) Provider affiliations which are limited to staff privileges; or

(c) A specialist reviewer's relationship with an insurer as a contracting health care provider, except for a specialist reviewer proposing to provide the service under review.

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

(a) ***For external reviews conducted under Section 11 of this Act and KRS 304.17A-623 and 304.17A-625:***

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

2.~~[(b)]~~ The number of independent review decisions in favor of insurers;

3.~~[(c)]~~ The average turnaround time for an independent review decision;

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

5.~~[(e)]~~ The reasons for any delay***; and***

(b) For external reviews conducted under subsection (2)(a)1. of Section 3 of this Act:

1. The number of external review decisions in favor of health care providers;

2. The number of external review decisions in favor of insurers and private review agents;

3. The average turnaround time for an independent review decision;

4. The number of cases in which the independent review entity did not reach a decision in the time specified in statute or administrative regulation; and

5. The reasons for any delay.

➔Section 13. KRS 304.17A-633 is amended to read as follows:

(1) The commissioner shall report every six (6) months to the Interim Joint Committee on Banking and Insurance~~[,]~~ and to the Governor on***:***

(a) The state of the Independent External Review Program ***established under***

Section 11 of this Act; and

(b) The external reviews conducted under Section 3 of this Act.

(2) The report ***required under subsection (1) of this section*** shall include a summary of***:***

(a) The number of reviews conducted***;*** ~~[,]~~

(b) Medical specialties affected***;*** ~~[,]~~ and

(c) ~~[a summary of]~~The findings and recommendations made by the independent external review entity.

➔Section 14. KRS 304.17A-706 is amended to read as follows:

(1) An insurer may contest a clean claim only in the following instances:

(a) The insurer has reasonable documented grounds to believe that the clean claim involves a preexisting condition, coordination of benefits within the meaning of KRS 304.18-085, or that another insurer is primarily responsible for the claim;

(b) The insurer will conduct a retrospective review of the services identified on the claim***, except that an insurer shall not contest a clean claim under this paragraph based solely on a lack of prior authorization***;

(c) The insurer has information that the claim was submitted fraudulently; or

(d) The covered person's or group's premium has not been paid.

(2) (a) If an insurer requires a provider to submit health claim attachments to the claim before the claim will be paid, the insurer shall identify the specific required health claim attachments in its provider manual or other document that sets forth the procedure for filing claims with the insurer. The insurer shall provide sixty (60) days' advance written notice of modifications to the provider manual that materially change the type or content of the health claim attachments or other documents to be submitted.

(b) If a provider submits a clean claim with the required health claim attachments

as specified in the provider manual or other document that sets forth the procedure for filing claims with the insurer, the insurer shall pay or deny the claim within the required claims payment time frame established in KRS 304.17A-702.

(c) If an insurer conducts a retrospective review of a claim and requires an attachment not specified in the provider manual or other document that sets forth the procedure for filing claims, the insurer shall:

1. Notify the provider, in writing or electronically within the claims payment time frame established in KRS 304.17A-702, of the service that will be retrospectively reviewed and the specific information needed from the provider regarding the insurer's review of a claim;

2. Complete the retrospective review within twenty (20) business days of the insurer's receipt of the medical information described in this subsection; and

3. Subject to paragraph (d) of this subsection, add interest to the amount of the claim, to be paid at a rate of twelve percent (12%) per annum, or at a rate in accordance with KRS 304.17A-730, accruing from the appropriate claim payment time frame established in KRS 304.17A-613 after the claim was received by the insurer through the date upon which the claim is paid.

(d) If the provider fails to submit the information requested under subparagraph (c) 1. of this subsection within fifteen (15) business days from the date of the receipt of the notice, the insurer shall not be required to pay interest.

(3) (a) If a claim or portion thereof is contested by an insurer on the basis that the insurer has not received information reasonably necessary to determine insurer liability for the claim or portion thereof, or if the insurer contests the claim on the reasonable and documented belief that the claim involves the

coordination of benefits within the meaning of KRS 304.18-085, or questions of pre-existing conditions, the insurer shall, within the applicable claims payment time frame established in KRS 304.17A-702, provide written or electronic notice to the provider, covered person, group policyholder, or other insurer, as appropriate, with an itemization of all new, never-before-provided information that is needed.

(b) The insurer shall pay or deny the claim within thirty (30) calendar days of receiving the additional information described in paragraph (a) of this subsection. If the insurer does not receive the additional information described in paragraph (a) of this subsection within fifteen (15) business days from the date of receipt of the notice set forth in paragraph (a) of this subsection, the insurer may deny the claim. Any claim denied under this paragraph may be resubmitted by the provider and any resubmitted claim shall not be denied on the basis of timeliness if the resubmitted claim is made with the timeframe for submitting claims established by the insurer beginning on the date of denial.

➔Section 15. KRS 205.536 is amended to read as follows:

(1) A Medicaid managed care organization shall have a utilization review plan, as defined in KRS 304.17A-600, that meets the requirements established in 42 C.F.R. pts. 431, 438, and 456. If the Medicaid managed care organization utilizes a private review agent, as defined in KRS 304.17A-600, the agent shall comply with all applicable requirements of KRS 304.17A-600 to 304.17A-633.

(2) In conducting utilization reviews for Medicaid benefits, each Medicaid managed care organization shall use the medical necessity criteria selected by the Department of Insurance pursuant to KRS 304.38-240~~[,]~~ for making determinations of medical necessity and clinical appropriateness pursuant to the utilization review plan required by subsection (1) of this section.

(3) To the extent consistent with the federal regulations referenced in subsection (1) of

this section, the Department for Medicaid Services or any managed care organization contracted to provide Medicaid benefits pursuant to KRS Chapter 205 shall***:***

(a) Not require or conduct a prospective or concurrent review, as defined in KRS 304.17A-600, for a prescription drug:

1.~~[(a)]~~ That:

a.~~[1.]~~Is used in the treatment of alcohol or opioid use disorder; and

b.~~[2.]~~Contains Methadone, Buprenorphine, or Naltrexone; or

2.~~[(b)]~~ That was approved before January 1, 2022, by the United States Food and Drug Administration for the mitigation of opioid withdrawal symptoms***; and***

(b) Comply with Sections 1 to 7 of this Act.

➔Section 16. KRS 222.422 is amended to read as follows:

(1) As used in this section, "third-party payor" means any person required to comply with KRS 304.17A-611(2) or 205.536(3)***(a)***.

(2) Prior to the discharge of a patient that has received medication for addiction-treatment, the treating facility shall submit a written discharge plan to the patient, and the patient's third-party payor, if any, which shall describe arrangements for additional services needed following discharge.

➔Section 17. This Act shall apply to contracts delivered, entered, renewed, extended, or amended on or after the effective date of this Act.

➔Section 18. If the Cabinet for Health and Family Services determines that a waiver or any other authorization from a federal agency is necessary to implement Section 15 of this Act for any reason, including the loss of federal funds, the cabinet shall, within 90 days of the effective date of this section, request the waiver or authorization, and may only delay implementation of those provisions for which a waiver was deemed necessary until the waiver or authorization is granted.

➔Section 19. Sections 1 to 17 of this Act take effect January 1, 2024.