

LAWS OF NEW YORK, 1998

CHAPTER 586

AN ACT to amend the public health law and the insurance law, in relation to authorizing external appeals of adverse determinations relating to health care services; and in relation to contract terms of health care plans

Became a law August 5, 1998, with the approval of the Governor. Passed on message of necessity pursuant to Article III, section 14 of the Constitution by a majority vote, three-fifths being present.

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The article heading of article 49 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

UTILIZATION REVIEW **AND EXTERNAL APPEAL**

§ 2. Sections 4900 through 4908 of article 49 of the public health law are designated Title I of article 49, and a new title heading is added to read as follows:

CERTIFICATION OF AGENTS AND UTILIZATION REVIEW PROCESS

§ 3. Paragraph (c) of subdivision 2 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(c) The provisions by which an enrollee, the enrollee's designee, or a health care provider may seek reconsideration of, or appeal from, adverse determinations by the utilization review agent, in accordance with the provisions of this [~~article~~] **title**, including provisions to ensure a timely appeal and that an enrollee, the enrollee's designee, and, in the case of an adverse determination involving a retrospective determination, the enrollee's health care provider, is informed of their right to appeal adverse determinations;

§ 4. Paragraph (d) of subdivision 2 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(d) Procedures by which a decision on a request for utilization review for services requiring preauthorization shall comply with timeframes established pursuant to this [~~article~~] **title**;

§ 5. Subparagraph (ii) of paragraph (j) of subdivision 2 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

EXPLANATION--Matter in **italics** is new; matter in brackets [-] is old law to be omitted.

(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 subdivision three of section forty-nine hundred three of this [article] title or an expedited appeal filed pursuant to subdivision two of section forty-nine hundred four of this [article] title, on a twenty-four hour a day, seven day a week basis;

§ 6. Paragraph (l) of subdivision 2 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(l) A copy of the materials to be disclosed to an enrollee or prospective enrollee pursuant to this [article] title and section forty-four hundred eight of this chapter;

§ 7. Paragraph (m) of subdivision 2 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(m) A description of the mechanisms employed by the utilization review agent to assure that all contractors, subcontractors, subvendors, agents and employees affiliated by contract or otherwise with such utilization review agent will adhere to the standards and requirements of this [article] title; and

§ 8. Subdivision 4 of section 4901 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

4. A registration issued under this [article] title shall be valid for a period of not more than two years, and may be renewed for additional periods of not more than two years each.

§ 9. The opening paragraph of subdivision 1 of section 4902 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

Each utilization review agent shall adhere to utilization review program standards consistent with the provisions of this [article] title which shall, at a minimum, include:

§ 10. Subparagraph (ii) of paragraph (f) of subdivision 1 of section 4902 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(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 subdivision three of section forty-nine hundred three of this [article] title or an expedited appeal filed pursuant to subdivision two of section forty-nine hundred four of this [article] title, on a twenty-four hour a day, seven day a week basis;

§ 11. Article 49 of the public health law is amended by adding a new title II to read as follows:

TITLE II

RIGHT TO EXTERNAL APPEAL

Section 4910. Right to external appeal established.

4911. Powers of the commissioner.

4912. Standards for certification.

4913. Conflict of interest.

4914. Procedures for external appeals of adverse determinations.

4915. Prohibited practices.

4916. Oversight and surveillance of the external appeal process.

§ 4910. Right to external appeal established. 1. There is hereby established an enrollee's right to an external appeal of a final adverse determination by a health care plan.

2. An enrollee, the enrollee's designee and, in connection with retrospective adverse determinations, an enrollee's health care provider, shall have the right to request an external appeal when:

(a) (i) the enrollee has had coverage of a health care service, which would otherwise be a covered benefit under a subscriber contract or governmental health benefit program, denied on appeal, in whole or in part, pursuant to title one of this article on the grounds that such health care service is not medically necessary, and

(ii) the health care plan has rendered a final adverse determination with respect to such health care service or both the plan and the enrollee have jointly agreed to waive any internal appeal; or

(b) (i) the enrollee has had coverage of a health care service denied on the basis that such service is experimental or investigational, and such denial has been upheld on appeal under title one of this article or both the plan and the enrollee have jointly agreed to waive any internal appeal, and

(ii) the enrollee's attending physician has certified that the enrollee has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or would be medically inappropriate, or (b) for which there does not exist a more beneficial standard health service or procedure covered by the health care plan, or (c) for which there exists a clinical trial, and

(iii) the enrollee's attending physician, who must be a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's life threatening or disabling condition or disease, must have recommended either (a) a health service or procedure (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph b of subdivision five of section forty-nine hundred of this article) that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the enrollee than any covered standard health service or procedure; or (b) a clinical trial for which the enrollee is eligible. Any physician certification provided under this section shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation, and

(iv) the specific health service or procedure recommended by the attending physician would otherwise be covered under the policy except for the health care plan's determination that the health service or procedure is experimental or investigational.

3. The health care plan may charge the enrollee a fee of up to fifty dollars per external appeal; provided that, in the event the external appeal agent overturns the final adverse determination of the plan, such

fee shall be refunded to the enrollee. Notwithstanding the foregoing, the health plan shall not require the enrollee to pay any such fee if the enrollee is a recipient of medical assistance or is covered by a policy pursuant to title one-A of article twenty-five of this chapter. Notwithstanding the foregoing, the health plan shall not require the enrollee to pay any such fee if such fee shall pose a hardship to the enrollee as determined by the plan.

4. An enrollee covered under the Medicare or Medicaid program may appeal the denial of a health care service pursuant to the provisions of this title, provided, however, that any determination rendered concerning such denial pursuant to existing federal and state law relating to

the Medicare or Medicaid program or pursuant to federal law enacted subsequent to the effective date of this title and providing for an external appeal process for such denials shall be binding on the enrollee and the insurer and shall supersede any determinations rendered pursuant to this title.

§ 4911. Powers of the commissioner. 1. The commissioner shall have the power to grant and revoke certifications of external appeal agents to conduct external appeals requested pursuant to either paragraph (a) or (b) of subdivision two of section forty-nine hundred ten of this title or pursuant to both such paragraphs.

2. If, after reviewing the application authorized by section forty-nine hundred twelve of this title, the commissioner is satisfied that the applicant meets the requirements of this section, the commissioner shall issue a certificate to the applicant. A certificate issued under this section shall be valid for a period of not more than two years.

3. In order to be re-certified, an external appeal agent must demonstrate to the commissioner on forms prescribed by the commissioner that it continues to meet all applicable standards required by this title. Re-certification under this section shall be valid for a period of not more than two years.

§ 4912. Standards for certification. 1. The commissioner shall develop an application for certification. At a minimum, applicants shall provide:

(a) a description of the qualifications of the clinical peer reviewers retained to conduct external appeals of final adverse determinations, including such reviewers' current and past employment history and practice affiliations;

(b) a description of the procedures employed to ensure that clinical peer reviewers conducting external appeals are:

(i) appropriately licensed, registered or certified;

(ii) trained in the principles, procedures and standards of the external appeal agent; and

(iii) knowledgeable about the health care service which is the subject of the final adverse determination under appeal;

(c) a description of the methods of recruiting and selecting impartial clinical peer reviewers and matching such reviewers to specific cases;

(d) the number of clinical peer reviewers retained by the external appeal agent, and a description of the areas of expertise available from such reviewers and the types of cases such reviewers are qualified to review;

(e) a description of the policies and procedures employed to protect the confidentiality of individual medical and treatment records in accordance with applicable state and federal laws;

(f) a description of the quality assurance program established by the external appeal agent pursuant to paragraph (c) of subdivision two of this section;

(g) the names of all corporations and organizations owned or controlled by the external appeal agent or which owns or controls such agent, and the nature and extent of any such ownership or control;

(h) the names and biographies of all directors, officers, and executives of the external appeal agent;

(i) an experimental and investigational treatment review plan to conduct appeals pursuant to subparagraph (B) of paragraph (d) of subdivision two of section forty-nine hundred fourteen of this title; and

(j) a description of the fees to be charged by agents for external appeals.

