AMENDMENTS TO SENATE BILL NO. 225

Sponsor: REPRESENTATIVE PICKETT

Printer's No. 1837

Amend Bill, page 1, lines 11 through 29, by striking out "in quality health care" in line 11 and all of lines 12 through 29 and inserting

in quality health care accountability and protection, further providing for definitions, for responsibilities of managed care plans, for financial incentives prohibition, for medical gag clause prohibition, for emergency services, for continuity of care, for procedures, for confidentiality, for required disclosure and for internal complaint process, providing for internal complaint process for enrollees, further providing for appeal of complaint, for complaint resolution, for certification and for operational standards, providing for utilization review standards, further providing for internal grievance process, for external grievance process and for records, providing for adverse benefit determinations, further providing for prompt payment of claims, for health care provider and managed care plan protection, for departmental powers and duties and for penalties and sanctions, providing for regulations, further providing for compliance with national accrediting standards and for exceptions; making editorial changes; and making repeals.

Amend Bill, page 2, lines 2 through 30; pages 3 through 49, lines 1 through 30; by striking out all of said lines on said pages and inserting

Section 1. Section 2102, Subdivision (b) heading of Article XXI, sections 2111, 2112, 2113, 2116, 2117, 2121 and 2131, Subdivision (f) heading of Article XXI and section 2136 of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, are amended to read:

Section 2102. Definitions.--As used in this article, the following words and phrases shall have the meanings given to them in this section:

"Active clinical practice." The practice of clinical

medicine by a health care provider for an average of not less than twenty (20) hours per week.

"Administrative denial." An adverse benefit determination of prior authorization, coverage or payment based on a lack of eligibility, failure to submit complete information or other failure to comply with an administrative policy. The term does not include an adverse benefit determination based on medical necessity.

"Administrative policy." A written document or collection of documents reflecting the terms of the contractual or operating relationship between an insurer or MA or CHIP managed care plan and a health care provider.

"Adverse benefit determination." An adverse benefit determination may be any of the following:

(1) A determination by an insurer or a utilization review entity on behalf of an insurer that, based upon the information provided and upon application of utilization review, a request for a benefit under a health insurance policy does not meet the insurer's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness or is determined to be experimental or investigational, such that the requested benefit is therefore denied, reduced or terminated or payment is not provided or made, in whole or in part, for the benefit.

(2) The denial, reduction, termination or failure to provide or make payment, in whole or in part, for a benefit based on a determination by an insurer of a person's eligibility for coverage under a health insurance policy or noncompliance with an administrative policy.

(3) A rescission of coverage determination.

"Agreement with the Department of Human Services." A contract between an MA or CHIP managed care plan and the Department of Human Services or primary contractor of the Department of Human Services to manage the purchase and provision of medical, behavioral health or home and community-based services.

"Ancillary service plans." Any individual or group health insurance plan, subscriber contract or certificate that provides exclusive coverage for dental services or vision services. The term also includes Medicare Supplement Policies subject to section 1882 of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1395ss) and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement.

"Applicable governmental guidelines." Clinical practice and associated guidelines issued under the authority of the United States Department of Health and Human Services, United States Food and Drug Administration, Centers for Disease Control and Prevention, Pennsylvania Department of Health or other similarly situated Federal or State agency, department or subunit thereof focused on the provision or regulation of medical care, prescription drugs or public health within the United States.

"Authorized representative." One of the following:

(1) A person, including a health care provider, to whom a covered person or enrollee has given express written consent to represent the covered person or enrollee in a complaint, grievance, adverse benefit determination, internal appeal or external review process.

(2) A person authorized by law to provide substituted consent for a covered person or enrollee.

(3) A family member or treating health care provider involved in providing health care to a covered person or enrollee if the covered person or enrollee is incapacitated or unavailable to provide consent due to a medical emergency or necessary to prevent a serious and imminent threat to the health or safety of the covered person or enrollee.

"Clean claim." A claim for payment for a health care service which has no defect or impropriety. A defect or impropriety shall include lack of required substantiating documentation or a particular circumstance requiring special treatment which prevents timely payment from being made on the claim. The term shall not include a claim from a health care provider who is under investigation for fraud or abuse regarding that claim.

"Clinical review criteria." The set of written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer or MA or CHIP managed care plan to determine the necessity and appropriateness of health care services.

"Closely-related service." A health care service subject to prior authorization that is closely related in purpose, diagnostic utility or designated health care billing code, and provided on the same date of service as an authorized service, such that a prudent health care provider, acting within the scope of the provider's license and expertise, may reasonably be expected to perform the service in conjunction with or in lieu of the originally authorized service in response to minor differences in observed patient characteristics or needs for diagnostic information that were not readily identifiable until the provider was actually performing the originally authorized service. The term does not include an order for or administration of a prescription drug or any part of a series or course of treatments.

"Commissioner." The Insurance Commissioner of the Commonwealth.

"Complaint." A dispute or objection regarding a participating health care provider or the coverage, operations or management policies of [a] an insurer or MA or CHIP managed care plan which has not been resolved by the insurer or MA or CHIP managed care plan and has been filed with the insurer, MA or CHIP managed care plan or [with the Department of Health or the Insurance Department of the Commonwealth] department. The term does not include a grievance or an adverse benefit determination eligible for external review.

"Concurrent [utilization] review." A review [by a utilization review entity] performed by an insurer or MA or CHIP managed care plan, or by a utilization review entity acting on behalf of an insurer or MA or CHIP managed care plan of all reasonably necessary supporting information which occurs during an enrollee's hospital stay or course of treatment and results in a decision to approve or deny payment for the health care service.

"Covered benefit." A health care service as set forth in the terms of a health insurance policy or an agreement with the Department of Human Services. The term includes a covered service.

"Covered person." A policyholder, subscriber or other individual who is entitled to receive health care services under a health insurance policy.

"Covered service." A health care service eligible for payment under the terms of a health insurance policy or an agreement with the Department of Human Services.

"Department." The [Department of Health] Insurance Department of the Commonwealth.

"Discharge planning." The formal process for determining, prior to discharge from a facility, the coordination and management of care that a covered person or enrollee will receive following the discharge.

"Drug formulary." A listing of health insurance policy or MA or CHIP managed care plan preferred therapeutic drugs.

"Emergency service." [Any] A health care service provided to [an] a covered person or enrollee after the sudden onset of a medical condition that manifests itself by acute symptoms of sufficient severity or severe pain such that a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in:

(1) placing the health of the covered person or enrollee in serious jeopardy or, with respect to a pregnant woman, the health of the woman or her unborn child in serious jeopardy;

(2) serious impairment to bodily functions; or

(3) serious dysfunction of any bodily organ or part.

[Emergency transportation and related emergency service provided by a licensed ambulance service shall constitute an emergency service.] The term includes emergency transportation and related emergency services provided by a licensed ambulance service.

"Enrollee." [Any policyholder, subscriber, covered person or other individual] An individual who is entitled to receive health care services under [a managed care plan] an agreement with the Department of Human Services.

"Evidence-based standard." Interventions and treatment approaches that have been proven effective through appropriate empirical analysis.

"Facility." A health care setting or institution providing health care services, including:

(1) A general, special, psychiatric or rehabilitation hospital.
(2) An ambulatory surgical facility.
(3) A cancer treatment center.
(4) A birth center.
(5) A skilled nursing center.
(6) An inpatient, outpatient or residential drug and alcohol treatment facility.
(7) A laboratory, imaging, diagnostic or other outpatient medical service or testing facility.
(8) A health care provider office or clinic.

"Final adverse benefit determination." An adverse benefit determination that has been upheld by an insurer or a utilization review entity designated by the insurer at the completion of the insurer's internal claim and appeal procedures as specified in section 2161.1.

"Grievance." [As provided in subdivision (i), a] A request to an MA or CHIP managed care plan by an enrollee or [a health care provider, with the written consent of the enrollee,] an enrollee's authorized representative to have [a] an MA or CHIP managed care plan [or utilization review entity] reconsider a decision solely concerning the medical necessity [and], appropriateness, health care setting, level of care or effectiveness of a health care service. If the MA or CHIP managed care plan is unable to resolve the matter, a grievance may be filed regarding the decision that:

(1) disapproves full or partial payment for a requested health care service;

(2) approves the provision of a requested health care service for a lesser scope or duration than requested; or

(3) disapproves payment for the provision of a requested health care service but approves payment for the provision of an alternative health care service.

The term does not include a complaint or an adverse benefit determination.

"Health care provider." A licensed hospital or health care facility, medical equipment supplier or person who is licensed, certified or otherwise regulated to provide health care services under the laws of this Commonwealth, including a physician, podiatrist, optometrist, psychologist, physical therapist, certified nurse practitioner, registered nurse, nurse midwife, physician's assistant, chiropractor, dentist, pharmacist or an individual accredited or certified to provide behavioral health services. For MA or CHIP managed care plans, the term shall also refer to an individual providing personal assistance or rehabilitative services.

"Health care service." Any covered treatment, admission, procedure, medical supplies and equipment or other services, including behavioral health, prescribed or otherwise provided or proposed to be provided by a health care provider to [an] a covered person or enrollee [under a managed care plan contract.]

for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury, disease or functional limitation under the terms of either a health insurance policy or an agreement with the Department of Human Services. The term includes home-and-community-based services provided to an enrollee under the terms of an agreement with the Department of Human Services.

"Health insurance policy." A policy, subscriber contract, certificate or plan issued by an insurer that provides medical or health care coverage. The term does not include any of the following:

(1) An accident only policy.

(2) A credit only policy.

