§ 4902. Utilization review program standards. (a) Each utilization review agent shall adhere to utilization review program standards consistent with the provisions of this title which shall, at a minimum, include:

(1) Appointment of a medical director, who is a licensed physician; provided, however, that the utilization review agent may appoint a clinical director when the utilization review performed is for a discrete category of health care service and provided further that the clinical director is a licensed health care professional who typically manages the category of service. Responsibilities of the medical director, or, where appropriate, the clinical director, shall include, but not be limited to, the supervision and oversight of the utilization review process;

(2) Development of written policies and procedures that govern all aspects of the utilization review process and a requirement that a utilization review agent shall maintain and make available to insureds and health care providers a written description of such procedures including procedures to appeal an adverse determination together with a description, jointly promulgated by the superintendent and the commissioner of health as required pursuant to subsection (e) of section four thousand nine hundred fourteen of this article, of the external appeal process established pursuant to title two of this article and the time frames for such appeals;

(3) Utilization of written clinical review criteria developed pursuant to a utilization review plan;

(4) Establishment of a process for rendering utilization review determinations which shall, at a minimum, include: written procedures to assure that utilization reviews and determinations are conducted within the timeframes established herein; procedures to notify an insured, an insured's designee and/or an insured's health care provider of adverse determinations; and procedures for appeal of adverse determinations including the establishment of an expedited appeals process for denials of continued inpatient care or where there is imminent or serious threat to the health of the insured;

(5) (i) Establishment of a written procedure to assure that the notice of an adverse determination includes:

(A) the reasons for the determination including the clinical

rationale, if any;

(B) instructions on how to initiate standard and expedited appeals pursuant to section four thousand nine hundred four of this article and an external appeal pursuant to section four thousand nine hundred fourteen of this article; (C) notice of the availability, upon request of the insured or the insured's designee, of the clinical review criteria relied upon to make such determination;

(D) what, if any, additional necessary information must be provided to, or obtained by, the utilization review agent in order to render a decision on appeal; and

(E) for an adverse determination related to a step therapy protocol override determination, information that includes the clinical review criteria relied upon to make such determination and any applicable alternative prescription drugs subject to the step therapy protocol of the utilization review agent.

(ii) A utilization review agent may provide a notice of an adverse determination related to a step therapy protocol override determination electronically pursuant to subsection (i) of section four thousand nine hundred three of this title, including by electronic mail or through the health care plan's member portal and provider portal. An electronic notice of such an adverse determination may meet the requirements of clause (E) of subparagraph (i) of this paragraph by linking to information posted on the website of the health care plan;

(6) Establishment of a requirement that appropriate personnel of the utilization review agent are reasonably accessible by toll-free telephone:

(i) not less than forty hours per week during normal business hours to discuss patient care and allow response to telephone requests, and to ensure that such utilization review agent has a telephone system capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours and to ensure response to accepted or recorded messages not less than one business day after the date on which the call was received; or

(ii) notwithstanding the provisions of subparagraph (i) of this paragraph, not less than forty hours per week during normal business hours, to discuss patient care and allow response to telephone requests, and to ensure that, in the case of a request submitted pursuant to

subsection (a) of section four thousand nine hundred three of this title or an expedited appeal filed pursuant to subsection (b) of section four thousand nine hundred four of this title, on a twenty-four hour a day, seven day a week basis;

(7) Establishment of appropriate policies and procedures to ensure that all applicable state and federal laws to protect the confidentiality of individual medical records are followed;

(8) Establishment of a requirement that emergency services rendered to an insured shall not be subject to prior authorization nor shall reimbursement for such services be denied on retrospective review; provided, however, that such services are medically necessary to stabilize or treat an emergency condition.

* (9) When conducting utilization review for purposes of determining health care coverage for substance use disorder treatment, a utilization review agent shall utilize an evidence-based and peer reviewed clinical review tool that is appropriate to the age of the patient. When conducting such utilization review for treatment provided in this state, a utilization review agent shall utilize an evidence-based and peer reviewed clinical tool designated by the office of alcoholism and substance abuse services that is consistent with the treatment service levels within the office of alcoholism and substance abuse services system. All approved tools shall have inter rater reliability testing completed by December thirty-first, two thousand sixteen.