2. The commissioner shall, at a minimum, require an external appeal

agent to:

(a) appoint a medical director, who is a physician in possession of a current and valid non-restricted license to practice medicine. Such director shall be responsible for the supervision and oversight of the external appeal process;

(b) develop written policies and procedures governing all aspects of the appeal process, including, at a minimum:

(i) procedures to ensure that appeals are conducted within the time frames specified in section forty-nine hundred fourteen of this title, and any required notices are provided in a timely manner;

(ii) procedures to ensure the selection of qualified and impartial clinical peer reviewers. Such reviewers shall be qualified to render determinations relating to the health care service which is the subject of the final adverse determination under appeal;

(iii) procedures to ensure the confidentiality of medical and treatment records and review materials; and

(iv) procedures to ensure adherence to the requirements of this title by any contractor, subcontractor, subvendor, agent or employee affiliated by contract or otherwise with such external appeal agent;

(c) establish a quality assurance program. Such program shall include written descriptions, to be provided to all individuals involved in such program, of the organizational arrangements and ongoing procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in external appeals performed by the external appeal agent and to ensure the maintenance of program standards pursuant to this section;

(d) establish a toll-free telephone service to receive information on a 24-hour-a-day 7-day-a-week basis relating to external appeals pursuant to this title. Such system shall be capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours, and;

(e) develop procedures to ensure that:

(i) appropriate personnel are reasonably accessible not less than forty hours per week during normal business hours to discuss patient care and to allow response to telephone requests, and

(ii) response to accepted or recorded messages shall be made not less than one business day after the date on which the call was received.

3. No entity shall be qualified to submit such request for application if it owns or controls, is owned or controlled by, or exercises common control with, any of the following:

(a) any national, state or local illness, health benefit or public advocacy group;

(b) any national, state or local society or association of hospitals, physicians, or other providers of health care services; or

(c) any national, state or local association of health care plans.

4. A health care plan shall transmit, and an external appeal agent shall be authorized to receive and review, an enrollee's medical and treatment records in order to conduct an external appeal pursuant to this title.

5. An external appeal agent shall provide ready access to the commissioner to all data, records, and information collected and maintained concerning such agent's external appeal activities.

6. An external appeal agent shall agree to provide the commissioner such data, information, and reports as the commissioner determines necessary to evaluate the external appeal process established pursuant to this title.

7. The commissioner shall provide, upon the request of any interested person, a copy of all non-proprietary information filed with the commissioner by the external appeal agent. The commissioner may charge a reasonable fee to the interested person for reproducing the requested information.

§ 4913. Conflict of interest. 1. No external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal pursuant to this title, shall have any material professional affiliation, material familial affiliation, material financial affiliation, or other affiliation prescribed pursuant to regulation, with any of the following:

(a) the health care plan;

(b) any officer, director, or management employee of the health care plan;

(c) any health care provider, physician's medical group, independent practice association, or provider of pharmaceutical products or services or durable medical equipment, proposing to provide or supply the health service;

(d) the facility at which the health service would be provided;

(e) the developer or manufacturer of the principal health service which is the subject of the appeal; or

(f) the enrollee whose health care service is the subject of the appeal, or the enrollee's designee.

2. Notwithstanding the provisions of subdivision one of this section, the commissioner shall promulgate regulations to minimize any conflict of interest where such conflict may be unavoidable.

§ 4914. Procedures for external appeals of adverse determinations. 1. The commissioner shall establish procedures by regulation to randomly assign an external appeal agent to conduct an external appeal, provided that the commissioner may establish a maximum fee which may be charged for any such external appeal, or the commissioner may exclude from such random assignment any external appeal agent which charges a fee which she deems to be unreasonable.

2. (a) The enrollee shall have forty-five days to initiate an external appeal after the enrollee receives notice from the health care plan, or such plan's utilization review agent if applicable, of a final adverse determination or denial or after both the plan and the enrollee have jointly agreed to waive any internal appeal. Such request shall be in writing in accordance with the instructions and in such form prescribed by subdivision five of this section. The enrollee, and the enrollee's health care provider where applicable, shall have the opportunity to

submit additional documentation with respect to such appeal to the external appeal agent within such forty-five-day period; provided however that when such documentation represents a material change from the documentation upon which the utilization review agent based its adverse determination or upon which the health plan based its denial, the health plan shall have three business days to consider such documentation and amend or confirm such adverse determination.

(b) The external appeal agent shall make a determination with respect to the appeal within thirty days of the receipt of the enrollee's request therefor, submitted in accordance with the commissioner's instructions. The external appeal agent shall have the opportunity to request additional information from the enrollee, the enrollee's health care provider and the enrollee's health care plan within such thirty-day period, in which case the agent shall have up to five additional business days if necessary to make such determination. The external appeal agent shall notify the enrollee and the health care plan, in writing, of

the appeal determination within two business days of the rendering of such determination.

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this subdivision, if the enrollee's attending physician states that a delay in providing the health care service would pose an imminent or serious threat to the health of the enrollee, the external appeal shall be completed within three days of the request therefor and the external appeal agent shall make every reasonable attempt to immediately notify the enrollee and the health plan of its determination by telephone or facsimile, followed immediately by written notification of such determination.

(d) (A) For external appeals requested pursuant to paragraph (a) of subdivision two of section forty-nine hundred ten of this title, the external appeal agent shall review the utilization review agent's final adverse determination and, in accordance with the provisions of this title, shall make a determination as to whether the health care plan acted reasonably and with sound medical judgment and in the best interest of the patient. When the external appeal agent makes its determination, it shall consider the clinical standards of the plan, the information provided concerning the patient, the attending physician's recommendation, and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations. Provided that such determination shall:

(i) be conducted only by one or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a notice of appeal determination which shall include the reasons for the determination; provided, however, that where the final adverse determination is upheld on appeal, the notice shall include the clinical rationale, if any, for such determination,

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the enrollee, and

(v) be admissible in any court proceeding.

(B) For external appeals requested pursuant to paragraph (b) of subdivision two of section forty-nine hundred ten of this title, the external appeal agent shall review the proposed health service or procedure for which coverage has been denied and, in accordance with the provisions of this title and the external agent's experimental and investigational treatment review plan, make a determination as to whether the patient

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costs of such health service or procedure shall be covered by the health care plan; provided that such determination shall:

(i) be conducted by a panel of three or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a written statement:

(1) that the patient costs of the proposed health service or procedure shall be covered by the health care plan either: when a majority of the panel of reviewers determines, upon review of the applicable medical and scientific evidence (or upon confirmation that the recommended treatment is a clinical trial), the enrollee's medical record, and any other pertinent information, that the proposed health service or treatment (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph (b) of subdivision five of section forty-nine hundred of this article) is likely to be more beneficial than any standard treatment or treatments for the enrollee's life-threatening or disabling condition or disease (or, in the case of a clinical trial, is likely to benefit the enrollee in the treatment of the enrollee's condition or

disease); or when a reviewing panel is evenly divided as to a determination concerning coverage of the health service or procedure, or

(2) upholding the health plan's denial of coverage,

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the enrollee, and

(v) be admissible in any court proceeding.