(3) A long-term care or disability income policy.

(4) A specified disease policy.

(5) A Medicare supplement policy.

(6) A TRICARE policy, including a Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement policy.

(7) A fixed indemnity policy.

(8) A hospital indemnity policy.

(9) A dental only policy.

(10) A vision only policy.

(11) A workers' compensation policy.

(12) An automobile medical payment policy under 75 Pa.C.S. (relating to vehicles).

(13) A homeowner's insurance policy.

(14) Any other similar policies providing for limited benefits.

"Independent review organization" or "IRO." An entity approved by the department under section 2161.10 that conducts independent reviews of adverse benefit determinations, final adverse benefit determinations and grievances.

"Inpatient admission." Admission to a facility for purposes of receiving a health care service.

"Insurer." An entity licensed by the department that offers, issues or renews an individual or group health insurance policy that is offered or governed under any of the following:

(1) This act, including section 630 and Article XXIV.

(2) The act of December 29, 1972 (P.L.1701, No.364), known as the "Health Maintenance Organization Act."

(3) 40 Pa.C.S. Ch. 61 (relating to health plan corporations) or 63 (relating to professional health services plan corporations).

The term does not include an entity operating as an MA or CHIP managed care plan.

["Managed care plan." A health care plan that uses a gatekeeper to manage the utilization of health care services, integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate on the basis of specific standards and provides

financial incentives for enrollees to use the participating health care providers in accordance with procedures established by the plan. A managed care plan includes health care arranged through an entity operating under any of the following:

(1) Section 630.

(2) The act of December 29, 1972 (P.L.1701, No.364), known as the "Health Maintenance Organization Act."

(3) The act of December 14, 1992 (P.L.835, No.134), known as the "Fraternal Benefit Societies Code."

(4) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

(5) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

The term includes an entity, including a municipality, whether licensed or unlicensed, that contracts with or functions as a managed care plan to provide health care services to enrollees. The term does not include ancillary service plans or an indemnity arrangement which is primarily fee for service.]

"Medical Assistance or Children's Health Insurance Program managed care plan" or "MA or CHIP managed care plan." A health care plan that uses a gatekeeper to manage the utilization of health care services by medical assistance or children's health insurance program enrollees and integrates the financing and delivery of health care services to enrollees by arrangements with health care providers selected to participate.

"Medical policy." A written document adopted, maintained and applied by an insurer or MA or CHIP managed care plan that combines the clinical review criteria and any additional administrative requirements, as applicable, necessary to articulate the insurer's or MA or CHIP managed care plan's standards for coverage of a given health care service or set of health care services under the terms of a health insurance policy or an agreement with the Department of Human Services.

"Medical or scientific evidence." Evidence found in any of the following sources:

(1) A peer-reviewed scientific study published in or accepted for publication by a medical journal that meets nationally recognized requirements for scientific manuscripts and which journal submits most of its published articles for review by experts who are not part of the journal's editorial staff.

(2) Peer-reviewed medical literature, including literature relating to a therapy reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Limited for indexing in Excerpta Medica (EMBASE).

(3) A medical journal recognized by the Secretary of Health and Human Services under section 1861(t)(2) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1395x(t)(2)).

(4) One of the following standard reference compendia:
(i) The American Hospital Formulary Service-Drug Information.
(ii) DRUGDEX Information System.
(iii) The American Dental Association Accepted Dental Therapeutics.
(iv) The United States Pharmacopoeia-Drug Information.
(5) Findings, studies or research conducted by or under the auspices of a United States government agency or nationally recognized Federal research institute, including:
(i) The United States Agency for Healthcare Research and Quality.
(ii) The National Institutes of Health.
(iii) The National Cancer Institute.
(iv) The National Academy of Sciences.
(v) The United States Department of Health and Human Services.
(vi) The Food and Drug Administration.
(vii) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services.
(6) Other medical or scientific evidence that is comparable to the sources specified in paragraphs (1), (2), (3), (4) and (5).
"Medication assisted treatment." United States Food and Drug Administration-approved prescription drugs used in combination with counseling and behavioral health therapies and management in the treatment of opioid use disorders.
"NAIC." The National Association of Insurance Commissioners.
"Nationally recognized medical standards." Clinical criteria, practice guidelines and related standards established by national quality and accreditation entities generally recognized in the United States health care industry.
"Participating health care provider." A health care provider that has entered into a contractual or operating relationship with an insurer or MA or CHIP managed care plan to participate in one or more designated networks of the insurer and to provide health care services to covered persons or enrollees under the terms of the insurer's administrative policy or an agreement with the Department of Human Services.
["Plan." A managed care plan.]
"Prescription drug." A drug or biological product, as both of those terms are defined in the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law.
"Primary care provider." A health care provider who, within the scope of the provider's practice, supervises, coordinates, prescribes or otherwise provides or proposes to provide health care services to [an] a covered person or enrollee, initiates [enrollee] a referral for specialist care and maintains continuity of [enrollee] care for the covered person or

enrollee.

"Primary contractor." A county, consortium of counties, MA or CHIP managed care plan or other entity that has an agreement with the Department of Human Services to manage the purchase and provision of behavior health services.

"Prior authorization." A prospective utilization review performed by an insurer or MA or CHIP managed care plan, or by a utilization review entity acting on behalf of an insurer or MA or CHIP managed care plan, of all reasonably necessary supporting information that occurs prior to the delivery or provision of a health care service and results in a decision to approve or deny payment for the health care service. The term includes step therapy and step therapy exception requests.

"Prior authorization request." A request for prior authorization of a health care service that meets an insurer's or MA or CHIP managed care plan's administrative policy requirements for such a request and includes the specific clinical information necessary to evaluate the request under the terms of the applicable medical policy.

["Prospective utilization review." A review by a utilization review entity of all reasonably necessary supporting information that occurs prior to the delivery or provision of a health care service and results in a decision to approve or deny payment for the health care service.]

"Protected health information." Information or data, whether oral or recorded in any form or medium, and personal facts or information about events or relationships that identifies an individual who is the subject of the information or for which there is a reasonable basis to believe that the information could be used to identify an individual, that relates to any of the following:

(1) The past, present, or future physical, mental or behavioral health or condition of an individual or a member of the individual's family.

(2) The provision of health care services to an individual.

(3) payment for the provision of health care services to an individual.

"Provider network." The health care providers designated by [a] an insurer or MA or CHIP managed care plan to provide health care services under a health insurance policy or an agreement with the Department of Human Services.

"Provider portal." A designated section or functional software module accessible via an insurer's or MA or CHIP managed care plan's publicly accessible Internet website that facilitates health care provider submission of electronic prior authorization requests.

"Referral." A prior authorization from [a] an insurer, MA or CHIP managed care plan or a participating health care provider that allows [an] a covered person or enrollee to have one or more appointments with a health care provider for a health care service.

"Retrospective utilization review." [A review by a utilization review entity of all reasonably necessary supporting information which occurs following delivery or provision of a health care service and results in a decision to approve or deny payment for the health care service.] Review of medical necessity performed by an insurer or MA or CHIP managed care plan, or by a utilization review entity acting on behalf of an insurer or MA or CHIP managed care plan and conducted after health care services have been provided to a covered person or enrollee, not including the review of a claim that is limited to an evaluation of the reimbursement levels, veracity of documentation, accuracy of coding or adjustment for payment.

"Service area." The geographic area for which [the] an insurer or MA or CHIP managed care plan is licensed or has been issued a certificate of authority.

"Specialist." A health care provider whose practice is not limited to primary health care services and who has additional postgraduate or specialized training, has board certification or practices in a licensed specialized area of health care. The term includes a health care provider who is not classified by [a] an insurer or MA or CHIP managed care plan solely as a primary care provider.

"Step therapy." A course of treatment in which certain designated drugs or treatment protocols must be either contraindicated, or used and found to be ineffective, prior to approval of coverage of other designated drugs or treatment protocols. The term does not include requests for coverage of nonformulary drugs.

"Urgent health care service." A covered health care service subject to prior authorization that is delivered on an expedited basis for the treatment of an acute condition with symptoms of sufficient severity pursuant to a determination by a licensed treating physician, operating with the individual's scope of practice and professional expertise, that the failure to provide the service is likely to result in serious, long-term health complications or a material deterioration in the covered person's or enrollee's condition and prognosis.

"Urgent request." A request for prior authorization of an urgent healthcare service.

"Utilization review." [A system of prospective, concurrent or retrospective utilization review performed by a utilization review entity of the medical necessity and appropriateness of health care services prescribed, provided or proposed to be provided to an enrollee. The term does not include any of the following:

(1) Requests for clarification of coverage, eligibility or health care service verification.

(2) A health care provider's internal quality assurance or utilization review process unless the review results in denial of payment for a health care service.] A set of formal techniques designed to monitor the use of or evaluate the

medical necessity, appropriateness, efficacy or efficiency of health care services, procedures or settings, including prior authorization, second opinion, certification, concurrent review, case management, discharge planning or retrospective review, in order to make a determination regarding coverage of the service under the terms of a health insurance policy or an agreement with the Department of Human Services.

"Utilization review entity." Any entity certified pursuant to subdivision (h) that performs utilization review on behalf of [a] an insurer or MA or CHIP managed care plan.

(b) Insurer and MA and CHIP Managed Care Plan Requirements.

Section 2111. Responsibilities of Insurers and MA and CHIP Managed Care Plans.--[A] An insurer or MA or CHIP managed care plan shall do all of the following:

(1) Assure availability and accessibility of adequate health care providers in a timely manner, which enables covered persons or enrollees to have access to quality care and continuity of health care services.

