AN ACT relating to exemptions from prior authorization requirements.

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) 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 for that health care service under this section.

(2) A health care provider shall qualify for an exemption for a particular health care service if, in the most recent evaluation period as described in subsection (3) of this section, 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.

(3) (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 this section for each health care service:

1. Provided by the provider 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 this section.

(b) An insurer or its private review agent shall not require a health care provider to request an exemption in order to qualify for the exemption.

(4) (a) Not later than five (5) days after qualifying for an exemption under this section, an insurer or its private review agent shall provide a health care provider with a notice that includes:

1. A statement:
a. Notifying the health care provider that the provider has been granted an exemption under 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 under this section if:

1. The health care provider does not have the exemption at the time of the relevant evaluation period; and

2. The insurer or private review agent provides the health care provider with:

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

   b. Detailed information sufficient to demonstrate that the health care provider does not meet the criteria under subsection (2) of this section for the particular health care service.

(5) 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 this section, the insurer or its private review agent shall promptly provide the health care provider with a notice that includes:

   (a) The information required under subsection (4)(a) of this section; and

   (b) A notification of the insurer's payment requirements.

(6) An exemption granted under subsection (4)(a) of this section shall remain in effect until it is rescinded under Section 2 of this Act.

(7) When a health care provider's exemption has been denied under subsection (4)(b) of this section or rescinded under Section 2 of this Act, the health care provider may be granted an exemption under subsection (4)(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) 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 or July of each year, rescind an exemption granted under Section 1 of this Act if the insurer or private review agent:

(a) Makes a determination, on the basis of a retrospective review of a random sample of not fewer than five (5) and no 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

(b) Notifies the health care provider of the rescission determination. The notification shall include:

1. The sample information used to make the rescission determination;

and

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

(2) (a) 1. Except as provided in subparagraph 2. of this paragraph, the evaluation periods under subsection (1) 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 the exemption was granted to the health care provider under subsection (4)(a) of Section 1 of this Act, the evaluation period shall be extended to include the
next full evaluation period set forth in subparagraph 1. of this paragraph.

(b) A rescission determination under subsection (1) 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; and

2. Take effect:
   a. Except as provided by subdivision b. of this subparagraph, on the thirtieth (30th) day after the date the insurer or its private review agent notifies the health care provider of the insurer or private review agent's rescission determination; or
   b. If the health care provider timely requests an external review under Section 3 of this Act, on the fifth (5th) day after the date the independent review entity affirms the determination.

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

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

(b) An insurer or its private review agent shall not require a health care provider to engage in an internal appeal before requesting an external review under this section.

(c) Requests for an external review 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.

(2) 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 this section. The system established by the department shall be prospective and shall 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. The department shall contract with no less than two (2) independent review entities.

(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 (2) of Section 1 of this Act.

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

(a) A health care provider may request that the independent review entity, as part of its review, consider another random sample of not less than five (5) and no 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 (1)(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 (1)(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
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, and 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 the thirtieth (30th) day after the date the health care provider files a request under subsection (1) of this section.

(b) The external review decision 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 or its private review agent's determination is overturned by the 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 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 a 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 and KRS 61.870 to 61.884.

(9) (a) The insurer, private review agent, or health care provider involved in an external review under 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) 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. The department’s actions 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) An insurer or its private review agent shall not retrospectively:

(a) Deny, or reduce payment to a health care provider for, a health care service for which the health care provider qualified for, or had, an exemption under Section 1 of this Act based on medical necessity or appropriateness of care unless the health care provider:

1. 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

2. Failed to substantially perform the health care service; or

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

(2) 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 for, or had, an exemption under 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 5. A NEW SECTION OF KRS 304.17A-600 TO 304.17A-633 IS CREATED TO READ AS FOLLOWS:

Nothing in Sections 1 to 4 of this Act shall be construed to:
Section 6. 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) "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;

(8) "Insurer" means any of the following entities authorized to issue health benefit plans
as defined in subsection (6) of this section: an insurance company, health
maintenance organization; self-insurer or multiple employer welfare arrangement
not exempt from state regulation by ERISA; provider-sponsored integrated health
delivery network; self-insured employer-organized association; nonprofit hospital,
medical-surgical, or health service corporation; or any other entity authorized to
transact health insurance business in Kentucky;

(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;

(10) "Nationally recognized accreditation organization" means a private nonprofit entity
that sets national utilization review and internal appeal standards and conducts
review of insurers, agents, or independent review entities for the purpose of
accreditation or certification. Nationally recognized accreditation organizations
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;

(11) "Private review agent" or "agent" 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. "Private review agent" or "agent" does not include an independent review entity which performs external review of adverse determinations;

(12) "Prospective review" means a utilization review that is conducted prior to the provision of health care services. "Prospective review" also 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, preadmission review, pretreatment review, utilization, and case management;

(13) "Qualified personnel" means 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;

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

(15) "Retrospective review" means utilization review that is conducted after health care services have been provided to a covered person. "Retrospective review" does not include the review of a claim that is limited to an evaluation of reimbursement levels, or adjudication of payment;

(16) (a) "Urgent health care services" 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.

(b) Urgent health care services include all requests for hospitalization and
outpatient surgery;

(17) "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. Areas of review include concurrent, prospective, and retrospective review; and

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

Section 7. KRS 304.17A-605 is amended to read as follows:

(1) Sections 1, 2, 3, 4, and 5 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 8. 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.

Section 9. 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, 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 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, be a specialist in the treatment of the covered person's medical condition under review, and have actual clinical experience in that medical condition.

(7) The independent review entity shall have a quality assurance mechanism to ensure the timeliness and quality of the review, the qualifications and independence of the
physician reviewer, and 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 KRS 304.17A-621, 304.17A-623, and 304.17A-625:

1. The insurer involved in the review;

2. Any officer, director, or management employee of the insurer;

3. The provider proposing the service or treatment or any associated independent practice association;

4. The institution at which the service or treatment would be provided;

5. 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. The covered person; and

(b) For external reviews conducted in accordance with 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 KRS 304.17A-621, 304.17A-623, and
304.17A-625:
1. The number of independent review decisions in favor of covered
   persons;
2. The number of independent review decisions in favor of insurers;
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; and

(b) For external reviews conducted under 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 Section 3 of this Act; and
5. The reasons for any delay.

Section 10. KRS 304.17A-633 is amended to read as follows:
The commissioner shall report every six (6) months to the Interim Joint Committee on Banking and Insurance and to the Governor on the state of the Independent External Review Program established under Section 8 of this Act and external reviews conducted under Section 3 of this Act. The report shall include a summary of the number of reviews conducted, medical specialties affected, and a summary of the findings and recommendations made by the independent external review entity.

Section 11. 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. That:

         a. Is used in the treatment of alcohol or opioid use disorder; and

         b. Contains Methadone, Buprenorphine, or Naltrexone; or

      2. 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 5 of this Act.

Section 12. 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 13. This Act shall apply to contracts delivered, entered, renewed, extended, or amended on or after the effective date of this Act.

Section 14. 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 11 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 15. Sections 1 to 13 of this Act take effect January 1, 2023.