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 I. Title: This Act may be known and cited as the “Ensuring Transparency in Prior Authorization”

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

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

(b) Prior authorization programs can place attempted cost savings ahead of optimal patient care;

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

(d) Further, prior authorization programs must include the use of written clinical criteria and reviews by appropriate physicians to ensure a fair process for patients.

Section III. Definitions.

a) “Adverse determination” means a decision by a utilization review entity that the health care services furnished or proposed to be furnished to a subscriber 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 which
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 care 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” 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) “NCPDP SCRIPT Standard” means the National Council for Prescription Drug
Programs SCRIPT Standard Version 201310, 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, provided that the new version of
the standard is backward compatible to the current version adopted by HHS.

h) “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 including, but not limited to,
preadmission review, pretreatment review, utilization, and case management. “Prior
authorization” also includes any health insurer’s or utilization review entity’s requirement
that a subscriber or health care provider notify the health insurer or utilization review
entity prior to providing a health care service.
i) “Step therapy protocol” means a protocol or program that establishes the specific sequence in which prescription drugs for a medical condition that are medically appropriate for a particular subscriber are authorized by a utilization review entity.; j) “Subscriber” 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 “subscriber” includes a subscriber’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 nonexpedited prior authorization, which, in the opinion of a physician with knowledge of the subscriber’s medical condition: (i) could seriously jeopardize the life or health of the subscriber or the ability of the subscriber to regain maximum function; or (ii) could subject the subscriber to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review. 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, or other health benefits to a person treated by a health care professional in ________________(indicate name of state) under a policy, plan, or contract.
A health insurer is a utilization review entity if it performs prior authorization.

Section III. Disclosure and review of prior authorization requirements.

A utilization review entity shall make any current prior authorization requirements and restrictions readily accessible on its Web site to subscribers, health care professional, 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 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 utilizing 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; and

(iv) Reason for denial.
Section IV: 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 subscriber and the subscriber’s health care provider of the prior authorization or adverse determination within two (2) working days 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 V: 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 care services, and notify the subscriber and the subscriber’s health care provider of that prior authorization or adverse determination not later than one (1) business day after receiving all information needed to complete the review of the requested health care services.

Section VI: Utilization review entity’s obligations with respect to prior authorization concerning emergency health care services.

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

b) A utilization review entity shall allow a subscriber and the subscriber’s health care provider a minimum of twenty-four (24) hours following an emergency admission or provision of emergency health care services for the subscriber 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 a subscriber. If a health care provider certifies in writing to a utilization
review entity within seventy-two (72) hours of a subscriber’s admission that the
subscriber’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 or not 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 a subscriber 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 VII. Appropriate use of step therapy protocols. A utilization review entity shall not:
(a) Require a health care provider offering services to a subscriber to participate in a step
therapy protocol if the provider deems that the step therapy protocol is not in the patient’s
best interests;
(b) Require that a health care provider first obtain a waiver, exception, or other override
when deeming a step therapy protocol to not be in a patient’s best interests.
(c) Sanction or otherwise penalize a health care provider for recommending or issuing a
prescription, performing or recommending a procedure or performing a test that may
conflict with the step therapy protocol of the health insurer or health insurance plan.

Section VIII. Retrospective denial. The utilization review entity may not revoke, limit,
condition or restrict a prior authorization if care is provided within 45 working days from the
date the health care provider received the prior authorization. Any language attempting to
disclaim payment for services that have been pre-authorized within that 45 day period shall be
null and void.

Section IX. Length of prior authorization. A prior authorization shall be valid for one year
from the date the health care provider receives the prior authorization.

[Drafting Note: Alternatively, states may want to connect this provision for prescription drugs to
the statutory length of a prescription under their Pharmacy Practice Act, if it is greater than one
year.]

Section X. 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, and electronic forms shall not be considered electronic
transmission.
[Drafting note: Alternatively, states may wish to coordinate implementation of ePA requirements with approval by the U.S. Department of Health and Human Services of the NCPDP SCRIPT Standard ePA transaction.]

Section XI. Health care services deemed preauthorized 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 preauthorized.

Section XII. Severability. If any provision of this Act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and to this end the provisions of this Act are declared to be severable.