(2) Consult with health care providers in active clinical practice regarding professional qualifications and necessary specialists to be included in [the plan.] coverage under a health insurance policy or an agreement with the Department of Human Services.

(3) Adopt and maintain a definition of medical necessity used by [the] an insurer or MA or CHIP managed care plan in determining health care services.

(4) Ensure that emergency services are provided twenty-four (24) hours a day, seven (7) days a week and provide reasonable payment or reimbursement for emergency services.

(5) Adopt and maintain procedures by which [an] a covered person or enrollee can obtain health care services outside the health insurance policy's or MA or CHIP managed care plan's service area.

(6) Adopt and maintain procedures by which [an] a covered person or enrollee with a life-threatening, degenerative or disabling disease or condition shall, upon request, receive an evaluation and, if the health insurance policy's [plan's] established standards are met or the standards established by an agreement with the Department of Human Services, be permitted to receive:

(i) a standing referral to a specialist with clinical expertise in treating the disease or condition; or

(ii) the designation of a specialist to provide and coordinate the covered person's or enrollee's primary and specialty care.

The referral to or designation of a specialist shall be pursuant to a treatment plan approved by the insurer or MA or CHIP managed care plan in consultation with the primary care provider, the covered person or enrollee and, as appropriate, the specialist. When possible, the specialist must be a health

care provider participating in the [plan.] health insurance policy or MA or CHIP managed care plan's provider network.

(7) Provide direct access to obstetrical and gynecological services by permitting [an] a covered person or enrollee to select a health care provider participating in the [plan] health insurance policy or MA or CHIP managed care plan's provider network to obtain maternity and gynecological care, including medically necessary and appropriate follow-up care and referrals for diagnostic testing related to maternity and gynecological care, without prior approval from a primary care provider. The health care services shall be within the scope of practice of the selected health care provider. The selected health care provider shall inform the covered person's or enrollee's primary care provider of all health care services provided.

(8) Adopt and maintain a complaint process as set forth in subdivision (g).

(9) Adopt and maintain a grievance process as set forth in subdivision (i).

(10) Adopt and maintain credentialing standards for health care providers as set forth in subdivision (d).

(11) Ensure that there are participating health care providers that are physically accessible to people with disabilities and can communicate with individuals with sensory disabilities in accordance with Title III of the Americans with Disabilities Act of 1990 (Public Law 101-336, 42 U.S.C. § 12181 et seq.).

(12) Provide a list of health care providers participating in the [plan] health insurance policy or MA or CHIP managed care plan's provider network to the department every two (2) years or as may otherwise be required by the department. The list shall include the extent to which health care providers in the [plan] health insurance policy or MA or CHIP managed care plan's provider network are accepting new enrollees.

(13) Report to the department [and the Insurance Department] in accordance with the requirements of this article. Such information shall include the number, type and disposition of all complaints [and], grievances [filed with the plan.] and adverse benefit determinations filed with the insurer under a health insurance policy or with the MA or CHIP managed care plan, as applicable.

Section 2112. Financial Incentives Prohibition.--No insurer or MA or CHIP managed care plan [shall] may use any financial incentive that compensates a health care provider for providing less than medically necessary and appropriate care to [an] a covered person or enrollee. Nothing in this section shall be deemed to prohibit [a] an insurer or MA or CHIP managed care plan from using a capitated payment arrangement or other risk-sharing arrangement.

Section 2113. Medical Gag Clause Prohibition.--(a) No insurer or MA or CHIP managed care plan may penalize or restrict a health care provider from discussing any of the following:

(1) [the] The process that the insurer or MA or CHIP managed care plan or any entity contracting with the insurer or MA or CHIP managed care plan uses or proposes to use to deny payment for a health care service[;].

(2) [medically] Medically necessary and appropriate care with or on behalf of [an] a covered person or enrollee, including information regarding the nature of treatment; risks of treatment; alternative treatments; or the availability of alternate therapies, consultation or tests[; or].

(3) [the] The decision of [any] an insurer or MA or CHIP managed care plan to deny payment for a health care service.

(b) A provision to prohibit or restrict disclosure of medically necessary and appropriate health care information contained in a contract with a health care provider is contrary to public policy and shall be void and unenforceable.

(c) No insurer or MA or CHIP managed care plan [shall] may terminate the employment of or a contract with a health care provider for any of the following:

(1) Advocating for medically necessary and appropriate health care consistent with the degree of learning and skill ordinarily possessed by a reputable health care provider practicing according to the applicable legal standard of care.

(2) Filing a complaint, grievance or external review pursuant to the procedures set forth in this article.

(3) Protesting a decision, policy or practice that the health care provider, consistent with the degree of learning and skill ordinarily possessed by a reputable health care provider practicing according to the applicable legal standard of care, reasonably believes interferes with the health care provider's ability to provide medically necessary and appropriate health care.

(d) Nothing in this section shall:

(1) Prohibit [a] an insurer or MA or CHIP managed care plan from making a determination not to pay for a particular medical treatment, supply or service, enforcing reasonable peer review or utilization review protocols or making a determination that a health care provider has or has not complied with appropriate protocols.

(2) Be construed as requiring [a] an insurer or MA or CHIP managed care plan to provide, reimburse for or cover counseling, referral or other health care services if the insurer or MA or CHIP managed care plan:

(i) objects to the provision of that service on moral or religious grounds; and

(ii) makes available information on its policies regarding such health care services to covered person or enrollees and prospective covered person or enrollees.

Section 2116. Emergency Services.--(a) If [an] a covered person or enrollee seeks emergency services and the emergency health care provider determines that emergency services are necessary, the emergency health care provider shall initiate

necessary intervention to evaluate and, if necessary, stabilize the condition of the covered person or enrollee without seeking or receiving authorization from the insurer or MA or CHIP managed care plan. The insurer or MA or CHIP managed care plan may not require a health care provider to submit a request for prior authorization for an emergency service. The insurer or MA or CHIP managed care plan shall pay all reasonably necessary costs associated with emergency services provided during the period of emergency, subject to all copayments, coinsurances or deductibles. When processing a reimbursement claim for emergency services, [a] an insurer or MA or CHIP managed care plan shall consider both the presenting symptoms and the services provided.

(a.1) The emergency health care provider shall notify the covered person's insurer or enrollee's MA or CHIP managed care plan of the provision of emergency services and the condition of the covered person or enrollee.

(1) The health care provider shall notify a covered person's insurer of the provision of emergency services and the condition of the covered person within two business days following the period of emergency.

(2) The health care provider shall notify the enrollee's MA or CHIP managed care plan of the provision of emergency services and the condition of the enrollee within ten days following the period of emergency.

(a.2) If [an] a covered person's or enrollee's condition has stabilized and the covered person or enrollee can be transported without suffering detrimental consequences or aggravating the covered person's or enrollee's condition, the covered person or enrollee may be relocated to another facility to receive continued care and treatment as necessary.

(b) For emergency services rendered by a licensed emergency medical services agency, as defined in 35 Pa.C.S. § 8103 (relating to definitions), that has the ability to transport patients or is providing and billing for emergency services under an agreement with an emergency medical services agency that has that ability, the insurer or MA or CHIP managed care plan may not deny a claim for payment solely because the enrollee did not require transport or refused to be transported.

(c) For emergency services provided to [medical assistance participants] MA or CHIP managed care plan enrollees, the following provisions shall apply:

(1) The provisions of subsection (b) shall apply to the same services provided to medical assistance participants under Article IV of the act of June 13, 1967 (P.L.31, No.21), known as the Human Services Code.

(2) Payment for the services shall be in accordance with the current MA or CHIP managed care contracted rates.

(3) Sufficient funds shall be appropriated each fiscal year for payment of the services.

[(d) The provisions of subsection (b) shall apply to all group and individual major medical health insurance policies

issued by a licensed health insurer.]

Section 2117. Continuity of Care.--(a) Except as provided under subsection (b), if [a] an insurer or MA or CHIP managed care plan initiates termination of its contract with a participating health care provider, [an] a covered person or enrollee may continue an ongoing course of treatment with that health care provider at the covered person's or enrollee's option for a transitional period of up to sixty (60) days from the date the covered person or enrollee was notified by the insurer or MA or CHIP managed care plan of the termination or pending termination. The insurer or MA or CHIP managed care plan, in consultation with the covered person or enrollee and the health care provider, may extend the transitional period if determined to be clinically appropriate. In the case of [an] a covered person or enrollee in the second or third trimester of pregnancy at the time of notice of the termination or pending termination, the transitional period shall extend through postpartum care related to the delivery. Any health care service provided under this section shall be covered by the insurer or MA or CHIP managed care plan under the same terms and conditions as applicable for participating health care providers.

(b) If [the] an insurer or MA or CHIP managed care plan terminates the contract of a participating health care provider for cause, including breach of contract, fraud, criminal activity or posing a danger to [an] a covered person or enrollee or the health, safety or welfare of the public as determined by the insurer or MA or CHIP managed care plan, the insurer or MA or CHIP managed care plan shall not be responsible for health care services provided to the covered person or enrollee following the date of termination.

(c) If [the] an insurer or MA or CHIP managed care plan terminates the contract of a participating primary care provider, the insurer or MA or CHIP managed care plan shall notify every covered person or enrollee served by that provider of the insurer's or MA or CHIP managed care plan's termination of its contract and shall request that the covered person or enrollee select another primary care provider.

