IN THE GENERAL ASSEMBLY STATE OF _____

Ensuring Transparency in Prior Authorization Act

Be it enacted by the People of the State of _____, represented in the General Assembly:

Section 1. Title. This act shall be known as and may be cited as the Ensuring Transparency in Prior Authorization Act."

Section 2. Purpose. The Legislature hereby finds and declares that:

a) The patient-physician relationship is paramount and should not be subject to third-party intrusion;

b) Prior authorization programs place cost savings ahead of optimal patient care; and

c) Prior authorization programs shall not be permitted to hinder patient care or intrude on the practice of medicine.

Section 3. Definitions.

a) "**Adverse determination**" means a decision by a utilization review entity that the health care services furnished or proposed to be furnished to an enrollee are not medically necessary or are experimental or investigational; and benefit coverage is therefore denied, reduced, or terminated. A decision to deny, reduce, or terminate services that are not covered for reasons other than their medical necessity, or experimental or investigational nature is not an "adverse determination" for purposes of this Act.

b) **"Authorization"** means a determination by a utilization review entity that a health care service has been reviewed and, based on the information provided, satisfies the utilization review entity's requirements for medical necessity and appropriateness and that payment will be made for that health care service.

c) **"Clinical criteria"** means the written policies, written screening procedures, drug formularies or lists of covered drugs, determination rules, determination abstracts, clinical protocols, practice

guidelines, medical protocols, and any other criteria or rationale used by the utilization review entity to determine the necessity and appropriateness of health services.

d) **"Emergency health care services"** means those health care services that are provided in an emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in: (i) placing the patient's health in serious jeopardy; (ii) serious impairment to bodily function; or (iii) serious dysfunction of any bodily organ or part.

e) **"Health care service"** means health care procedures, treatments or services: (i) provided by a facility licensed in (indicate the name of the state); or (ii) provided by a doctor of medicine, a doctor of osteopathy, or within the scope of practice for which a health care professional is licensed in (indicate the name of the state). The term "health care service" also includes the provision of pharmaceutical products or services or durable medical equipment.

f) **"Medically necessary health care services"** Medically necessary health care services" means health care services that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (i) in accordance with generally accepted standards of medical practice; (ii) clinically appropriate in terms of type, frequency, extent, site and duration; and (iii) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

g) **"Medications for opioid use disorder (MOUD)"** means the use of medications, commonly in combination with counseling and behavioral therapies, to provide a comprehensive approach to the treatment of opioid use disorder. FDA-approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone) and extended-release

injectable naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavior therapy, motivational incentives, and other modalities.

h) **"NCPDP SCRIPT Standard"** means the National Council for Prescription Drug Programs SCRIPT Standard Version 2017071, or the most recent standard adopted by the United States Department of Health and Human Services (HHS). Subsequently released versions of the NCPDP SCRIPT Standard may be used.

i) **"Prior authorization"** means the process by which utilization review entities determine the medical necessity and/or medical appropriateness of otherwise covered health care services prior to the rendering of such health care services. "Prior authorization" also includes any health insurers or utilization review entity's requirement that an enrollee or health care provider notify the health insurer or utilization review entity prior to providing a health care service.

j) **"Enrollee"** means an individual eligible to receive health care benefits by a health insurer pursuant to a health plan or other health insurance coverage. The term "enrollee" includes an enrollee's legally authorized representative.

k) **"Urgent health care service"** means a health care service with respect to which the application of the time periods for making a non-expedited prior authorization, which, in the opinion of a physician with knowledge of the enrollee's medical condition:

   i. could seriously jeopardize the life or health of the enrollee or the ability of the enrollee to regain maximum function; or

   ii. could subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review.

For the purpose of this Act, urgent health care service shall include mental and behavioral health care services.

l) **"Utilization review entity"** means an individual or entity that performs prior authorization for one or more of the following entities:

i. an employer with employees in_(*indicate name of state*) who are covered under a health benefit plan or health insurance policy;

ii. an insurer that writes health insurance policies;

iii. a preferred provider organization, or health maintenance organization; and

iv. any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, prescription drug, or other health benefits to a person treated by a health care professional in _____(*indicate name of state*) under a policy, plan or contract.

Section 4. Disclosure and review of prior authorization requirements.

