§ 4900. Definitions. For purposes of this article:

1. "Adverse determination" means a determination by a utilization review agent that an admission, extension of stay, or other health care service, upon review based on the information provided, is not medically necessary.

2. "Clinical peer reviewer" means:

(a) for purposes of section four thousand nine hundred three of this article:

(i) a physician who possesses a current and valid non-restricted license to practice medicine; or

(ii) a health care professional other than a licensed physician who:

(A) where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; and

(B) is in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under review; or

* (iii) for purposes of a determination involving substance use disorder treatment:

(A) a physician who possesses a current and valid non-restricted license to practice medicine and who specializes in behavioral health and has experience in the delivery of substance use disorder courses of treatment; or

(B) a health care professional other than a licensed physician who specializes in behavioral health and has experience in the delivery of substance use disorder courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; or

* NB Effective until January 1, 2027

* (iii) for purposes of a determination involving substance-related and addictive disorder treatment:

(A) a physician who possesses a current and valid non-restricted license to practice medicine and who specializes in behavioral health and has experience in the delivery of substance-related and addictive disorder courses of treatment; or

(B) a health care professional other than a licensed physician who specializes in behavioral health and has experience in the delivery of substance-related and addictive disorder courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; or

* NB Effective January 1, 2027

(iv) for purposes of a determination involving treatment for a mental health condition:

(A) a physician who possesses a current and valid non-restricted license to practice medicine and who specializes in behavioral health and has experience in the delivery of mental health courses of treatment; or

(B) a health care professional other than a licensed physician who specializes in behavioral health and has experience in the delivery of a mental health courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate, or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; and

(b) for purposes of section four thousand nine hundred four and title two of this article:

(i) a physician who:

(A) possesses a current and valid non-restricted license to practice medicine;

(B) where applicable, is board certified or board eligible in the same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under appeal;

(C) for purposes of title two of this article, has been practicing in such area of specialty for a period of at least five years;

* (D) for purposes of a determination involving substance use disorder

treatment, possesses a current and valid non-restricted license to practice medicine and specializes in behavioral health and has experience in the delivery of substance use disorder courses of treatment;

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* (D) for purposes of a determination involving substance-related and addictive disorder treatment, possesses a current and valid non-restricted license to practice medicine and specializes in behavioral health and has experience in the delivery of substance-related and addictive disorder courses of treatment;

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(E) for purposes of a determination involving treatment for a mental health condition, possesses a current and valid non-restricted license to practice medicine and who specializes in behavioral health and has experience in the delivery of mental health courses of treatment; and

(F) is knowledgeable about the health care service or treatment under appeal; or

(ii) a health care professional other than a licensed physician who:

(A) where applicable, possesses a current and valid non-restricted license, certificate or registration;

(B) where applicable, is credentialed by the national accrediting body appropriate to the profession in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under appeal;

(C) for purposes of title two of this article, has been practicing in such area of specialty for a period of at least five years;

(D) is knowledgeable about the health care service or treatment under appeal;

* (E) for purposes of a determination involving substance use disorder, specializes in behavioral health and has experience in the delivery of substance use disorder courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession;

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* (E) for purposes of a determination involving substance-related and addictive disorder, specializes in behavioral health and has experience in the delivery of substance-related and addictive disorder courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession;

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(F) for purposes of a determination involving treatment for a mental health condition, specializes in behavioral health and has experience in the delivery of mental health courses of treatment and, where applicable, possesses a current and valid non-restricted license, certificate, or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; and

(G) where applicable to such health care professional's scope of practice, is clinically supported by a physician who possesses a current and valid non-restricted license to practice medicine.

(c) Nothing in this subdivision shall be construed to change any statutorily-defined scope of practice.

2-a. "Clinical standards" means those guidelines and standards set forth in the utilization review plan by the utilization review agent whose adverse determination is under appeal or, in the case of medically fragile children, those guidelines and standards as required by section forty-four hundred six-i of this chapter.