(d) A new covered person or enrollee may continue an ongoing course of treatment with a nonparticipating health care provider for a transitional period of up to sixty (60) days from the effective date of enrollment in a health insurance policy or MA or CHIP managed care plan. The insurer or MA or CHIP managed care plan, in consultation with the covered person or enrollee and the health care provider, may extend this transitional period if determined to be clinically appropriate. In the case of a new covered person or enrollee in the second or third trimester of pregnancy on the effective date of enrollment, the transitional period shall extend through postpartum care related to the delivery. Any health care service provided under this section shall be covered by the health insurance policy or MA or CHIP managed care plan under the same terms and conditions as

applicable for participating health care providers.

(e) [A] An insurer or MA or CHIP managed care plan may require a nonparticipating health care provider whose health care services are covered under this section to meet the same terms and conditions as a participating health care provider.

(f) Nothing in this section shall require [a] an insurer or MA or CHIP managed care plan to provide health care services that are not otherwise covered under the terms and conditions of the [plan] covered person's health insurance policy or an agreement with the Department of Human Services.

Section 2121. Credentialing Procedures.--(a) [A] An insurer or MA or CHIP managed care plan shall establish a credentialing process to enroll qualified health care providers and create an adequate provider network. [The process shall be approved by the department and shall include written criteria and procedures for initial enrollment, renewal, restrictions and termination of credentials for health care providers.]

(a.1) An insurer's or MA or CHIP managed care plan's credentialing process shall be subject to approval by the department and shall include written criteria and procedures for at least the following:

(1) Initial credentialing.

(2) Renewal of credentialing.

(3) Restricting and terminating the credentials for health care providers.

(b) The department shall establish credentialing standards for insurers and MA or CHIP managed care plans. The department may adopt nationally recognized accrediting standards to establish the credentialing standards for insurers and MA or CHIP managed care plans.

(c) [A] An insurer or MA or CHIP managed care plan shall submit a report to the department regarding its credentialing process at least every two (2) years or as may otherwise be required by the department.

(d) [A] An insurer or MA or CHIP managed care plan shall disclose relevant credentialing criteria and procedures to health care providers that apply to participate or that are participating in the insurer's or managed care plan's provider network. [A] An insurer or MA or CHIP managed care plan shall also disclose relevant credentialing criteria and procedures pursuant to a court order or rule. Any individual providing information during the credentialing process of [a] an insurer or MA or CHIP managed care plan shall have the protections set forth in the act of July 20, 1974 (P.L.564, No.193), known as the "Peer Review Protection Act."

(e) No insurer or MA or CHIP managed care plan [shall] may exclude or terminate a health care provider from participation in the [plan] insurer's or MA or CHIP managed care plan's provider network due to any of the following:

(1) The health care provider engaged in any of the activities set forth in section 2113(c).

(2) The health care provider has a practice that includes a substantial number of patients with expensive medical conditions.

(3) The health care provider objects to the provision of or refuses to provide a health care service on moral or religious grounds.

(f) If [a] an insurer or MA or CHIP managed care plan denies enrollment or renewal of credentials to a health care provider, the insurer or MA or CHIP managed care plan shall provide the health care provider with written notice of the decision. The notice shall include a clear rationale for the decision.

Section 2131. Confidentiality.--(a) [A] An insurer or MA or CHIP managed care plan [and a utilization review entity] shall adopt and maintain procedures to ensure that all [identifiable] protected health information regarding covered person or enrollee health, diagnosis and treatment is adequately protected and remains confidential in compliance with all applicable Federal and State laws and regulations and professional ethical standards.

(b) To the extent [a] an insurer or MA or CHIP managed care plan maintains medical records, the insurer or MA or CHIP managed care plan shall adopt and maintain procedures to ensure that covered persons and enrollees have timely access to their medical records, including medical records provided by a health care provider in the context of utilization review or a complaint, grievance or adverse benefit determination, unless prohibited by Federal or State law or regulation.

(c) (1) Information regarding [an] a covered person's or enrollee's health or treatment shall be available to the covered person or enrollee, the covered person's or enrollee's [designee] authorized representative or as necessary to prevent death or serious injury.

(2) Nothing in this section shall:

(i) Prevent disclosure necessary to determine coverage, review complaints [or], grievances or adverse benefit determinations, conduct utilization review or facilitate payment of a claim.

(ii) Deny the department[, the Insurance Department] or the Department of [Public Welfare] Human Services access to records for purposes of quality assurance, investigation of complaints [or], grievances or adverse benefit determinations, enforcement or other activities related to compliance with this article and other laws of this Commonwealth. Records shall be accessible only to department employes or agents with direct responsibilities under the provisions of this subparagraph.

(iii) Deny access to information necessary for a utilization review entity to conduct a review under this article.

(iv) Deny access to the insurer or MA or CHIP managed care plan for internal quality review, including reviews conducted as part of the insurer's or MA or CHIP managed care plan's quality oversight process. During such reviews, covered persons and

enrollees shall remain anonymous to the greatest extent possible.

(v) Deny access to insurers or MA or CHIP managed care plans, health care providers and their respective designees for the purpose of providing patient care management, outcomes improvement and research. For this purpose, covered persons and enrollees shall provide consent and shall remain anonymous to the greatest extent possible.

(f) Information for Covered Persons and Enrollees.

Section 2136. Required Disclosure.--(a) [A] An insurer or MA or CHIP managed care plan shall supply each covered person or enrollee and, upon written request, each prospective covered person or enrollee or health care provider with the following written information. Such information shall be easily understandable by the layperson and shall include, but not be limited to:

(1) A description of coverage, benefits and benefit maximums, including benefit limitations and exclusions of coverage, health care services and the definition of medical necessity used by the insurer or MA or CHIP managed care plan in determining whether these benefits will be covered. The following statement or substantially similar statement shall be included in all marketing materials in boldface type:

> For Insurers: This [managed care plan] health insurance policy may not cover all your health care expenses. Read your contract or member handbook carefully to determine which health care services are covered.
>
> For MA or CHIP managed care plans: Your managed care plan may not cover all your health care expenses. Read your member handbook carefully to determine which health care services are covered.

The notice shall be followed by a telephone number to contact the insurer or MA or CHIP managed care plan.

(2) A description of all necessary prior authorizations or other requirements for nonemergency health care services as required by section 2155.

(3) An explanation of [an] a covered person's or enrollee's financial responsibility for payment of premiums, coinsurance, copayments, deductibles and other charges, annual limits on [an] a covered person's or enrollee's financial responsibility and caps on payments for health care services provided under the [plan] health insurance policy or an agreement with the Department of Human Services.

(4) An explanation of [an] a covered person's or enrollee's financial responsibility for payment when a health care service is provided by a nonparticipating health care provider, when a health care service is provided by any health care provider without required authorization or when the care rendered is not covered [by the plan] under the health insurance policy or by an agreement with the Department of Human Services.

(5) A description of how the insurer or MA or CHIP managed care plan addresses the needs of non-English-speaking covered persons or enrollees.

(6) A notice of mailing addresses and telephone numbers necessary to enable [an] a covered person or enrollee to obtain approval or authorization of a health care service or other information regarding the health insurance policy or services covered by the MA or CHIP managed care plan.

(7) A summary of the insurer's or MA or CHIP managed care plan's utilization review policies and procedures.

(8) A summary of all complaint [and], grievance or adverse benefit determination procedures used to resolve disputes between the insurer or MA or CHIP managed care plan and [an] a covered person or enrollee or a health care provider, including:

(i) The procedure to file a complaint [or], grievance or adverse benefit determination appeal as set forth in this article, including a toll-free telephone number to obtain information regarding the filing and status of a complaint [or], grievance or adverse benefit determination.

(ii) The right to appeal a decision relating to a complaint [or], grievance or adverse benefit determination.

(iii) The covered person's or enrollee's right to designate a representative to participate in the complaint [or], grievance or adverse benefit determination process as set forth in this article.

(iv) A notice that all [disputes] decisions involving denial of payment for a health care service will be made by qualified personnel with experience in the same or similar scope of practice and that all notices of decisions will include information regarding the basis for the determination.

(9) A description of the procedure for providing emergency services twenty-four (24) hours a day. The description shall include:

(i) A definition of emergency services as set forth in this article.

(ii) Notice that emergency services are not subject to prior approval.

(iii) The covered person's or enrollee's financial and other responsibilities regarding emergency services, including the receipt of these services outside the insurer's or MA or CHIP managed care plan's service area.

(10) A description of the procedures for covered persons or enrollees to select a participating health care provider, including how to determine whether a participating health care provider is accepting new [enrollees] patients.

(11) A description of the procedures for changing primary care providers and specialists.

(12) A description of the procedures by which [an] a covered person or enrollee may obtain a referral to a health care provider outside the health insurance policy's or MA or CHIP managed care plan's provider network when that provider network

does not include a health care provider with appropriate training and experience to meet the health care service needs of [an] a covered person or enrollee.

(13) A description of the procedures that [an] a covered person or enrollee with a life-threatening, degenerative or disabling disease or condition shall follow and satisfy to be eligible for either of the following:

(i) [a] A standing referral to a specialist with clinical expertise in treating the disease or condition[; or].

(ii) [the] The designation of a specialist to provide and coordinate the covered person's or enrollee's primary and specialty care.

(14) A list by specialty of the name, address and telephone number of all [participating] health care providers participating in the provider network for the health insurance policy or MA or CHIP managed care plan. The list may be a separate document and shall be updated at least [annually.] once every 90 days or more frequently as may be required by Federal or State law, including section 2799A-5 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 201 et seq.)

(15) A list of the information available to covered persons or enrollees or prospective covered persons or enrollees, upon written request, under subsection (b).