As used in this subparagraph (B) with respect to a clinical trial, patient costs shall include all costs of health services required to provide treatment to the enrollee according to the design of the trial. Such costs shall not include the costs of any investigational drugs or devices themselves, the cost of any nonhealth services that might be required for the enrollee to receive the treatment, the costs of managing the research, or costs which would not be covered under the policy for noninvestigational treatments.

3. No external appeal agent or clinical peer reviewer conducting an external appeal shall be liable in damages to any person for any opinions rendered by such external appeal agent or clinical peer reviewer upon completion of an external appeal conducted pursuant to this section, unless such opinion was rendered in bad faith or involved gross negligence.

4. Payment for an external appeal shall be the responsibility of the health care plan. The health care plan shall make payment to the external appeal agent within forty-five days from the date the appeal determination is received by the health care plan, and the health care plan shall be obligated to pay such amount together with interest thereon calculated at a rate which is the greater of the rate set by the commissioner of taxation and finance for corporate taxes pursuant to paragraph one of subsection (e) of section one thousand ninety-six of the tax law or twelve percent per annum, to be computed from the date the bill was required to be paid, in the event that payment is not made within such forty-five days.

5. The commissioner, in consultation with the superintendent of insurance, shall promulgate by regulation a standard description of the external appeal process established under this section, which shall provide a standard form and instructions for the initiation of an external appeal by an enrollee.

§ 4915. Prohibited practices. An external appeal agent shall not, with respect to external appeal activities, permit or provide compensation or anything of value to its employees, agents, or contractors based on:

1. either a percentage of the amount by which a claim is reduced for payment or the number of claims or the cost of services for which the person has denied authorization or payment; or

2. any other method that encourages the upholding of an adverse determination.

§ 4916. Oversight and surveillance of the external appeal process. 1. The commissioner shall have the power to:

(a) review the activities of the health care plans and external appeal agents pursuant to this title, including the extent to which such plans and agents adhere to the standards and time frames required pursuant to this title;

(b) investigate complaints by enrollees regarding requests for and processing of external appeals; and

(c) conduct random audits of health care plans and external appeal agents to determine compliance with the provisions of this title.

2. Each health care plan and external appeal agent shall annually, in such form as the commissioner shall require, report the number of

external appeals requested by enrollees and the outcomes of any such external appeals.

3. The commissioner shall annually report, by plan and agent, such information to the governor and the legislature, provided that no such information shall be included which would otherwise be deemed confidential information within the meaning of this chapter.

§ 12. Paragraph (c) of subdivision 1 of section 4408 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(c) a description of utilization review policies and procedures used by the health maintenance organization, including:

(i) the circumstances under which utilization review will be undertaken;

(ii) the toll-free telephone number of the utilization review agent;

(iii) the timeframes under which utilization review decisions must be made for prospective, retrospective and concurrent decisions;

(iv) the right to reconsideration;

(v) the right to an appeal, including the expedited and standard appeals processes and the time frames for such appeals;

(vi) the right to designate a representative;

(vii) a notice that all denials of claims will be made by qualified clinical personnel and that all notices of denials will include information about the basis of the decision;

(viii) a notice of the right to an external appeal together with a description, jointly promulgated by the commissioner and the superintendent of insurance as required pursuant to subdivision five of section forty-nine hundred fourteen of this chapter, of the external appeal

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process established pursuant to title two of article forty-nine of this chapter and the timeframes for such appeals; and

(ix) further appeal rights, if any;

§ 13. Subdivisions 1, 2 and 5 of section 4900 of the public health law, as added by chapter 705 of the laws of 1996, are amended and thirteen new subdivisions 2-a, 2-b, 2-c, 4-a, 4-b, 4-c, 4-d, 4-e, 7-a, 7-b, 7-c, 7-d and 7-e are added to read as follows:

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

2. "Clinical peer reviewer" means:

(a) [~~a licensed physician and, in connection with an appeal of an adverse determination, a licensed physician who is in the same or similar specialty as the health care provider who typically manages the medical condition, procedure or treatment under review; or~~] for purposes of title one of this article:

(i) a physician who possesses a current and valid non-restricted

license to practice medicine; or

~~[(b) in the case of non-physician reviewers,]~~

(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[~~7 procedure~~] or disease or provides the health care service or treatment under review; and

(b) for purposes of 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) has been practicing in such area of specialty for a period of at least five years; and

(D) 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) 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; and

(E) 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 herein shall be construed to change any statutorily-defined scope of practice.

5. [~~"Health care services" means~~] (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[~~; a facility licensed~~] or pursuant to article nineteen, twenty-three or thirty-one 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[; ~~provided that nothing~~].

(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.

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.

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

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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.

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.

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.

§ 14. Paragraph (b) of subdivision 1 of section 4902 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(b) 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 enrollees 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 commissioner and the superintendent of insurance as required pursuant to subdivision five of section forty-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;

§ 15. Subparagraph (ii) of paragraph (e) of subdivision 1 of section 4902 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

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(ii) instructions on how to initiate ~~[an appeal]~~ standard and expedited appeals pursuant to section forty-nine hundred four and an external appeal pursuant to section forty-nine hundred fourteen of this article; and

§ 15-a. Section 4903 of the public health law is amended by adding a new subdivision 7 to read as follows:

7. Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section forty nine hundred four of this title.

§ 16. Paragraph (b) of subdivision 5 of section 4903 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(b) instructions on how to initiate ~~[an appeal]~~ standard and expedited appeals pursuant to section forty-nine hundred four and an external appeal pursuant to section forty-nine hundred fourteen of this article; and

§ 17. Paragraph (b) of subdivision 2 of section 4904 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(b) an adverse determination in which the health care provider believes an immediate appeal is warranted except any retrospective determination. Such process shall include mechanisms which facilitate resolution of the appeal including but not limited to the sharing of information from the enrollee's health care provider and the utilization review agent by

telephonic means or by facsimile. The utilization review agent shall provide reasonable access to its clinical peer reviewer within one business day of receiving notice of the taking of an expedited appeal. Expedited appeals ~~[must]~~ shall be determined within two business days of receipt of necessary information to conduct such appeal. Expedited appeals which do not result in a resolution satisfactory to the appealing party may be further appealed through the standard appeal process, or through the external appeal process pursuant to section forty-nine hundred fourteen of this article as applicable.

§ 18. Subdivisions 3 and 4 of section 4904 of the public health law, as added by chapter 705 of the laws of 1996, are amended and a new subdivision 5 is added to read as follows:

3. A utilization review agent shall establish a standard appeal process which includes procedures for appeals to be filed in writing or by telephone. A utilization review agent must establish a period of no less than forty-five days after receipt of notification by the enrollee of the initial utilization review determination and receipt of all necessary information to file the appeal from said determination. The utilization review agent must provide written acknowledgment of the filing of the appeal to the appealing party within fifteen days of such filing and shall make a determination with regard to the appeal within sixty days of the receipt of necessary information to conduct the appeal. The

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utilization review agent shall notify the enrollee, the enrollee's designee and, where appropriate, the enrollee's health care provider, in writing, of the appeal determination within two business days of the rendering of such determination. The notice of the appeal determination shall include:

(a) the reasons for the determination; provided, however, that where the adverse determination is upheld on appeal, the notice shall include the clinical rationale for such determination; and

(b) a notice of the enrollee's right to an external appeal together with a description, jointly promulgated by the commissioner and the superintendent of insurance as required pursuant to subdivision five of section forty-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 external appeals.

4. Both expedited and standard appeals shall only be conducted by clinical peer reviewers, provided that any such appeal shall be reviewed by a clinical peer reviewer other than the clinical peer reviewer who rendered the adverse determination.

5. Failure by the utilization review agent to make a determination within the applicable time periods in this section shall be deemed to be a reversal of the utilization review agent's adverse determination.