2-b. "Clinical trial" means a peer-reviewed study plan which has been

(a) reviewed and approved by a qualified institutional review board, and

(b) approved by one of the National Institutes of Health (NIH), or an NIH cooperative group or an NIH center, or the Food and Drug Administration in the form of an investigational new drug exemption, or the federal Department of Veteran Affairs, or a qualified nongovernmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants, or an institutional

review board of a facility which has a multiple project assurance approved by the Office of Protection from Research Risks of the National Institutes of Health.

As used in this subdivision, the term "cooperative groups" means formal networks of facilities that collaborate on research projects and have established NIH-approved peer review programs operating within their groups; and that include, but are not limited to, the National Cancer Institute (NCI) Clinical Cooperative Groups, the NCI Community Clinical Oncology Program (CCOP), the AIDS Clinical Trials Groups (ACTG), and the Community Programs for Clinical Research in AIDS (CPCRA).

* 2-c. "Disabling condition or disease" means a condition or disease which, according to the current diagnosis of the enrollee's attending physician, is consistent with the definition of "disabled person" pursuant to subdivision five of section two hundred eight of the social services law.

* NB Effective until January 1, 2027

* (2-c) "Chronic health condition" means a condition that is expected to last for at least one year and requires ongoing treatment to effectively manage the condition or prevent an adverse health event.

* NB Effective January 1, 2027

* 2-d. "Disabling condition or disease" means a condition or disease which, according to the current diagnosis of the enrollee's attending physician, is consistent with the definition of "disabled person" pursuant to subdivision five of section two hundred eight of the social services law.

* NB Effective January 1, 2027

3. "Emergency condition" means a medical or behavioral condition, that manifests itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in (a) placing the health of the person afflicted with such condition in serious jeopardy, or in the case of a behavioral condition, placing the health of such person or others in serious jeopardy; (b) serious impairment to such person's bodily

functions; (c) serious dysfunction of any bodily organ or part of such person; (d) serious disfigurement of such person; or (e) a condition described in clause (i), (ii) or (iii) of section 1867(e)(1)(A) of the Social Security Act.

4. "Enrollee" means a person subject to utilization review.

4-a. "Experimental and investigational treatment review plan" means:

(a) a description of the process for developing the written clinical review criteria used in rendering an experimental and investigational treatment review determination; and

(b) a description of the qualifications and experience of the clinical peers who developed the criteria, who are responsible for periodic evaluation of the criteria, and who use the written clinical review criteria in the process of reviewing proposed experimental and investigational health services and procedures.

4-b. "External appeal" means an appeal conducted by an external appeal agent in accordance with the provisions of section forty-nine hundred fourteen of this article.

4-c. "External appeal agent" means an entity certified by the commissioner pursuant to section forty-nine hundred eleven of this article.

4-d. "Final adverse determination" means an adverse determination which has been upheld by a utilization review agent with respect to a proposed health care service following a standard appeal, or an expedited appeal where applicable, pursuant to section forty-nine hundred four of this title.

4-e. "Health care plan" means any organization certified under article forty-four of this chapter.

5. (a) For purposes of this title and for appeals requested pursuant to paragraph (a) of subdivision two of section forty-nine hundred ten of title two of this article, "health care service" means:

(i) health care procedures, treatments or services

(A) provided by a facility licensed pursuant to article twenty-eight, thirty-six, forty-four or forty-seven of this chapter or pursuant to article nineteen, twenty-three, thirty-one or thirty-two of the mental hygiene law; or

(B) provided by a health care professional; and

(ii) the provision of pharmaceutical products or services or durable medical equipment.

(b) For purposes of appeals requested pursuant to paragraph (b) of subdivision two of section forty-nine hundred ten of title two of this article, "health care services" shall mean experimental or investigational procedures, treatments or services, including:

(A) services provided within a clinical trial, and

(B) the provision of a pharmaceutical product pursuant to prescription by the enrollee's attending physician for a use other than those uses for which such pharmaceutical product has been approved for marketing by the federal Food and Drug Administration;

to the extent that coverage for such services are prohibited by law from being excluded under the plan.