(b) Each insurer or MA or CHIP managed care plan shall, upon written request of [an] a covered person or enrollee or prospective covered person or enrollee, provide the following written information:

(1) A list of the names, business addresses and official positions of the membership of the board of directors or officers of the insurer or MA or CHIP managed care plan.

(2) The procedures adopted to protect the confidentiality of medical records and other covered person or enrollee information.

(3) A description of the credentialing process for health care providers.

(4) A list of the participating health care providers affiliated with participating hospitals.

(5) Whether a specifically identified drug is included or excluded from coverage.

(6) A description of the process by which a health care provider can prescribe specific drugs, drugs used for an off-label purpose, biologicals and medications not included in the drug formulary for prescription drugs [or biologicals] when the formulary's equivalent has been ineffective in the treatment of the covered person's or enrollee's disease or if the drug causes or is reasonably expected to cause adverse or harmful reactions to the covered person or enrollee.

(7) A description of the procedures followed by the insurer or MA or CHIP managed care plan to make decisions about the experimental nature of individual drugs, medical devices or treatments.

(8) A summary of the methodologies used by the insurer or MA or CHIP managed care plan to reimburse for health care services. Nothing in this paragraph shall be construed to require disclosure of individual contracts or the specific details of any financial arrangement between [a] an insurer or MA or CHIP managed care plan and a health care provider.

(9) A description of the procedures used in the insurer's or MA or CHIP managed care plan's quality assurance program.

(10) Other information as may be required by the department or the Insurance Department.

(c) (1) An insurer shall include a description of the insurer's external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage the insurer provides to covered persons, including whether the insurer has complied with the surprise billing and cost-sharing protections under the No Surprises Act (Pub. L. 116-260, Div. BB, Title I, 134 Stat. 2758).

(2) The disclosure required by paragraph (1) shall be in a format as prescribed by the department.

(3) The description of procedures required under subsection (a) shall include:

(i) A statement that informs the covered person of the right to file a request for external review of an adverse benefit determination or final adverse benefit determination, including whether the insurer has complied with the surprise billing and cost sharing protections under the No Surprise Act.

(ii) The telephone number and address of the department.

(iii) A statement that, when filing a request for an external review, the covered person is required to authorize the release of medical records of the covered person that may be required to be reviewed for the purpose of reaching a decision on the external review.

(iv) An explanation that external review is available when the adverse benefit determination or final adverse benefit determination involves an issue of medical necessity, appropriateness, health care setting, level of care or effectiveness.

Section 2. Section 2141 of the act is amended to read:

Section 2141. Internal Complaint Process for Covered Persons.--(a) [A managed care plan] An insurer shall establish and maintain an internal complaint process with two levels of review by which [an enrollee] a covered person or the covered person's authorized representative shall be able to file a complaint [regarding a participating health care provider or the coverage, operations or management policies of the managed care plan].

(b) The complaint process shall consist of an initial review to include all of the following:

(1) A review by an initial review committee consisting of one or more employes of the [managed care plan] insurer.

(2) The allowance of a written or oral complaint.
(3) The allowance of written data or other information.
(4) A review or investigation of the complaint which shall be completed within thirty (30) days of receipt of the complaint.
(5) A written notification to the [enrollee] covered person regarding the decision of the initial review committee within five (5) business days of the decision. Notice shall include the basis for the decision and the procedure to file a request for a second level review of the decision of the initial review committee.
(c) The complaint process shall include a second level review that includes all of the following:
(1) A review of the decision of the initial review committee by a second level review committee consisting of three or more individuals who did not participate in the initial review. At least one third of the second level review committee shall not be employed by the [managed care plan] insurer.
(2) A written notification to the [enrollee] covered person of the right to appear before the second level review committee.
(3) A requirement that the second level review be completed within forty-five (45) days of receipt of a request for such review.
(4) A written notification to the [enrollee] covered person regarding the decision of the second level review committee within five (5) business days of the decision. The notice shall include the basis for the decision and the procedure for appealing the decision to the department [or the Insurance Department].
Section 3. The act is amended by adding a section to read:
Section 2141.1. Internal Complaint Process for Enrollees.--
(a) An MA or CHIP managed care plan shall establish and maintain an internal complaint process by which an enrollee or the enrollee's authorized representative shall be able to file a complaint.
(b) The complaint process shall consist of a review to include all of the following:
(1) A review by a review committee consisting of one or more employes of the MA or CHIP managed care plan.
(2) The allowance of a written or oral complaint.
(3) The allowance of written data or other information.
(4) Written notification to the enrollee of the decision of the review committee within thirty (30) days of receipt of the complaint, unless the time frame for deciding the complaint has been extended by up to fourteen (14) days at the request of the enrollee.
(5) The written notification of the decision shall include the basis for the decision and the procedure to file a request for a second level review of the decision of the review committee, except as provided in paragraph (6).
(6) The written notification of the decision shall include

the basis for the decision and the procedure to file an appeal of a complaint if the complaint is about one of the following:

(i) A denial because the service or item is not a covered service.

(ii) The failure of the MA or CHIP managed care plan to meet the required time frames for providing a service or item in a timely manner.

(iii) The failure of the MA or CHIP managed care plan to decide a complaint or grievance within the required time frames.

(iv) A denial of payment by the MA or CHIP managed care plan after the service or item has been delivered because the service or item was provided by a health care provider not enrolled in the medical assistance program.

(v) A denial of payment by the MA or CHIP managed care plan after the service or item has been delivered because the service or item provided is not a covered service or item for the enrollee.

(vi) A denial of an enrollee's request to dispute a financial liability.

(c) For all complaints except complaints listed in subsection (b)(6), the complaint process shall include a second level review that includes all of the following:

(1) A review of the decision of the review committee by a second level review committee consisting of three or more individuals who did not participate in the initial review. At least one-third of the second level review committee shall not be employed by the MA or CHIP managed care plan.

(2) A written notification to the enrollee of the right to appear before the second level review committee.

(3) A written notification to the enrollee of the decision of the second level review committee within forty-five (45) days of receipt of the second level complaint, which shall include the basis for the decision and the procedure for appealing the decision to the department.

Section 4. Sections 2142 and 2143, Subdivision (h) heading of Article XXI and sections 2151 and 2152 of the act are amended to read:

Section 2142. Appeal of Complaint or Administrative Adverse Benefit Determination.--[(a) An enrollee shall have fifteen (15) days from receipt of the notice of the decision from the second level review committee to appeal the decision to the department or the Insurance Department, as appropriate.

(b) All records from the initial review and second level review shall be transmitted to the appropriate department in the manner prescribed. The enrollee, the health care provider or the managed care plan may submit additional materials related to the complaint.]

(a) The following shall apply:

(1) A covered person may appeal a decision about the coverage, operations or management policies of an insurer, other than decisions that are adverse benefit determinations.

(2) An enrollee or the enrollee's authorized representative shall have fifteen (15) days from receipt of the notice of decision to appeal the decision to the department if the subject of the complaint is listed in section 2141.1(b)(6).

(3) A covered person or enrollee, or covered person's or enrollee's authorized representative, shall have fifteen (15) days from receipt of the notice of the decision from the second level review committee to appeal the decision to the department.

(4) All records from the review shall be transmitted to the department in the manner prescribed. The covered person, enrollee, health care provider or insurer or MA or CHIP managed care plan may submit additional materials related to the complaint.

(b) (1) A covered person shall have fifteen (15) days from receipt of the notice of a decision on an administrative adverse benefit determination conducted under section 2161.1 to appeal the decision to the department.

(2) All records from the internal claim and appeal procedure shall be transmitted to the department in the manner prescribed. The covered person, health care provider or insurer may submit additional materials related to the administrative adverse benefit determination.

(c) The covered person or enrollee may be represented by an attorney or other individual before the appropriate department.

(d) The [appropriate] department shall determine whether a violation of this article has occurred and may impose any penalties authorized by this article.

Section 2143. Complaint or Administrative Adverse Benefit Determination Resolution.--Nothing in this subdivision shall prevent the department [or the Insurance Department] from communicating with the covered person or enrollee[,] or the health care provider [or the], insurer or MA or CHIP managed care plan as appropriate to assist in the resolution of a complaint or administrative adverse benefit determination. Such communication may occur at any time during the [complaint] process.

(h) Utilization Review Entity Standards.

Section 2151. Certification.--(a) A utilization review entity may not review health care services delivered or proposed to be delivered in this Commonwealth unless the entity is certified by the department to perform utilization review. [A utilization review entity operating in this Commonwealth on or before the effective date of this article shall have one year from the effective date of this article to apply for certification.]

(b) The department [shall] may grant certification to a utilization review entity that meets the requirements of this section. Certification shall be renewed every three years unless otherwise subject to additional review, suspension or revocation by the department.

(c) The department may adopt a nationally recognized

accrediting body's standards to certify utilization review entities to the extent the standards meet or exceed the standards set forth in this article.

(d) The department may prescribe application and renewal fees for certification. The fees shall reflect the administrative costs of certification [and shall be deposited in the General Fund].

(e) [A licensed insurer or a] An insurer or MA or CHIP managed care plan with a certificate of authority shall comply with the standards and procedures of this subdivision but shall not be required to obtain separate certification as a utilization review entity.

Section 2152. Operational Standards.--(a) A utilization review entity shall do all of the following:

(1) Respond to inquiries relating to utilization review determinations by:

(i) providing toll-free telephone access at least forty (40) hours per week during normal business hours;

(ii) maintaining a telephone answering service or recording system during nonbusiness hours; and

(iii) responding to each telephone call received by the answering service or recording system regarding a utilization review determination within one (1) business day of the receipt of the call.