§ 19. The article heading of article 49 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

UTILIZATION REVIEW AND EXTERNAL APPEAL

§ 20. Sections 4900 through 4908 of the insurance law are designated Title I of article 49 and a new title heading is added to read as follows:

REGISTRATION OF AGENTS AND REVIEW PROCESS

§ 21. Paragraph 3 of subsection (b) of section 4901 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(3) The provisions by which an insured, the insured's designee, or a health care provider may seek reconsideration of or appeal from adverse determinations by the utilization review agent, in accordance with the provisions of this **[article] title**, including provisions to ensure a timely appeal and that an insured, the insured's designee, and, in the case of an adverse determination involving a retrospective determination, the insured's health care provider is informed of their right to appeal adverse determinations;

§ 22. Paragraph 4 of subsection (b) of section 4901 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(4) Procedures by which a decision on a request for utilization review for services requiring preauthorization shall comply with timeframes established pursuant to this **[article] title**;

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§ 23. Subparagraph (ii) of paragraph 10 of subsection (b) of section 4901 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

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

§ 24. Paragraph 12 of subsection (b) of section 4901 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(12) A copy of the materials to be disclosed to an insured or prospective insured pursuant to sections three thousand two hundred seventeen-a or four thousand three hundred twenty-four of this chapter, whichever is applicable, and this **[article] title**;

§ 25. Paragraph 13 of subsection (b) of section 4901 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(13) A description of the mechanisms employed by the utilization review agent to assure that all subcontractors, subvendors, agents or employees affiliated by contract or otherwise with such utilization review agent will adhere to the standards and requirements of this **[article] title**; and

§ 26. The opening paragraph of subsection (a) of section 4902 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

Each utilization review agent shall adhere to utilization review program standards consistent with the provisions of this **[article] title** which shall, at a minimum, include:

§ 27. Subparagraph (ii) of paragraph 6 of subsection (a) of section 4902 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

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

§ 28. Section 4906 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

§ 4906. Waiver. Any agreement which purports to waive, limit, disclaim, or in any way diminish the rights set forth in this article, except as provided pursuant to section four thousand nine hundred ten of this article shall be void as contrary to public policy.

§ 28-a. Section 4906 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

§ 4906. Waiver. Any agreement which purports to waive, limit, disclaim, or in any way diminish the rights set forth in this article, except as provided pursuant to section four thousand nine hundred ten of this article shall be void as contrary to public policy.

§ 29. Article 49 of the insurance law is amended by adding a new title II to read as follows:

TITLE II

RIGHT TO EXTERNAL APPEAL

Section 4910. Right to external appeal established.

4911. Powers of the superintendent.

4912. Standards for certification.

4913. Conflict of interest.

4914. Procedures for external appeals of adverse determinations.

4915. Prohibited practices.

4916. Oversight and surveillance of the external appeal process.

§ 4910. Right to external appeal established. (a) There is hereby established an insured's right to an external appeal of a final adverse determination by a health plan.

(b) An insured, the insured's designee and, in connection with retrospective adverse determinations, an insured's health care provider, shall have the right to request an external appeal when:

(1) (A) the insured has had coverage of the health care service, which would otherwise be a covered benefit under a subscriber contract or governmental health benefit program, denied on appeal, in whole or in part, pursuant to title one of this article on the grounds that such health care service is not medically necessary, and

(B) the health care plan has rendered a final adverse determination with respect to such health care service or both the plan and the insured have jointly agreed to waive any internal appeal; or

(2) (A) the insured has had coverage of a health care service denied on the basis that such service is experimental or investigational, and such denial has been upheld on appeal under section four thousand nine hundred four of this article or both the plan and the insured have jointly agreed to waive any internal appeal, and

(B) the insured's attending physician has certified that the insured has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or would be medically inappropriate, or (b) for which there does not exist a more beneficial standard health service or procedure covered by the health

care plan, or (c) for which there exists a clinical trial, and

(C) the insured's attending physician, who must be a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's life-threatening or disabling condition or disease, must have recommended either (a) a health service or procedure (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph two of subsection (e) of

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section four thousand nine hundred of this article) that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the insured than any covered standard health service or procedure; or (b) a clinical trial for which the insured is eligible. Any physician certification provided under this section shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation, and

(D) the specific health service or procedure recommended by the attending physician would otherwise be covered under the policy except for the health care plan's determination that the health service or procedure is experimental or investigational.

(c) The health care plan may charge the insured a fee of up to fifty dollars per external appeal; provided that, in the event the external appeal agent overturns the final adverse determination of the plan, such fee shall be refunded to the insured. Notwithstanding the foregoing, the health plan shall not require the enrollee to pay any such fee if the enrollee is a recipient of medical assistance or is covered by a policy pursuant to title one-A of article twenty-five of the public health law. Notwithstanding the foregoing, the health plan shall not require the insured to pay any such fee if such fee shall pose a hardship to the enrollee as determined by the plan.

(d) An enrollee covered under the Medicare or Medicaid program may appeal the denial of a health care service pursuant to the provisions of this title, provided, however, that any determination rendered concerning such denial pursuant to existing federal and state law relating to the Medicare or Medicaid program or pursuant to federal law enacted subsequent to the effective date of this title and providing for an external appeal process for such denial shall be binding on the enrollee and the insurer and shall supersede any determinations rendered pursuant to this title.

§ 4911. Powers of the superintendent. (a) The superintendent shall have the power to grant and revoke certifications of external appeal agents to conduct external appeals requested pursuant to paragraph one or two of subsection (b) of section four thousand nine hundred ten of this title or pursuant to both such paragraphs.

(b) If, after reviewing the application authorized by section four thousand nine hundred twelve of this title, the superintendent is satisfied that the applicant meets the requirements of this section, the superintendent shall issue a certificate to the applicant. A certificate issued under this section shall be valid for a period of not more than two years.

(c) In order to be re-certified, an external appeal agent must demonstrate to the superintendent on forms prescribed by the superintendent that it continues to meet all applicable standards required by this title. Re-certification under this section shall be valid for a period of not more than two years.

§ 4912. Standards for certification. (a) The superintendent shall develop an application for certification. At a minimum, applicants

shall provide:

(1) a description of the qualifications of the clinical peer reviewers retained to conduct external appeals of final adverse determinations including such reviewers' current and past employment history and practice affiliations;

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(2) a description of the procedures employed to ensure that clinical peer reviewers conducting external appeals are:

(i) appropriately licensed, registered or certified;

(ii) trained in the principles, procedures and standards of the external appeal agent; and

(iii) knowledgeable about the health care service which is the subject of the final adverse determination under appeal;

(3) a description of the methods of recruiting and selecting impartial clinical peer reviewers and matching such reviewers to specific cases;

(4) the number of clinical peer reviewers retained by the external appeal agent, and a description of the areas of expertise available from such reviewers and the types of cases such reviewers are qualified to review;

(5) a description of the policies and procedures employed to protect the confidentiality of individual medical and treatment records in accordance with applicable state and federal laws;

(6) a description of the quality assurance program established by the external appeal agent pursuant to paragraph three of subsection (b) of this section;

(7) the names of all corporations and organizations owned or controlled by the external appeal agent, or which owns or controls such agent, and the nature and extent of any such ownership or control;

(8) the names and biographies of all directors, officers, and executives of the external appeal agent;

(9) an experimental and investigational treatment review plan to conduct appeals pursuant to subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this title; and

(10) a description of the fees to be charged by agents for external appeals.