* NB Effective until January 1, 2027

* (9) When conducting utilization review for purposes of determining health care coverage for substance-related and addictive disorder treatment, a utilization review agent shall utilize an evidence-based and peer reviewed clinical review tool that is appropriate to the age of the patient. When conducting such utilization review for treatment provided in this state, a utilization review agent shall utilize an evidence-based and peer reviewed clinical tool designated by the office of addiction services and supports that is consistent with the treatment service levels within the office of addiction services and supports system. All approved tools shall have inter rater reliability testing completed by December thirty-first, two thousand sixteen.

* NB Effective January 1, 2027

10. When establishing a step therapy protocol, a utilization review agent shall utilize recognized evidence-based and peer reviewed clinical review criteria that also takes into account the needs of atypical patient populations and diagnoses when establishing the clinical review criteria.

11. When conducting utilization review for a step therapy protocol override determination, a utilization review agent shall utilize, in addition to any other requirements of this article, recognized evidence-based and peer reviewed clinical review criteria that is appropriate for the insured and the insured's medical condition.

(12) When conducting utilization review for purposes of determining health care coverage for a mental health condition, a utilization review agent shall utilize evidence-based and peer reviewed clinical review criteria that is appropriate to the age of the patient. The utilization review agent shall use clinical review criteria deemed appropriate and approved for such use by the commissioner of the office of mental health, in consultation with the commissioner of health and the superintendent. Approved clinical review criteria shall have inter rater reliability testing completed by December thirty-first, two thousand nineteen.

(13) Establishment of a requirement that emergency department and inpatient hospital services rendered by a general hospital certified pursuant to article twenty-eight of the public health law to an insured to treat COVID-19 during a declared state disaster emergency related to COVID-19 shall not be denied on retrospective review on the basis that such services were not medically necessary.

(14) The superintendent, in consultation with the commissioner of health, may, as necessary, promulgate by regulation special considerations and processes for utilization review related to medically fragile children. Such regulations may include, at a minimum, considerations and processes related to:

(i) medically necessary covered services to medically fragile children;

(ii) determinations specific to the needs of medically fragile children;

(iii) stabilization and discharge plans; and

(iv) payment for the care of medically fragile children.

(15) When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol cannot:

(i) require a prescription drug that has not been approved by the United States Food and Drug Administration for the medical condition being treated or is not supported by current evidence-based guidelines for the medical condition being treated;

(ii) require an insured to try and fail on more than two drugs used to treat the same medical condition or disease before providing coverage to the insured for the prescribed drug;

(iii) require the use of a step therapy-required drug for longer than thirty days or a duration of treatment supported by current evidence-based treatment guidelines appropriate to the specific disease state being treated;

(iv) be imposed on an insured if a therapeutic equivalent to the prescribed drug is not available, or if the health care plan has documentation that it has covered the drug for the insured within the past three hundred sixty-five days;

(v) require a newly enrolled insured to repeat a step therapy protocol for a prescribed drug where that insured already completed a step therapy protocol for that drug under a prior health care plan, so long as the enrollee or provider submits information demonstrating completion of a step therapy protocol of the prior health care plan within the past three hundred sixty-five days; and

(vi) be imposed on an insured for a prescribed drug that was previously approved for coverage by the insured's current health care plan for a specific medical condition after the insured's current health care plan implements a formulary change or utilization management that impacts the coverage criteria for the prescribed drug until the approved override expires, unless a specifically identified and current evidence-based safety concern exists and a different therapeutic alternative drug exists.

(16) When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any written or electronic attestation submitted by the insured's health care professional, as defined in section four thousand nine hundred of this title, who prescribed the drug and stating that a required drug has failed, as

evidence that the required drug has failed.

(b) Each utilization review agent shall assure adherence to the requirements stated in subsection (a) of this section by all contractors, subcontractors, subvendors, agents and employees affiliated by contract or otherwise with such utilization review agent.