(2) Protect the confidentiality of covered person or enrollee medical records as set forth in section 2131.

(3) Ensure that a health care provider is able to verify that an individual requesting information on behalf of the insurer or MA or CHIP managed care plan is [a legitimate] an authorized representative of the insurer or MA or CHIP managed care plan.

(4) Conduct utilization reviews based on the medical necessity [and], appropriateness, health care setting, level of care or effectiveness of the health care service being reviewed [and provide notification within the following time frames:].

(4.1) If performing a utilization review for a request for health care services for an covered person or enrollee of an insurer or MA or CHIP managed care plan, provide notification within the following time frames:

(i) A prospective utilization review decision shall be communicated within [two (2) business days of the receipt of all supporting information reasonably necessary to complete the review] the time frame specified in section 2155.

(ii) A concurrent utilization review decision shall be communicated within one (1) business day of the receipt of all supporting information reasonably necessary to complete the review.

(iii) A retrospective utilization review decision shall be communicated within thirty (30) days of the receipt of all supporting information reasonably necessary to complete the review.

(5) Ensure that personnel conducting a utilization review have current licenses in good standing or other required credentials, without restrictions, from the appropriate agency.

(6) Provide all decisions in writing to include the basis and clinical rationale for the decision.

(7) Notify the health care provider of additional facts or documents required to complete the utilization review within [forty-eight (48) hours of receipt of the request for review] the time frames specified in section 2155.

(8) Maintain a written record of utilization review decisions adverse to covered persons or enrollees for not less than three (3) years, including a detailed justification and all required notifications to the health care provider and the covered person or enrollee.

(b) Compensation to any person or entity performing utilization review may not contain incentives, direct or indirect, for the person or entity to approve or deny payment for the delivery of any health care service.

(c) Utilization review that results in a denial of payment for a health care service shall be made by a licensed physician that meets the qualifications in section 2155(c), except as provided in [subsection (d)] subsections (d) and (e).

(d) A licensed psychologist may perform a utilization review for behavioral health care services within the psychologist's scope of practice if the psychologist's clinical experience provides sufficient experience to review that specific behavioral health care service. The use of a licensed psychologist to perform a utilization review of a behavioral health care service shall be approved by the department as part of the certification process under section 2151. A licensed psychologist shall not review the denial of payment for a health care service involving inpatient care or a prescription drug.

(e) A licensed dentist may perform a utilization review for dental services within the dentist's scope of practice if the dentist's clinical experience provides sufficient experience to review that specific dental service. The use of a licensed dentist to perform a utilization review of a dental service shall be approved by the department as part of the certification process under section 2151.

Section 5. Article XXI of the act is amended by adding a subdivision to read:

(h.1) Utilization Review Standards.

Section 2153. Provider portal.

(a) Establishment of provider portal.--Within 18 months following the effective date of this section, an insurer or MA or CHIP managed care plan shall establish a provider portal that includes, at minimum, the following features:

(1) Electronic submission of prior authorization requests.

(2) Access to the insurer's or MA or CHIP managed care plan's applicable medical policies.

(3) Information necessary to request a peer-to-peer review.

(4) Contact information for the insurer's or MA or CHIP managed care plan's relevant clinical or administrative staff.

(5) For prior authorization service not subject to electronic submission via the provider portal, copies of applicable submission forms.

(6) Instructions for the submission of prior authorization requests if the insurer's or MA or CHIP managed care plan's provider portal is unavailable for any reason.

(b) Training and support for portal use.--Within six months following the establishment of a provider portal under subsection (a), an insurer or MA or CHIP managed care plan shall make available to health care providers and their affiliated or employed staff access to training on the use of the insurer's or MA or CHIP managed care plan's provider portal.

(c) Required use of provider portal.--

(1) Within 18 months following the establishment of a provider portal under subsection (a), a health care provider seeking prior authorization shall submit the request via an insurer's or MA or CHIP managed care plan's provider portal unless an exception applies.

(2) An insurer or MA or CHIP managed care plan may require a health care provider to submit a prior authorization request through the provider portal unless any of the following exceptions applies:

(i) The portal is not available and operational at the time of attempted submission.

(ii) The health care provider does not have access to the insurer's or MA or CHIP managed care plan's operational provider portal.

(iii) The health care provider satisfies an allowance by the insurer or MA or CHIP managed care plan for submission other than through the provider portal.

Section 2154. Medical policies and clinical review criteria.

(a) Medical policies.--

(1) An insurer or MA or CHIP managed care plan shall make available its current medical policies through the insurer's or MA or CHIP managed care plan's publicly accessible Internet website and provider portal.

(2) Each medical policy developed by an insurer or MA or CHIP managed care plan shall identify the clinical review criteria used in the policy's development. The insurer or MA or CHIP managed care plan shall identify any third-party licensure restrictions preventing disclosure of all or part of clinical review criteria.

(3) An insurer or MA or CHIP managed care plan shall review each adopted medical policy on at least an annual basis.

(4) (i) An insurer or MA or CHIP managed care plan

shall notify providers of a change to a medical policy as follows:

(A) In the case of policy change due to a change in Federal or State law or binding agency guidance, when the required implementation date of that policy change is sooner than 30 days, as soon as practicable.

(B) In the case of a change to a medical policy that modifies, eliminates or suspends either clinical or administrative criteria and that directly results in less restrictive coverage of a given service, within 30 days after application of the change.

(C) In cases other than in clauses (A) and (B), at least 30 days prior to application of the change.

(ii) A change notification may be provided through reasonable means, including posting of an updated and dated medical policy reflecting the change.

(b) Clinical review criteria.--

(1) Clinical review criteria adopted by an insurer or MA or CHIP managed care plan at the time of medical policy development or review shall:

(i) Be based on applicable nationally recognized medical standards.

(ii) Be consistent with applicable governmental guidelines.

(iii) Provide for the delivery of a health care service in a clinically appropriate type, frequency and setting and for a clinically appropriate duration.

(iv) Reflect the current medical and scientific evidence regarding emerging procedures, clinical guidelines and best practices as articulated in independent, peer-reviewed medical literature.

(2) Nothing in this section shall require an insurer or MA or CHIP managed care plan to provide coverage for a health care service to a covered person or enrollee that is otherwise excluded from coverage under a health insurance policy or an agreement with the Department of Human Services.

Section 2155. Prior authorization review.

(a) General rule.--

(1) An insurer or MA or CHIP managed care plan shall make a determination relating to prior authorization based on the insurer's or MA or CHIP managed care plan's review of a prior authorization request and the following:

(i) The insurer's or MA or CHIP managed care plan's medical policy.

(ii) The insurer's or MA or CHIP managed care plan's administrative policy.

(iii) All medical information related to the enrollee or covered person.

(iv) Any medical or scientific evidence submitted by the requesting provider.

(2) At the time of review, an insurer or MA or CHIP managed care plan shall verify the covered person's or enrollee's eligibility for coverage under the terms of the applicable health insurance policy or an agreement with the Department of Human Services.

(3) Appeals of administrative adverse benefit determinations shall be subject to the complaint process in section 2142.

(b) List of services subject to review.--An insurer or MA or CHIP managed care plan shall make available a list, posted in a publicly accessible format and location on the insurer's or MA or CHIP managed care plan's publicly accessible Internet website, that indicates the health care services for which the insurer or MA or CHIP managed care plan requires prior authorization.

(c) Information submission.--

(1) Upon receipt of a submission of a prior authorization request, an insurer, MCO or CHIP managed care plan shall notify the health care provider submitting the prior authorization request of any missing information needed by the insurer, MCO or CHIP managed care plan to make a prior authorization determination. An insurer, MCO or CHIP managed care plan shall identify the missing information necessary to make a prior authorization determination with sufficient specificity to enable the health care provider to submit the information to allow the insurer to make a determination in accordance with this chapter.

(2) If an insurer or MA or CHIP managed care plan requires a participating health care provider to transmit medical records in support of a prior authorization request electronically, and a health care provider is capable of transmitting medical records in support of a prior authorization request electronically, the health care provider shall ensure that the insurer or MA or CHIP managed care plan has electronic access to the medical records, including ability to print any medical records transmitted electronically, subject to applicable law and the health care provider's corporate policies. The inability of a health care provider to provide electronic access shall not constitute a reason to deny an authorization request.

(d) Clinical knowledge of reviewer.--

(1) Other than an administrative denial of a prior authorization request, a request for prior authorization may only be denied upon review by either of the following:

(i) A licensed health care provider with appropriate training, knowledge or experience in the same or similar specialty that typically manages or consults on the health care service in question.

(ii) A licensed health care provider, in consultation with an appropriately qualified third-party health care provider, licensed in the same or similar

medical specialty as the requesting health care provider or type of health care provider that typically manages the covered person's or enrollee's associated condition, except that any compensation paid to the consulting health care provider may not be contingent upon the outcome of the review.

(2) (Reserved).

(e) Peer-to-peer review available.--In the case of a denied prior authorization other than an administrative adverse benefit determination of a claim by a covered person or an MA or CHIP managed care plan's denial of a prior authorization request that does not involve medical judgment, an insurer or MA or CHIP managed care plan shall make available to the requesting provider a licensed medical professional for a peer-to-peer review discussion. The peer-to-peer reviewer provided by the insurer or MA or CHIP managed care plan shall meet the standards specified in subsection (c) and have authority to modify or overturn the prior authorization decision. The following shall apply:

(1) The procedure for requesting a peer-to-peer review, including contact information for the insurer or its utilization review entity, or MA or CHIP managed care plan or its utilization review entity, shall be available on the insurer's or MA or CHIP managed care plan's publicly accessible Internet website or provider portal.