(b) The superintendent shall, at a minimum, require an external appeal agent to:

(1) appoint a medical director, who is a physician in possession of a current and valid non-restricted license to practice medicine. Such director shall be responsible for the supervision and oversight of the external appeal process;

(2) develop written policies and procedures governing all aspects of the appeal process, including, at a minimum:

(i) procedures to ensure that appeals are conducted within the time frames specified in section four thousand nine hundred fourteen of this title, and any required notices are provided in a timely manner;

(ii) procedures to ensure the selection of qualified and impartial clinical peer reviewers. Such reviewers shall be qualified to render and impartial determinations relating to the health care service which is the subject of the final adverse determination under appeal;

(iii) procedures to ensure the confidentiality of medical and treatment records and review materials; and

(iv) procedures to ensure adherence to the requirements of this title by any contractor, subcontractor, subvendor, agent or employee affiliated by contract or otherwise with such external appeal agent;

(3) establish a quality assurance program. Such program shall include written descriptions, to be provided to all individuals involved in such

program, of the organizational arrangements and ongoing procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in external appeals performed by the external appeal

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agent and to ensure the maintenance of program standards pursuant to this section;

(4) establish a toll-free telephone service to receive information on a 24-hour-a-day 7-day-a-week basis relating to external appeals pursuant to this title. Such system shall be capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours, and;

(5) develop procedures to ensure that:

(i) appropriate personnel are reasonably accessible not less than forty hours per week during normal business hours to discuss patient care and to allow response to telephone requests, and

(ii) response to accepted or recorded messages shall be made not less than one business day after the date on which the call was received.

(c) No entity shall be qualified to submit such request for application if it owns or controls, is owned or controlled by, or exercises common control with, any of the following:

(1) any national, state or local illness, health benefit or public advocacy group;

(2) any national, state or local society or association of hospitals, physicians, or other providers of health care services; or

(3) any national, state or local association of health care plans.

(d) A health care plan shall transmit, and an external appeal agent shall be authorized to receive and review, an insured's medical and treatment records in order to conduct an external appeal pursuant to this title.

(e) An external appeal agent shall provide ready access to the superintendent to all data, records, and information collected and maintained concerning such agent's external appeal activities.

(f) An external appeal agent shall agree to provide the superintendent such data, information, and reports as the superintendent determines necessary to evaluate the external appeal process established pursuant to this title.

(g) The superintendent shall provide, upon the request of any interested person, a copy of all non-proprietary information filed with the superintendent by the external appeal agent. The superintendent may charge a reasonable fee to the interested person for reproducing the requested information.

§ 4913. Conflict of interest. (a) No external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal pursuant to this title, shall have any material professional affiliation, material familial affiliation, material financial affiliation, or other affiliation prescribed pursuant to regulation, with any of the following:

(1) the health care plan;

(2) any officer, director, or management employee of the health care plan;

(3) any health care provider, physician's medical group, independent practice association, or provider of pharmaceutical products or services or durable medical equipment, proposing to provide or supply the health service;

(4) the facility at which the health service would be provided;

(5) the developer or manufacturer of the principal health service which is the subject of the appeal; or

(6) the insured whose health care service is the subject of the

(b) Notwithstanding subsection (a) of this section, the superintendent shall promulgate regulations to minimize any conflict of interest where such conflict may be unavoidable.

§ 4914. Procedures for external appeals of adverse determinations.

(a) The superintendent shall establish procedures by regulation to randomly assign an external appeal agent to conduct an external appeal, provided that the superintendent may establish a maximum fee which may be charged for any such external appeal, or the superintendent may exclude from such random assignment any external appeal agent which charges a fee which he deems to be unreasonable.

(b) (1) The insured shall have forty-five days to initiate an external appeal after the insured receives notice from the health care plan, or such plan's utilization review agent if applicable, of a final adverse determination or denial or after both the plan and the enrollee have jointly agreed to waive any internal appeal. Such request shall be in writing in accordance with the instructions and in such form prescribed by subsection (e) of this section. The insured, and the insured's health care provider where applicable, shall have the opportunity to submit additional documentation with respect to such appeal to the external appeal agent within such forty-five-day period; provided however that when such documentation represents a material change from the documentation upon which the utilization review agent based its adverse determination or upon which the health plan based its denial, the health plan shall have three business days to consider such documentation and amend or confirm such adverse determination.

(2) The external appeal agent shall make a determination with regard to the appeal within thirty days of the receipt of the insured's request therefor, submitted in accordance with the superintendent's instructions. The external appeal agent shall have the opportunity to request additional information from the insured, the insured's health care provider and the insured's health care plan within such thirty-day period, in which case the agent shall have up to five additional business days if necessary to make such determination. The external appeal agent shall notify the insured and the health care plan, in writing, of the appeal determination within two business days of the rendering of such determination.

(3) Notwithstanding the provisions of paragraphs one and two of this subsection, if the insured's attending physician states that a delay in providing the health care service would pose an imminent or serious threat to the health of the insured, the external appeal shall be completed within three days of the request therefor and the external appeal agent shall make every reasonable attempt to immediately notify the insured and the health plan of its determination by telephone or facsimile, followed immediately by written notification of such determination.

(4) (A) For external appeals requested pursuant to paragraph one of subsection (b) of section four thousand nine hundred ten of this title, the external appeal agent shall review the utilization review agent's final adverse determination and, in accordance with the provisions of this title, shall make a determination as to whether the health care plan acted reasonably and with sound medical judgment and in the best interest of the patient. When the external appeal agent makes its determination, it shall consider the clinical standards of the plan, the information provided concerning the patient, the attending physician's recommendation, applicable and generally accepted practice guidelines developed by the federal government, national or professional medical

societies, boards and associations. Provided that such determination shall:

(i) be conducted only by one or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a notice of appeal determination which shall include the reasons for the determination; provided, however, that where the final adverse determination is upheld on appeal, the notice shall include the clinical rationale, if any, for such determination,

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the insured, and

(v) be admissible in any court proceeding.

(B) For external appeals requested pursuant to paragraph two of subsection (b) of section four thousand nine hundred ten of this title, the external appeal agent shall review the proposed health service or procedure for which coverage has been denied and, in accordance with the provisions of this title and the external agent's investigational treatment review plan, make a determination as to whether the patient costs of such health service or procedure shall be covered by the health care plan; provided that such determination shall:

(i) be conducted by a panel of three or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a written statement:

(a) that the patient costs of the proposed health service or procedure shall be covered by the health care plan either: when a majority of the panel of reviewers determines, upon review of the applicable medical and scientific evidence (or upon confirmation that the recommended treatment is a clinical trial), the insured's medical record, and any other pertinent information, that the proposed health service or treatment (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph two of subsection (e) of section four thousand nine hundred of this article is likely to be more beneficial than any standard treatment or treatments for the insured's life-threatening or disabling condition or disease (or, in the case of a clinical trial, is likely to benefit the insured in the treatment of the insured's condition or disease); or when a reviewing panel is evenly divided as to a determination concerning coverage of the health service or procedure, or

(b) upholding the health plan's denial of coverage;

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the insured, and

(v) be admissible in any court proceeding.

As used in this subparagraph (B) with respect to a clinical trial, patient costs shall include all costs of health services required to provide treatment to the insured according to the design of the trial. Such costs shall not include the costs of any investigational drugs or devices themselves, the cost of any nonhealth services that might be required for the insured to receive the treatment, the costs of managing the research, or costs which would not be covered under the policy for noninvestigational treatments.

(c) No external appeal agent or clinical peer reviewer conducting an external appeal shall be liable in damages to any person for any opinions rendered by such external appeal agent or clinical peer reviewer upon completion of an external appeal conducted pursuant to this section, unless such opinion was rendered in bad faith or involved gross negligence.