A utilization review entity shall make any current prior authorization requirements and restrictions readily accessible on its website to enrollees, health care professionals, and the general public. This includes the written clinical criteria. Requirements shall be described in detail but also in easily understandable language.

a) If a utilization review entity intends either to implement a new prior authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall ensure that the new or amended requirement is not implemented unless the utilization review entity's Web site has been updated to reflect the new or amended requirement or restriction.

b) If a utilization review entity intends either to implement a new prior authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall provide contracted health care providers of enrollees written notice of the new or amended requirement or amendment no less than sixty (60) days before the requirement or restriction is implemented.

c) Entities using prior authorization shall make statistics available regarding prior authorization approvals and denials on their Web site in a readily accessible format. They should include categories for:

i. physician specialty;

ii. medication or diagnostic test/procedure;

iii. indication offered;

iv. reason for denial;

v. if appealed;

vi. if approved or denied on appeal;

vii. the time between submission and the response.

Section 5. Reporting data to Department of Insurance.

(a) By March 1 of each year, each utilization review entity shall submit a report to the Department of Insurance using forms and, in a manner, specified by the Insurance Commissioner, that contains all of the following information for prior authorization requests for previous calendar year. For each health care service listed in (i), the information required by (ii-ix) should be individualized for each listed health care service.

i. A list of all health care services that require prior authorization;

ii. The number and percentage of prior authorization requests that were approved;

iii. The number and percentage of prior authorization requests that were denied;

iv. The number and percentage of prior authorization requests that were initially denied and approved after appeal;

v. The number and percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved;

vi. The average and median time that elapsed between the submission of a non-urgent prior authorization request and a determination by a utilization review entity;

vii. The average and median time that elapsed between the submission of an urgent prior authorization request and a determination by the utilization review entity;

viii. The average and median time that elapsed to process an appeal submitted by a health care professional initially denied by the utilization review entity for non-urgent prior authorizations; and

ix. The average and median time that elapsed to process an appeal submitted by a health care professional initially denied by the utilization review entity for urgent prior authorizations.

(b) Each utilization review entity shall make the report identified in subsection(a) available through the utilization review entity's website in the format prescribed by the Department of Insurance.

(c) By May 1 of each year, the Department of Insurance shall submit a report to the legislature that includes a summary of the reports identified in subsection (a), including all data that the Department of Insurance receives from each utilization review entity, and recommendations for the removal of prior authorization requirements by utilization review entities on health care services that are regularly approved for prior authorization. Any health care service that is approved more than 80% of the time shall be considered regularly approved.

(d) The Department of Insurance shall promulgate rules and regulations necessary to implement this section within 6 months of this law taking effect.

Section 6. Personnel qualified to make adverse determinations. A utilization review entity must ensure that all adverse determinations are made by a physician. The physician must:

a) possess a current and valid non-restricted license to practice medicine in_ (*the state in which the proposed services would have been provided if authorized*);

b) be of the same specialty as the physician who typically manages the medical condition or disease or provides the health care service involved in the request;

c) have experience treating patients with the medical condition or disease for which the health care service is being requested; and

d) make the adverse determination under the clinical direction of one of the utilization review entity's medical directors who is responsible for the provision of health care services provided to enrollees of____(*state in which the proposed health care items or services would have been provided if authorized*). All such medical directors must be physicians licensed in_____(*the state in which the proposed health care items or services would have been provided if authorized*).

Section 7. Consultation prior to issuing an adverse determination. If a utilization review entity is questioning the medical necessity of a health care service, the utilization review entity must notify the enrollee's physician that medical necessity is being questioned. Prior to issuing an adverse determination, the enrollee's physician must have the opportunity to discuss the medical necessity of the health care service on the telephone with the physician who will be responsible for determining authorization of the health care service under review.