Provided that nothing in this subdivision shall be construed to define what are covered services pursuant to a subscriber contract or governmental health benefit program.

6. "Health care professional" means an appropriately licensed, registered or certified health care professional pursuant to title eight of the education law or a health care professional comparably licensed, registered or certified by another state.

7. "Health care provider" means a health care professional or a facility licensed pursuant to articles twenty-eight, thirty-six, forty-four or forty-seven of this chapter or a facility licensed pursuant to article nineteen, twenty-three, thirty-one or thirty-two of the mental hygiene law.

7-a. "Life-threatening condition or disease" means a condition or disease which, according to the current diagnosis of the enrollee's

attending physician, has a high probability of causing the enrollee's death.

7-b. "Material familial affiliation" means any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, or sibling's spouse.

7-c. "Material financial affiliation" means any financial interest of more than five percent of total annual revenue or total annual income of an external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal. The term "material financial affiliation" shall not include revenue received from a health care plan by (a) an external appeal agent to conduct an external appeal pursuant to section forty-nine hundred fourteen of title two of this article, or (b) a clinical peer reviewer for health services rendered to enrollees.

7-d. "Material professional affiliation" means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent organization.

7-e. "Medical and scientific evidence" means the following sources:

(a) peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(b) peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus, Medline and MEDLARS database Health Services Technology Assessment Research;

(c) peer-reviewed abstracts accepted for presentation at major medical

association meetings;

(d) peer-reviewed literature shall not include publications or supplements to publications sponsored to a significant extent by a pharmaceutical manufacturing company or medical device manufacturer;

(e) medical journals recognized by the secretary of Health and Human Services, under section 1861 (t)(2) of the federal Social Security Act;

(f) the following standard reference compendia:

(i) the American Hospital Formulary Service - Drug Information;

(ii) the American Medical Association Drug Evaluation;

(iii) the American Dental Association Accepted Dental Therapeutics; and

(iv) the United States Pharmacopeia - Drug Information;

(g) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

7-f. "Out-of-network denial" means a denial of a request for pre-authorization to receive a particular health service from an out-of-network provider on the basis that such out-of-network health service is not materially different than the health service available in-network. The notice of an out-of-network denial provided to an enrollee shall include information explaining what information the enrollee must submit in order to appeal the out-of-network denial pursuant to subdivision one-a of section four thousand nine hundred four of this article. An out-of-network denial under this subdivision does not constitute an adverse determination as defined in this article. Notwithstanding any other provision of this subdivision, an out-of-network denial shall not be construed to include a denial for a referral to an out-of-network provider on the basis that a health care provider is available in-network to provide the particular health service requested by the enrollee.

7-f-1. "Out-of-network referral denial" means a denial of a request for an authorization or referral to an out-of-network provider on the basis that the health care plan has a health care provider in the in-network benefits portion of its network with appropriate training and experience to meet the particular health care needs of an enrollee, and who is able to provide the requested health service. The notice of an out-of-network referral denial provided to an enrollee shall include information explaining what information the enrollee must submit in order to appeal the out-of-network referral denial pursuant to subdivision one-b of section four thousand nine hundred four of this article. An out-of-network referral denial under this subdivision does not constitute an adverse determination as defined in this article. An out-of-network referral denial shall not be construed to include an out-of-network denial as defined in subdivision seven-f of this section.

7-f-2. "Step therapy protocol override determination" means a determination made by a utilization review agent as defined in subdivision nine of this section to override a step therapy protocol pursuant to subdivisions three-a, three-b and three-c of section forty-nine hundred three of this title granting coverage for the health care professional's selected prescription drug or drugs. Any step therapy protocol override determination as defined by this subdivision shall be eligible for appeal by an enrollee pursuant to this article.