(2) A provider may request a peer-to-peer review discussion:

(i) During normal business hours.

(ii) Outside normal business hours, subject to reasonable limitations on the availability of qualified insurer or MA or CHIP managed care plan or utilization review entity staff.

(f) Peer-to-peer proxy.--

(1) A health care provider may designate, and an insurer or MA or CHIP managed care plan shall accept, another licensed member of the provider's affiliated or employed clinical staff with knowledge of the covered person's or enrollee's condition and requested procedure as a qualified proxy for purposes of completing a peer-to-peer discussion.

(2) Individuals eligible to receive a proxy designation shall be limited to licensed health care providers whose actual authority and scope of practice is inclusive of performing or prescribing the requested health care service.

(3) Authority may be established through a supervising health care provider consistent with applicable State law for nonphysician practitioners.

(4) The insurer or MA or CHIP managed care plan must accept and review the information submitted by other members of a health care provider's affiliated or employed staff in support of a prior authorization request.

(5) The insurer or MA or CHIP managed care plan may not

limit interactions with an insurer's or MA or CHIP managed care plan's clinical staff solely to the requesting health care provider.

(g) Peer-to-peer timeline.--

(1) A peer-to-peer discussion shall be available to a requesting health care provider from the time of a prior authorization denial until the internal grievance process or internal adverse benefit determination process commences.

(2) If a peer-to-peer discussion is available prior to adjudicating a prior authorization request, the peer-to-peer discussion shall be offered within the time lines specified in this subsection or subsection (h).

(h) Review time lines for requests submitted to an MA or CHIP managed care plan.--

(1) An MA or CHIP managed care plan's decision to approve or deny prior authorization shall be communicated within two business days of the receipt of all supporting information reasonably necessary to complete the review.

(2) If at any time after requesting prior authorization the provider determines the enrollee's medical condition requires emergency services, the emergency services may be provided under section 2116.

(3) The following shall apply:

(i) If a prior authorization request is missing clinical information that is reasonably necessary to constitute a prior authorization request, the MA or CHIP managed care plan shall notify the health care provider of the specific information necessary to complete the review as soon as possible, but not later than 48 hours after receipt of the prior authorization request.

(ii) The requesting health care provider or a member of the requesting health care provider's clinical or administrative staff may submit the specified information within 14 days of the notification that clinical information is missing.

(iii) If additional information is requested, the MA or CHIP managed care plan shall communicate a decision on the prior authorization request within two business days of receiving the additional information.

(4) An MA or CHIP managed care plan may supplement submitted information based on current clinical records or other current medical information for an enrollee as available, if the supplemental information is also made available to the enrollee or health care provider as part of the enrollee's authorization case file upon request. In response to a request for missing clinical information, an MA or CHIP managed care plan shall accept supplemental information from a member of the health care provider's clinical staff.

(i) Review time lines.--Determinations on prior authorization requests that may be subject to the adverse

benefit determination processes shall be in accordance with the following, unless otherwise required by Federal law or regulation:

(1) For a request related to an urgent health care service:

(i) If the urgent health care service has not yet been initiated, as soon as possible, but not more than 72 hours.

(ii) If related to an ongoing urgent health care service and the request is made at least 24 hours prior to reduction or termination of the treatment, within 24 hours.

(2) For a request involving concurrent care other than as set forth in paragraph (1)(ii), sufficiently in advance to permit an appeal before reduction or termination of the ongoing treatment.

(3) For prior authorization requests other than as specified in paragraphs (1) and (2), within 15 days. The 15-day deadline may be extended by the insurer subject to the following limitations:

(i) Upon receipt of the prior authorization request, the insurer provided notification of missing information under section 2155(c)(1).

(ii) The notification of missing information was communicated as soon as possible following the submission of the prior authorization request to allow an opportunity to respond prior to the expiration of the 15-day deadline with the identified missing information.

(iii) If the health care provider satisfied the requirements for an insurer to grant an extension, the insurer may extend the deadline for at least 45 days to allow the provider to respond. Upon receipt of the missing information, the insurer shall render a decision without delay.

(iv) No insurer shall unreasonably delay or withhold the specific notice of additional information needed to complete a review of a prior authorization request.

(v) Nothing in this paragraph shall require an insurer to extend the initial 15-day deadline.

(4) For a request related to a prescription drug authorization request or step therapy request:

(i) If the request is urgent, within 24 hours.

(ii) If the request is not urgent, within two business days, but not more than 72 hours.

(j) Closely related services.--If a health care provider performs a closely related service, an insurer or MA or CHIP managed care plan may not deny a claim for the closely related service for failure of the health care provider to seek or obtain prior authorization, if:

(1) The health care provider notifies the insurer or MA or CHIP managed care plan of the performance of the closely

related service no later than three business days following completion of the service but prior to the submission of the claim for payment. The submission of the notification shall include the submission of all relevant clinical information necessary for the insurer or MA or CHIP managed care plan to evaluate the medical necessity and appropriateness of the service.

(2) Nothing in this subsection shall be construed to limit an insurer's or MA or CHIP managed care plan's retrospective utilization review of medical necessity and appropriateness of the closely related service, nor limit the need for verification of the covered person's or enrollee's eligibility for coverage.

Section 2156. Step therapy considerations.

(a) Step therapy criteria.--If an insurer or MA or CHIP managed care plan has a medical policy that includes step therapy criteria for a prescription drug, the following apply:

(1) An insurer or MA or CHIP managed care plan shall consider as part of the insurer's or MA or CHIP managed care plan's prior authorization process a request for an exception to the insurer's or MA or CHIP managed care plan's step therapy criteria.

(2) A request for an exception to an insurer's or MA or CHIP managed care plan's step therapy criteria shall be based on the covered person's or enrollee's individualized clinical condition, and consider at least all of the following:

(i) Contraindications, including adverse reactions.

(ii) Clinical effectiveness or ineffectiveness of each required prerequisite prescription drug or therapy.

(iii) Past clinical outcome of each required prerequisite prescription drug or therapy.

(iv) The expected clinical outcomes of the requested prescription drug prescribed by the covered person's or enrollee's provider.

(v) For covered persons or enrollees who previously received health care coverage from another entity, whether the covered person or enrollee has already satisfied a step therapy protocol with their previous insurer or MA or CHIP managed care plan that required trials of prescription drugs from each of the classes that are required by the current insurer's or MA or CHIP managed care plan's step therapy protocol.

(b) Applicability.--The standards and time lines specified in section 2155 shall apply to a review of a request for a step therapy exception.

Section 2157. Medication assisted treatment.

(a) General rule.--An insurer or MA or CHIP managed care plan shall make available without initial prior authorization coverage of at least one prescription drug approved by the United States Food and Drug Administration for use in each component of a medication assisted treatment protocol.

(b) Preferred drug designation.--Nothing in this section shall prohibit an insurer or MA or CHIP managed care plan from designating preferred drugs for the relevant component of a medication assisted treatment protocol when multiple prescription drugs are available, subject to applicable medical policy or prescription drug formulary information availability requirements.

(c) Subsequent requests.--With the exception of prior authorization for initial coverage, nothing in this section shall prohibit an insurer or MA or CHIP managed care plan from requiring prior authorization on subsequent requests for medication assisted treatment to ensure adherence with clinical guidelines.

Section 6. Sections 2161, 2162 and 2163 of the act are amended to read:

Section 2161. Internal Grievance Process.--(a) [A] An MA or CHIP managed care plan shall establish and maintain an internal grievance process with two levels of review and an expedited internal grievance process by which an enrollee, an enrollee's authorized representative or a health care provider, with the written consent of the enrollee, shall be able to file a written grievance regarding the denial of payment for a health care service. An enrollee or an enrollee's authorized representative who consents to the filing of a grievance by a health care provider under this section may not file a separate grievance.

(b) The internal grievance process shall consist of an initial review that includes all of the following:

(1) A review by [one] three or more persons selected by the MA or CHIP managed care plan who did not previously participate in the decision to deny payment for the health care service.

(2) [The completion of the review within thirty (30) days of receipt of the grievance.] A written notification to the enrollee or the enrollee's authorized representative of the decision of the review committee within thirty (30) days of receipt of the grievance unless the time frame for deciding the grievance has been extended by up to fourteen (14) days at the request of the enrollee or the enrollee's authorized representative.

(3) [A written notification to the enrollee and health care provider regarding the decision within five (5) business days of the decision.] The notice shall include the basis and clinical rationale for the decision and the procedure [to file a request for a second level review of the decision] for appealing the decision.

(c) [The grievance process shall include a second level review that includes all of the following:

(1) A review of the decision issued pursuant to subsection (b) by a second level review committee consisting of three or more persons who did not previously participate in any decision to deny payment for the health care service.

(2) A written notification to the enrollee or the health

care provider of the right to appear before the second level review committee.

(3) The completion of the second level review within forty-five (45) days of receipt of a request for such review.

(4) A written notification to the enrollee and health care provider regarding the decision of the second level review committee within five (5) business days of the decision. The notice shall include the basis and clinical rationale for the decision and the procedure for appealing the decision.

(d) Any initial review or second level review conducted under this section shall include a licensed physician, or, where appropriate, an approved licensed psychologist, in the same or similar specialty that typically manages or consults on the health care service.] A review conducted under this section shall include a licensed physician or, where appropriate, an approved licensed psychologist or approved licensed dentist, in the same or similar specialty that typically manages or consults on the health care service.