Section 8. Requirements applicable to the physician who can review appeals. A utilization entity must ensure that all appeals are reviewed by a physician. The physician must:

a. possess a current and valid non-restricted license to practice medicine in _____ (*the state in which the proposed services would be provided if authorized)*;
b. be currently in active practice in the same or similar specialty as physician who typically manages the medical condition or disease for at least five (5) consecutive years;
c. be knowledgeable of, and having experience providing, the health care services under appeal;
d. not be employed by a utilization review entity or be under contract with the utilization review entity other than to participate in one or more of the utilization review entity's health care provider networks or to perform reviews of appeals, or otherwise have any financial interest in the outcome of the appeal;
e. not have been directly involved in making the adverse determination; and
f. consider all know clinical aspects of the health care service under review, including but not

limited to, a review of all pertinent medical records provided to the utilization review entity by the enrollee's health care provider, any relevant records provided to the utilization review entity by a health care facility, and any medical literature provided to the utilization review entity by the health care provider.

Section 9. Utilization review entity's obligations with respect to prior authorizations in non-urgent circumstances. If a utilization review entity requires prior authorization of a health care service, the utilization review entity must make a prior authorization or adverse determination and notify the enrollee and the enrollee's health care provider of the prior authorization or adverse determination within 48 hours of obtaining all necessary information to make the prior authorization or adverse determination. For purposes of this section, "necessary information" includes the results of any face-to-face clinical evaluation or second opinion that may be required.

Section 10. Utilization review entities' obligations with respect to prior authorizations concerning urgent health care services. A utilization review entity must render a prior authorization or adverse determination concerning urgent health care services. A utilization review entity must render a prior authorization or adverse determination concerning urgent care services, and notify the enrollee and the enrollee's health care provider of that prior authorization or adverse determination not later than twenty-four (24) hours after receiving all information needed to complete the review of the requested health care services.

Section 11. Utilization review entities' obligations with respect to prior authorizations concerning emergency health care services.

a. A utilization review entity cannot require prior authorization for pre-hospital transportation or for the provision of emergency health care services.

b. A utilization review entity shall allow an enrollee and the enrollee's health care provider a minimum of twenty-four (24) hours following an emergency admission or provision of emergency health care services for the enrollee or health care provider to notify the utilization

review entity of the admission or provision of health care services. If the admission or health care service occurs on a holiday or weekend, a utilization review entity cannot require notification until the next business day after the admission or provision of the health care services.

c. A utilization review entity shall cover emergency health care services necessary to screen and stabilize an enrollee. If a health care provider certifies in writing to a utilization review entity within seventy-two (72) hours of an enrollee's admission that the enrollee's condition required emergency health care services, that certification will create a presumption that the emergency health care services were medically necessary and such presumption may be rebutted only if the utilization review entity can establish, with clear and convincing evidence, that the emergency health care services were not medically necessary.

d. The medical necessity or appropriateness of emergency health care services cannot be based on whether those services were provided by participating or nonparticipating providers. Restrictions on coverage of emergency health care services provided by nonparticipating providers cannot be greater than restrictions that apply when those services are provided by participating providers.

e. If an enrollee receives an emergency health care service that requires immediate post evaluation or post-stabilization services, a utilization review entity shall make an authorization determination within sixty (60) minutes of receiving a request; if the authorization determination is not made within sixty (60) minutes, such services shall be deemed approved.

Section 12. No prior authorization for MOUD. A utilization review entity may not require prior authorization for provision of MOUD.

Section 13. Retrospective denial.

a. The utilization review entity may not revoke, limit, condition or restrict a prior authorization if care is provided within 45 business days from the date the health care provider received the prior authorization.

b. A utilization review entity must pay a health care provider at the contracted payment rate for a

health care service provided by the health care provider per a prior authorization unless:

i. the health care provider knowingly and materially misrepresented the health care service in the prior authorization request with the specific intent to deceive and obtain an unlawful payment from utilization review entity;

ii. The health care service was no longer a covered benefit on the day it was provided;

iii. The health care provider was no longer contracted with the patients' health insurance plan on the date the care was provided;

iv. The health care provider failed to meet the utilization review entity's timely filing requirements;

v. The utilization review entity does not have liability for a claim; or

vi. The patient was no longer eligible for health care coverage on the day the care was provided.

Section 14. Length of prior authorization. A prior authorization shall be valid for a minimum of one year from the date the health care provider receives the prior authorization, and the authorization period shall be effective regardless of any changes in dosage for a prescription drug prescribed by the health care provider.

Section 15. Length of prior authorization for treatment for chronic or long-term care conditions. If a utilization review entity requires a prior authorization for a health care service for the treatment of a chronic or long-term care condition, the prior authorization shall remain valid for the length of the treatment and the utilization review entity may not require the enrollee to obtain a prior authorization again for the health care service.