(d) Payment for an external appeal shall be the responsibility of the health care plan. The health care plan shall make payment to the external appeal agent within forty-five days, from the date the appeal determination is received by the health care plan, and the health care plan shall be obligated to pay such amount together with interest thereon calculated at a rate which is the greater of the rate set by the commissioner of taxation and finance for corporate taxes pursuant to paragraph one of subsection (e) of section one thousand ninety-six of the tax law or twelve percent per annum, to be computed from the date the bill was required to be paid, in the event that payment is not made within such forty-five days.

(e) The superintendent, in consultation with the commissioner of health, shall promulgate by regulation a standard description of the external appeal process established under this section, which shall provide a standard form and instructions for the initiation of an external appeal by an insured.

§ 4915. Prohibited practices. An external appeal agent shall not, with respect to external appeal activities, permit or provide compensation or anything of value to its employees, agents, or contractors based on:

(a) either a percentage of the amount by which a claim is reduced for payment or the number of claims or the cost of services for which the person has denied authorization or payment; or

(b) any other method that encourages the upholding of an adverse determination.

§ 4916. Oversight and surveillance of the external appeal process.

(a) The superintendent shall have the power to:

(1) review the activities of the health care plans and external appeal agents pursuant to this title, including the extent to which such plans and agents adhere to the standards and time frames required pursuant to this title;

(2) investigate complaints by insureds regarding requests for and processing of external appeals; and

(3) conduct random audits of health care plans and external appeal agents to determine compliance with the provisions of this title.

(b) Each health care plan and external appeal agent shall annually, in such form as the superintendent shall require, report the number of external appeals requested by insureds and the outcomes of any such external appeals.

(c) The superintendent shall annually report, by plan and by agent, such information to the governor and the legislature, provided that no such information shall be included which would otherwise be deemed confidential information within the meaning of this chapter.

§ 30. Paragraph 3 of subsection (a) of section 3217-a of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(3) a description of utilization review policies and procedures, used by the insurer, including:

(A) the circumstances under which utilization review will be undertaken;

(B) the toll-free telephone number of the utilization review agent;

(C) the time frames under which utilization review decisions must be made for prospective, retrospective and concurrent decisions;

(D) the right to reconsideration[7];

(E) the right to an appeal, including the expedited and standard appeals processes and the time frames for such appeals;

(F) the right to designate a representative;

(G) a notice that all denials of claims will be made by qualified clinical personnel and that all notices of denials will include information about the basis of the decision;

(H) a notice of the right to an external appeal 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 chapter, of the external appeal process established pursuant to title two of article forty-nine of this chapter and the time frames for such appeals; and

(I) further appeal rights, if any;

§ 31. Paragraph 3 of subsection (a) of section 4324 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(3) a description of utilization review policies and procedures, used by the corporation, including:

(A) the circumstances under which utilization review will be undertaken;

(B) the toll-free telephone number of the utilization review agent;

(C) the time frames under which utilization review decisions must be made for prospective, retrospective and concurrent decisions;

(D) the right to reconsideration;

(E) the right to an appeal, including the expedited and standard appeals processes and the time frames for such appeals;

(F) the right to designate a representative;

(G) a notice that all denials of claims will be made by qualified clinical personnel and that all notices of denials will include information about the basis of the decision;

(H) a notice of the right to an external appeal 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 chapter, of the external appeal process established pursuant to title two of article forty-nine of this chapter and the time frames for such appeals; and

(I) further appeal rights, if any;

§ 32. Subsections (a), (b) and (e) of section 4900 of the insurance law, as added by chapter 705 of the laws of 1996, are amended and thirteen new subsections (b-1), (b-2), (b-3), (d-1), (d-2), (d-3), (d-4), (d-5), (g-1), (g-2), (g-3), (g-4) and (g-5) are added to read as follows:

(a) "Adverse determination" means a determination by a utilization review agent that an admission, extension of stay, or other health care service [~~has been reviewed and~~], upon review based on the information provided, is not medically necessary.

(b) "Clinical peer reviewer" means:

(1) [~~a licensed physician and, in connection with an appeal of an adverse determination, a licensed physician who is in the same or similar specialty as the health care provider who typically manages the~~

~~medical condition, procedure or treatment under review; or~~ for purposes of title one of this article:

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

~~[(2) in the case of non-physician reviewers,]~~

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

(i) 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

(ii) is in the same profession and same or similar specialty as the health care provider who typically manages the medical condition[~~, procedure~~] or disease or provides the health care service or treatment under review; and

(2) for purposes of title two of this article:

(A) a physician who:

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

(ii) 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;

(iii) has been practicing in such area of specialty for a period of at least five years; and

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

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

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

(ii) 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;

(iii) has been practicing in such area of specialty for a period of at least five years;

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

(v) 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.

(3) Nothing herein shall be construed to change any statutorily-defined scope of practice.

(e) [~~"Health care services" means~~] (1) For purposes of this title and for appeals requested pursuant to paragraph one of subsection (b) of

section four thousand nine hundred ten of title two of this article, "health care service" means:

(A) health care procedures, treatments or services

(i) provided by a facility licensed pursuant to article twenty-eight, thirty-six, forty-four or forty-seven of the public health law[~~; a~~

~~facility licensed~~] or pursuant to article nineteen, twenty-three or thirty-one of the mental hygiene law; or

(ii) provided by a health care professional; and

(B) the provision of pharmaceutical products or services or durable medical equipment[; ~~provided that nothing~~].

(2) For purposes of appeals requested pursuant to paragraph two of subsection (b) of section four thousand 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 subsection shall be construed to define what are covered services pursuant to a subscriber contract or governmental health benefit program.

(b-1) "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.

(b-2) "Clinical trial" means a peer-reviewed study plan which has been:

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

(2) 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 subsection, 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).

(b-3) "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.

(d-1) "Experimental and investigational treatment review plan" means:

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

(2) 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.

(d-2) "External appeal" means an appeal conducted by an external appeal agent, pursuant to section four thousand nine hundred fourteen of this article.

(d-3) "External appeal agent" means an entity certified by the superintendent pursuant to section four thousand nine hundred eleven of this article.

(d-4) "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 four thousand nine hundred four of this title.

(d-5) "Health care plan" means an insurer subject to article thirty-two or forty-three of this chapter, or any organization licensed under article forty-three of this chapter.

(g-1) "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.

(g-2) "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.

(g-3) "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 (1) an external appeal agent to conduct an external appeal pursuant to section four thousand nine hundred fourteen of title two of this article, or (2) a clinical peer reviewer for health services rendered to enrollees.

(g-4) "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.

(g-5) "Medical and scientific evidence" means the following sources:

(1) 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;

(2) 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;

(3) peer-reviewed abstracts accepted for presentation at major medical association meetings;

(4) 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;

(5) medical journals recognized by the secretary of Health and Human Services, under section 1861 (t)(2) of the federal Social Security Act;
(6) the following standard reference compendia:
(A) the American Hospital Formulary Service - Drug Information;
(B) the American Medical Association Drug Evaluation;
(C) the American Dental Association Accepted Dental Therapeutics; and
(D) the United States Pharmacopeia - Drug Information;
(7) 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.

§ 33. Paragraph 2 of subsection (a) of section 4902 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(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;

§ 34. Subparagraph (ii) of paragraph 5 of subsection (a) of section 4902 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(ii) instructions on how to initiate ~~[an appeal]~~ 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; and

§ 34-a. Section 4903 of the insurance law is amended by adding a new subsection (g) to read as follows:

(g) Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section four thousand nine hundred four of this title.