7-f-3. "Step therapy protocol" means a policy, protocol or program established by a utilization review agent as defined in subdivision nine of this section that establishes the specific sequence in which prescription drugs for a specified medical condition are approved for a particular enrollee. Nothing in this chapter shall impair or prevent an insured from having the right to appeal pursuant to this article relating to the imposition of a step therapy protocol.

7-g. "Rare disease" means a condition or disease that (1)(A) is currently or has been subject to a research study by the National Institutes of Health Rare Diseases Clinical Research Network or (B) affects fewer than two hundred thousand United States residents per year, and (2) for which there does not exist a standard health service

or procedure covered by the health care plan that is more clinically beneficial than the requested health service or treatment. A physician, other than the enrollee's treating physician, shall certify in writing that the condition is a rare disease as defined in this subsection. The certifying physician shall be a licensed, board-certified or board-eligible physician who specializes in the area of practice appropriate to treat the enrollee's rare disease. The certification shall provide either: (1) that the insured's rare disease is currently or has been subject to a research study by the National Institutes of Health Rare Diseases Clinical Research Network; or (2) that the insured's rare disease affects fewer than two hundred thousand United States residents per year. The certification shall rely on medical and scientific evidence to support the requested health service or procedure, if such evidence exists, and shall include a statement that, based on the physician's credible experience, there is no standard treatment that is likely to be more clinically beneficial to the enrollee than the requested health service or procedure and the requested health service or procedure is likely to benefit the enrollee in the treatment of the enrollee's rare disease and that such benefit to the enrollee outweighs the risks of such health service or procedure. The certifying physician shall disclose any material financial or professional relationship with the provider of the requested health service or procedure as part of the application for external appeal of denial of a rare disease treatment. If the provision of the requested health service or procedure at a health care facility requires prior approval of an institutional review board, an enrollee or enrollee's designee shall also submit such approval as part of the external appeal application.

8. "Utilization review" means the review to determine whether health care services that have been provided, are being provided or are proposed to be provided to a patient, whether undertaken prior to, concurrent with or subsequent to the delivery of such services are medically necessary. For the purposes of this article none of the following shall be considered utilization review:

(a) Denials based on failure to obtain health care services from a designated or approved health care provider as required under a

subscriber's contract;

(b) Where any determination is rendered pursuant to subdivision three-a of section twenty-eight hundred seven-c of this chapter;

(c) The review of the appropriateness of the application of a particular coding to a patient, including the assignment of diagnosis and procedure;

(d) Any issues relating to the determination of the amount or extent of payment other than determinations to deny payment based on an adverse determination; and

(e) Any determination of any coverage issues other than whether health care services are or were medically necessary.

9. "Utilization review agent" means any company, organization or other entity performing utilization review, except:

(a) an agency of the federal government;

(b) an agent acting on behalf of the federal government, but only to the extent that the agent is providing services to the federal government;

(c) an agent acting on behalf of the state and local government for services provided pursuant to title XIX of the federal social security act;

(d) a hospital's internal quality assurance program except if associated with a health care financing mechanism; or

(e) any insurer subject to article thirty-two or forty-three of the insurance law and any independent utilization review agent performing utilization review under a contract with such insurer, which shall be subject to article forty-nine of the insurance law.

10. "Utilization review plan" means:

(a) a description of the process for developing the written clinical review criteria;

(b) a description of the types of written clinical information which the plan might consider in its clinical review, including but not limited to, a set of specific written clinical review criteria;

(c) a description of practice guidelines and standards used by a utilization review agent in carrying out a determination of medical necessity, which in the case of medically fragile children shall

incorporate the standards required by section forty-four hundred six-i of this chapter;

(d) the procedures for scheduled review and evaluation of the written clinical review criteria; and

(e) a description of the qualifications and experience of the health care professionals who developed the criteria, who are responsible for periodic evaluation of the criteria and of the health care professionals or others who use the written clinical review criteria in the process of utilization review.