Section 16. Continuity of care for enrollees.

a. On receipt of information documenting a prior authorization from the enrollee or from the enrollee's health care provider, a utilization review entity shall honor a prior authorization granted to an

enrollee from a previous utilization review entity for at least the initial 90 days of an enrollee's coverage under a new health plan.

b. During the time period described in paragraph (a) of this subsection, a utilization review entity may perform its own review to grant a prior authorization.

c. If there is a change in coverage of, or approval criteria for, a previously authorized health care service, the change in coverage or approval criteria does not affect an enrollee who received prior authorization before the effective date of the change for the remainder of the enrollee's plan year.

d. A utilization review entity shall continue to honor a prior authorization it has granted to an enrollee when the enrollee changes products under the same health insurance company.

Section 17. Provider exemptions from prior authorization requirements.

a. A utilization review entity may not require a health care provider to complete a prior authorization for a health care service in order for the enrollee to whom the service is being provided to receive coverage if in the most recent 12-month period, the utilization review entity has approved or would have approved not less than 80 percent of the prior authorization requests submitted by the health care provider for that health care service, including any approval granted after an appeal.

b. A utilization review entity may evaluate whether a health care provider continues to qualify for exemptions as described in Subsection (a) not more than once every 12 months. Nothing in this Section requires a utilization review entity to evaluate an existing exemption or prevents a utilization review entity from establishing a longer exemption period.

c. A health care provider is not required to request an exemption in order to qualify for an exemption.

d. A health care provider who does not receive an exemption may request from the utilization review entity at any time, but not more than once per year per service, evidence to support the

utilization review entity's decision. A health care provider may appeal a utilization review entity's decision to deny an exemption.

e. A utilization review entity may only revoke an exemption at the end of the 12-month period if the utilization review entity:

   i. makes a determination that the health care provider would not have met the 80 percent approval criteria based on a retrospective review of the claims for the particular service for which the exemption applies for the previous 3 months, or for a longer period if needed to reach a minimum of 10 claims for review;

   ii. provides the health care provider with the information it relied upon in making its determination to revoke the exemption; and

   iii. provides the health care provider a plain language explanation of how to appeal the decision.

f. An exemption remains in effect until the 30th day after the date the utilization review entity notifies the health care provider of its determination to revoke the exemption or, if the health care provider appeals the determination, the fifth day after the revocation is upheld on appeal.

g. A determination to revoke or deny an exemption must be made by a health care provider licensed in [state] of the same or similar specialty as the health care provider being considered for an exemption and have experience in providing the service for which the potential exemption applies.

h. A utilization review entity must provide a health care provider that receives an exemption a notice that includes:

   i. A statement that the health care provider qualifies for an exemption from preauthorization requirements;

   ii. A list of services for which the exemption(s) apply; and

   iii. A statement of the duration of the exemption.

i. A utilization review entity shall not deny or reduce payment for a health care service exempted from a prior authorization requirement under this section, including a health care service performed or supervised by another health care provider when the health care provider who ordered such service received a prior authorization exemption, unless the rendering health care provider: (1) knowingly and materially misrepresented the health care service in request for payment submitted to the utilization review entity with the specific intent to deceive an obtain an unlawful payment from utilization review entity; or (2) failed to substantially perform the health care service.

Section 18. Electronic standards for prior authorization. No later than January 1, 20XX, the payer must accept and respond to prior authorization requests under the pharmacy benefit through a secure electronic transmission using the NCPDP SCRIPT Standard ePA transactions. Facsimile, propriety payer portals, electronic forms, or any other technology not directly integrated with a physician's electronic health record/electronic prescribing system shall not be considered secure electronic transmission.

Section 19. Health care services deemed authorized if a utilization review entity fails to comply with the requirements of this Act. Any failure by a utilization review entity to comply with the deadlines and other requirements specified in this Act will result in any health care services subject to review to be automatically deemed authorized by the utilization review entity.

Section 20. Severability. If any provision of this Act is held by a court to be invalid, such invalidity shall not affect the remaining provisions of this Act, and to this end the provisions of this Act are hereby declared severable.