§ 35. Paragraph 2 of subsection (e) of section 4903 of the insurance law, as added by chapter 705 of the laws of 1996, are amended to read as follows:

(2) instructions on how to initiate ~~[an appeal]~~ standard appeals and expedited appeals pursuant to section four thousand nine hundred four and an external appeal pursuant to section four thousand nine hundred fourteen of this article; and

§ 36. Paragraph 2 of subsection (b) of section 4904 of the insurance law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(2) an adverse determination in which the health care provider believes an immediate appeal is warranted except any retrospective determination. Such process shall include mechanisms which facilitate resolution of the appeal including but not limited to the sharing of information from the insured's health care provider and the utilization review agent by telephonic means or by facsimile. The utilization review agent shall provide reasonable access to its clinical peer reviewer within one business day of receiving notice of the taking of an expedited appeal. Expedited appeals ~~[must]~~ shall be determined within two business days of receipt of necessary information to conduct such appeal. Expedited appeals which do not result in a resolution satisfactory to the appealing party may be further appealed through the standard appeal process, or through the external appeal process pursuant to section four thousand nine hundred fourteen of this article as applicable.

§ 37. Subsections (c) and (d) of section 4904 of the insurance law, as added by chapter 705 of the laws of 1996, are amended, and a new subsection (e) is added to read as follows:

(c) A utilization review agent shall establish a standard appeal process which includes procedures for appeals to be filed in writing or by telephone. A utilization review agent must establish a period of no less than forty-five days after receipt of notification by the insured of the initial utilization review determination and receipt of all necessary information to file the appeal from said determination. The utilization review agent must provide written acknowledgment of the filing of the appeal to the appealing party within fifteen days of such filing and shall make a determination with regard to the appeal within sixty days of the receipt of necessary information to conduct the appeal. The utilization review agent shall notify the insured, the insured's designee and, where appropriate, the insured's health care provider, in writing of the appeal determination within two business days of the rendering of such determination.

The notice of the appeal determination shall include:

(1) the reasons for the determination; provided, however, that where the adverse determination is upheld on appeal, the notice shall include the clinical rationale for such determination; and

(2) a notice of the insured's right to an external appeal 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

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appeal process established pursuant to title two of this article and the time frames for such external appeals.

(d) Both expedited and standard appeals shall only be conducted by clinical peer reviewers, provided that any such appeal shall be reviewed by a clinical peer reviewer other than the clinical peer reviewer who rendered the adverse determination.

(e) Failure by the utilization review agent to make a determination within the applicable time periods in this section shall be deemed to be a reversal of the utilization review agent's adverse determination.

§ 38. Provisions for joint certifications and implementation. The commissioner of health and the superintendent of insurance shall jointly certify external review agents pursuant to a memorandum of understanding for the implementation of the provisions of this act, and shall jointly develop guidelines to effectuate the coordination of the activities of the department of health and the state insurance department with regard

to their respective responsibilities pursuant to the provisions of this act.

§ 39. Subsection (i) of section 3216 of the insurance law is amended by adding a new paragraph 22 to read as follows:

(22) No policy shall exclude coverage of a health care service, as defined in paragraph two of subsection (e) of section four thousand nine hundred of this chapter, rendered or proposed to be rendered to an insured on the basis that such service is experimental or investigational, is rendered as part of a clinical trial as defined in subsection (b-2) of section forty-nine hundred of this chapter, or a prescribed pharmaceutical product referenced in subparagraph (B) of paragraph two of subsection (e) of section forty-nine hundred of this chapter provided that coverage of the patient costs of such service has been recommended for the insured by an external appeal agent upon an appeal conducted pursuant to subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter. The determination of the external appeal agent shall be binding on the parties. For purposes of this paragraph, patient costs shall have the same meaning as such term has for purposes of subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter; provided, however, that coverage for the services required under this paragraph shall be provided subject to the terms and conditions generally applicable to other benefits provided under the policy.

§ 40. Subsection (k) of section 3221 of the insurance law is amended by adding a new paragraph 12 to read as follows:

(12) No policy of group or blanket accident and health insurance delivered or issued for delivery in this state shall exclude coverage of a health care service, as defined in paragraph two of such subdivision (e) of section four thousand nine hundred of this chapter, rendered or proposed to be rendered to an insured on the basis that such service is experimental or investigational, is rendered as part of a clinical trial as defined in subsection (b-2) of section forty-nine hundred of this chapter, or a prescribed pharmaceutical product referenced in subparagraph (B) of paragraph two of subsection (e) of section forty-nine hundred of this chapter provided that coverage of the patient costs of

such service has been recommended for the insured by an external appeal agent upon an appeal conducted pursuant to subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter. The determination of the external appeal agent shall be binding on the parties. For purposes of this paragraph, patient costs shall have the same meaning as such term has for purposes of subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter; provided, however, that coverage for the services required under this paragraph shall be provided subject to the terms and conditions generally applicable to other benefits provided under the policy.

§ 41. Section 4303 of the insurance law is amended by adding a new subsection (z) to read as follows:

(z) No contract issued by a medical expense indemnity corporation, a hospital service corporation or a health service corporation shall exclude coverage of a health care service, as defined in paragraph two of subsection (e) of section four thousand nine hundred of this chapter, rendered or proposed to be rendered to an insured on the basis that such

service is experimental or investigational, is rendered as part of a clinical trial as defined in subsection (b-2) of section forty-nine hundred of this chapter, or a prescribed pharmaceutical product referenced in subparagraph (B) of paragraph two of subsection (e) of section forty-nine hundred of this chapter provided that coverage of the patient costs of such service has been recommended for the insured by an external appeal agent upon an appeal conducted pursuant to subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter. The determination of the external appeal agent shall be binding on the parties. For purposes of this paragraph, patient costs shall have the same meaning as such term has for purposes of subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter; provided, however, that coverage for the services required under this subsection shall be provided subject to the terms and conditions generally applicable to other benefits provided under the policy.

§ 41-a. Section 4321 of the insurance law is amended by adding a new subsection (f) to read as follows:

(f) No contract issued pursuant to this section or section four thousand three hundred twenty-two of this article shall exclude coverage of a health care service, as defined in paragraph two of subsection (e) of section four thousand nine hundred of this chapter, rendered or proposed to be rendered to an insured on the basis that such service is experimental or investigational, is rendered as part of a clinical trial as defined in subsection (b-2) of section forty-nine hundred of this chapter, or a prescribed pharmaceutical product referenced in subparagraph (B) of paragraph two of subsection (e) of section forty-nine hundred of this chapter provided that coverage of the patient costs of such service has been recommended for the insured by an external appeal agent upon an appeal conducted pursuant to subparagraph (B) of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter. The determination of the external appeal agent shall be binding on the parties. For purposes of this subsection, patient costs shall have the same meaning as such term has for purposes of subparagraph (B)

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of paragraph four of subsection (b) of section four thousand nine hundred fourteen of this chapter; provided, however, that coverage for the services required under this subsection shall be provided subject to the terms and conditions generally applicable to other benefits provided under the policy.

§ 41-b. Paragraph (a) of subdivision 5 of section 4403 of the public health law, as added by chapter 705 of the laws of 1996, is amended to read as follows:

(a) The commissioner, at the time of initial licensure, at least every three years thereafter, and upon application for expansion of service area, shall ensure that the health maintenance organization maintains a network of health care providers adequate to meet the comprehensive health needs of its enrollees and to provide an appropriate choice of providers sufficient to provide the services covered under its enrollee's contracts by determining that (i) there are a sufficient number of geographically accessible participating providers; (ii) there are opportunities to select from at least three primary care providers pursuant to travel and distance time standards, providing that such standards account for the conditions of accessing providers in rural areas; (iii) there are sufficient providers in each area of specialty

practice to meet the needs of the enrollment population; [and] (iv) there is no exclusion of any appropriately licensed type of provider as a class; and (v) contracts entered into with health care providers neither transfer financial risk to providers, in a manner inconsistent with the provisions of paragraph (c) of subdivision one of this section, nor penalize providers for unfavorable case mix so as to jeopardize the quality of or enrollees' appropriate access to medically necessary services; provided, however, that payment at less than prevailing fee for service rates or capitation shall not be deemed or presumed prima facie to jeopardize quality or access.

§ 41-c. Section 4406-c of the public health law is amended by adding two new subdivisions 5-a and 5-b to read as follows:

5-a. Contracts entered into between a plan and a health care provider shall include terms which prescribe:

(a) the method by which payments to a provider, including any prospective or retrospective adjustments thereto, shall be calculated;

(b) the time periods within which such calculations will be completed, the dates upon which any such payments and adjustments shall be determined to be due, and the dates upon which any such payments and adjustments will be made;

(c) a description of the records or information relied upon to calculate any such payments and adjustments, and a description of how the provider can access a summary of such calculations and adjustments;

(d) the process to be employed to resolved disputed incorrect or incomplete records or information and to adjust any such payments and adjustments which have been calculated by relying on any such incorrect or incomplete records or information and to adjust any such payments and adjustments which have been calculated by relying on any such incorrect

or incomplete records or information so disputed; provided, however, that nothing herein shall be deemed to authorize or require the disclosure of personally identifiable patient information or information related to other individual health care providers or the plan's proprietary data collection systems, software or quality assurance or utilization review methodologies; and

(e) the right of either party to the contract to seek resolution of a dispute arising pursuant to the payment terms of such contract through a proceeding under article seventy-five of the civil practice law and rules.

5-b. No contract entered into with health care providers shall be enforceable if it includes terms which transfer financial risk to providers, in a manner inconsistent with the provisions of paragraph (c) of subdivision one of section forty-four hundred three of this article, or penalize providers for unfavorable case mix so as to jeopardize the quality of or enrollees' appropriate access to medically necessary services; provided, however, that payment at less than prevailing fee for service rates or capitation shall not be deemed or presumed prima facie to jeopardize quality or access.

§ 41-d. Subsection (e) of section 3217-b of the insurance law is relettered subsection (g) and two new subsections (e) and (f) are added to

read as follows:

(e) Contracts entered into between an insurer and a health care provider shall include terms which prescribe:

(1) the method by which payments to a provider, including any prospective or retrospective adjustments thereto, shall be calculated;

(2) the time periods within which such calculations will be completed, the dates upon which any such payments and adjustments shall be determined to be due, and the dates upon which any such payments and adjustments will be made;

(3) a description of the records or information relied upon to calculate any such payments and adjustments, and a description of how the provider can access a summary of such calculations and adjustments;

(4) the process to be employed to resolve disputed incorrect or incomplete records or information and to adjust any such payments and adjustments which have been calculated by relying on any such incorrect or incomplete records or information so disputed; provided, however, that nothing herein shall be deemed to authorize or require the disclosure of personally identifiable patient information or information related to other individual health care providers or the plan's proprietary data collection systems, software or quality assurance or utilization review methodologies; and

(5) the right of either party to the contract to seek resolution of a dispute arising pursuant to the payment terms of such contracts through a proceeding under article seventy-five of the civil practice law and rules.

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(f) No contract entered into between an insurer and a health care provider shall be enforceable if it includes terms which transfer financial risk to providers, in a manner inconsistent with the provisions of paragraph (c) of subdivision one of section forty-four hundred three of the public health law, or penalize providers for unfavorable case mix so as to jeopardize the quality of or insureds' appropriate access to medically necessary services; provided, however, that payment at less than prevailing fee for service rates or capitation shall not be deemed or presumed prima facie to jeopardize quality or access.

§ 41-e. Subsection (e) of section 4325 of the insurance law is relettered subsection (g) and two new subsections (e) and (f) are added to read as follows:

(e) Contracts entered into between an insurer and a health care provider shall include terms which prescribe:

(1) the method by which payments to a provider, including any prospective or retrospective adjustments thereto, shall be calculated;

(2) the time periods within which such calculations will be completed, the dates upon which any such payments and adjustments shall be determined to be due, and the rates upon which any such payments and adjustments will be made;

(3) a description of the records or information relied upon to calculate any such payments and adjustments, and a description of how the provider can access a summary of such calculations and adjustments;

(4) the process to be employed to resolve disputed incorrect or incomplete records or information and to adjust any such payments and adjust-

ments which have been calculated by relying on any such incorrect or incomplete records or information so disputed; provided, however, that nothing herein shall be deemed to authorize or require the disclosure of personally identifiable patient information or information related to other individual health care providers or the plan's proprietary data collection systems, software or quality assurance or utilization review methodologies; and

(5) the right of either party to the contract to seek resolution of a dispute arising pursuant to the payment terms of such contract through a proceeding under article seventy-five of the civil practice law and rules.

(f) No contract entered into between an insurer and a health care provider shall be enforceable if it includes terms which transfer financial risk to providers, in a manner inconsistent with the provisions of paragraph (c) of subdivision one of section forty-four hundred three of the public health law, or penalize providers for unfavorable case mix so as to jeopardize the quality of or insureds' appropriate access to medically necessary services; provided, however, that payment at less than prevailing fee for service rates or capitation shall not be deemed or presumed prima facie to jeopardize quality or access.

§ 42. Nothing in this act shall bar, limit, impair, diminish or affect in any way any rights or remedies in any judicial or other forum pursuant to state or federal law of any enrollee, whether or not eligible to elect external appeal under this act, for coverage of a health service, including but not limited to an experimental or investigational service, a clinical trial treatment, or provision of a pharmaceutical product pursuant to prescription for a use other than those uses for which such pharmaceutical product has been approved for marketing by the federal

Food and Drug Administration. No enrollee may be required to pursue or exhaust external appeal prior to seeking judicial relief.

§ 43. The provisions of this act shall not apply to claims under the workers' compensation law nor shall the provisions of this act be construed to alter, limit, modify, or repeal any provision of such law.

§ 44. If any provision of this act or the application thereof shall be held to be invalid, such invalidity shall not affect other provisions of this act which can be given effect without the invalid provision, and to that end, the provisions of this act are severable.

§ 45. This act shall take effect immediately, provided:

1. Sections one through forty-one-e of this act shall take effect July 1, 1999; provided that:

(a) the commissioner of health and the superintendent of insurance may promulgate regulations prior to such date;

(b) a standard or expedited appeal in progress on the effective date of this act shall be subject to the provisions of law in effect when such an appeal was initiated, provided that any final adverse determination pursuant to such an appeal made after the effective date of this act may be externally appealed pursuant to the provisions of this act;

2. Sections thirty-nine through forty-one-a of this act shall apply to all policies and contracts issued, renewed, modified, altered or amended on or after such date; and

3. Notwithstanding any contrary provisions of sections 3216, 3221, 3231, 4304, 4305 and 4317 of the insurance law, or of any later amendments or successor provision or regulations or rules that implement said sections, an insurer, company, organization or other entity subject to article forty-nine of the public health law or article forty-nine of the insurance law may elect to unilaterally modify the coverage for a policy or contract of hospital, surgical or medical expense insurance, effective April 1, 2000, to comply with the requirements of sections thirty-nine through forty-one-a of this act without regard to the time of coverage renewal and without providing for the termination, non-renewal or discontinuance of said coverage.

The Legislature of the STATE OF NEW YORK ss:

Pursuant to the authority vested in us by section 70-b of the Public Officers Law, we hereby jointly certify that this slip copy of this session law was printed under our direction and, in accordance with such section, is entitled to be read into evidence.

JOSEPH L. BRUNO
Temporary President of the Senate

SHELDON SILVER
Speaker of the Assembly