(e) Should the enrollee's life, health or ability to regain maximum function be in jeopardy, an expedited internal grievance process, including an expedited external grievance process, shall be available which shall include a requirement that a decision with appropriate notification to the enrollee and health care provider be made within forty-eight (48) hours of the filing of the expedited grievance.

Section 2162. External Grievance Process.--(a) [A] An MA or CHIP managed care plan shall establish and maintain an external grievance process, including an expedited grievance process, by which an enrollee, an enrollee's authorized representative or a health care provider with the written consent of the enrollee or the enrollee's authorized representative may appeal the denial of a grievance following completion of the internal grievance process. The external grievance process shall be conducted by an independent utilization review entity not directly affiliated with the MA or CHIP managed care plan.

(b) To conduct external grievances filed under this section:

(1) The department shall randomly assign [a utilization review entity] an IRO on a rotational basis from the list maintained under subsection (d) and notify the assigned [utilization review entity] IRO and the MA or CHIP managed care plan within two (2) business days of receiving the request. If the department fails to select [a utilization review entity] an IRO under this subsection, the MA or CHIP managed care plan shall designate and notify a certified [utilization review entity] IRO to conduct the external grievance.

(2) The MA or CHIP managed care plan shall notify the enrollee, the enrollee's authorized representative or health care provider of the name, address and telephone number of the [utilization review entity] IRO assigned under this subsection within two (2) business days.

(c) The external grievance process shall meet all of the

following requirements:

(1) Any external grievance shall be filed with the MA or CHIP managed care plan within fifteen (15) days of receipt of a notice of denial resulting from the internal grievance process. The filing of the external grievance shall include any material justification and all reasonably necessary supporting information. Within five (5) business days of the filing of an external grievance, the MA or CHIP managed care plan shall notify the enrollee, the enrollee's authorized representative or the health care provider, the [utilization review entity] IRO that conducted the internal grievance and the department that an external grievance has been filed.

(2) The [utilization review entity] IRO that conducted the internal grievance shall forward copies of all written documentation regarding the denial, including the decision, all reasonably necessary supporting information, a summary of applicable issues and the basis and clinical rationale for the decision, to the utilization review entity conducting the external grievance within fifteen (15) days of receipt of notice that the external grievance was filed. Any additional written information may be submitted by the enrollee, the enrollee's authorized representative or the health care provider within [fifteen (15) days of receipt of notice that the external grievance was filed] twenty (20) days of the date the IRO assignment was mailed to the enrollee or enrollee's representative.

(3) The [utilization review entity] IRO conducting the external grievance shall review all information considered in reaching any prior decisions to deny payment for the health care service and any other written submission by the enrollee, the enrollee's authorized representative or the health care provider.

(4) An external grievance decision shall be made by:

(i) one or more licensed physicians [or], approved licensed psychologists or approved licensed dentists in active clinical practice or in the same or similar specialty that typically manages or recommends treatment for the health care service being reviewed; or

(ii) one or more physicians currently certified by a board approved by the American Board of Medical Specialists or the American Board of Osteopathic Specialties in the same or similar specialty that typically manages or recommends treatment for the health care service being reviewed.

(5) Within sixty (60) days of the filing of the external grievance, the [utilization review entity] IRO conducting the external grievance shall issue a written decision to the MA or CHIP managed care plan, the enrollee, the enrollee's authorized representative if the enrollee's authorized representative requested the external review, and the health care provider, including the basis and clinical rationale for the decision. The standard of review shall be whether the health care service

denied by the internal grievance process was medically necessary and appropriate under the terms of the MA or CHIP managed care plan. The external grievance decision shall be subject to appeal to a court of competent jurisdiction within sixty (60) days of receipt of notice of the external grievance decision. There shall be a rebuttable presumption in favor of the decision of the [utilization review entity] IRO conducting the external grievance.

(6) The MA or CHIP managed care plan shall authorize any health care service or pay a claim determined to be medically necessary and appropriate under paragraph (5) pursuant to section 2166 whether or not an appeal to a court of competent jurisdiction has been filed.

(7) All fees and costs related to an external grievance shall be paid by the nonprevailing party if the external grievance was filed by the health care provider. The health care provider and the [utilization review entity] IRO or MA or CHIP managed care plan shall each place in escrow an amount equal to one-half of the estimated costs of the external grievance process. If the external grievance was filed by the enrollee or the enrollee's authorized representative, all fees and costs related thereto shall be paid by the MA or CHIP managed care plan. For purposes of this paragraph, fees and costs shall not include attorney fees.

(d) The department shall compile and maintain a list of [certified utilization review entities] IROs that meet the requirements of this article. The department may remove [a utilization review entity] an IRO from the list if such an entity is incapable of performing its responsibilities in a reasonable manner, charges excessive fees or violates this article.

(e) A fee may be imposed by [a] an MA or CHIP managed care plan for filing an external grievance pursuant to this article which shall not exceed twenty-five ($25) dollars.

(f) Written contracts between MA or CHIP managed care plans and health care providers may provide an alternative dispute resolution system to the external grievance process set forth in this article if the department approves the contract. The alternative dispute resolution system shall be impartial, include specific time limitations to initiate appeals, receive written information, conduct hearings and render decisions and otherwise satisfy the requirements of this section. A written decision pursuant to an alternative dispute resolution system shall be final and binding on all parties. An alternative dispute resolution system shall not be utilized for any external grievance filed by an enrollee or enrollee's authorized representative.

Section 2163. Records.--Records regarding grievances filed under this subdivision that result in decisions adverse to enrollees shall be maintained by the MA or CHIP managed care plan for not less than three (3) years. These records shall be

provided to the department, if requested, in accordance with section 2131(c)(2)(ii).

Section 7. Article XXI of the act is amended by adding a subdivision to read:

(i.1) Adverse Benefit Determinations.

Section 2164. Internal adverse benefit determination process for insurer.

(a) Determination process.--An insurer shall establish and maintain an internal adverse benefit determination process that complies with section 2719 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 300gg-19) and regulations promulgated under the Public Health Service Act.

(b) Notice.--Following an adverse benefit determination and prior to any appeal of an adverse benefit determination under subsection (a), an insurer shall provide a covered person or covered person's authorized representative notice of the covered person's right to appeal an adverse benefit determination which shall be in a form approved by the department.

Section 2164.1. External review applicability and scope.

(a) Applicability.--The external review provisions of this subdivision shall apply to:

(1) An adverse benefit determination rendered by an insurer that are based on any of the following:

(i) Medical necessity.

(ii) Appropriateness of service.

(iii) Health care setting.

(iv) Level of care.

(v) Effectiveness of a covered benefit.

(2) (Reserved).

(b) Nonapplicability.--The external review provisions of this subdivision do not apply to:

(1) Complaints, which may be appealed under section 2142.

(2) Grievances, which may be reviewed under section 2162.

(3) Administrative adverse benefit determinations, which may be appealed under section 2142.

(c) No minimum threshold.-- The external review process is available to a covered person or covered person's authorized representative with respect to health care services of any monetary value. There is no minimum financial threshold for filing a request for external review.

Section 2164.2. Notice of right to external review.

(a) Timing of notice.--An insurer shall notify a covered person in writing of the covered person's right to request an external review under section 2164.5, 2164.6 or 2164.7 at the same time the insurer sends written notice in a form approved by the department of either of the following:

(1) An adverse benefit determination upon completion of the insurer's utilization review process.

(2) A final adverse benefit determination.

(b) Content of notice.--The notice shall include:

(1) The following, or substantially equivalent, language:

We have denied your request for the provision of or payment for a health care service or course of treatment. You may have the right to have our decision reviewed by health care providers who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested. You also have the right to a review of whether we have complied with the surprise billing and cost-sharing protections under the No Surprises Act. You may submit a request for external review to the Pennsylvania Insurance Department.

(2) For a notice related to an adverse benefit determination, a statement informing the covered person that:

(i) If the covered person has a medical condition for which the time frame for completion of an expedited review of an adverse benefit determination under section 2164 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the covered person, or the covered person's authorized representative, may file a request for an expedited external review at the same time as a request for an expedited review of an adverse benefit determination under section 2164. The IRO assigned to conduct the expedited external review shall determine whether the covered person is required to complete the expedited review of the adverse benefit determination prior to conducting the expedited external review. The request may be filed under section 2164.6 or 2164.7 if:

(A) The adverse benefit determination involves a denial of coverage based on a determination that the recommended or requested health care services are experimental or investigational.

(B) The covered person's treating health care provider certifies in writing that the recommended or requested health care services that are the subject of the adverse benefit determination would be significantly less effective if not promptly initiated.

(ii) The covered person or the covered person's authorized representative may file an appeal under the insurer's internal appeal process under section 2164, but shall be considered to have exhausted the insurer's internal appeal process for purposes of section 2164.4 and may immediately file a request for external review under section 2164.3 if:

(A) The insurer has not issued a written decision to the covered person or the covered person's authorized representative within 30 days following the date the covered person or the covered person's authorized representative files the appeal with the insurer.

(B) The covered person or the covered person's authorized representative has not requested or agreed to a delay.

(C) The insurer waives its internal claim and appeal process and the requirement for a covered person or covered person's authorized representative to exhaust the process before filing a request for an external review or an expedited external review.

(D) The insurer has failed to comply with the requirements of the internal claim and appeal process unless the failure or failures are based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the covered person or covered person's authorized representative.

(3) For a notice related to a final adverse benefit determination, a statement informing the covered person that:

(i) If the covered person has a medical condition for which the time frame for completion of a standard external review under section 2164.5 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function, the covered person or covered person's authorized representative may file a request for an expedited external review under section 2164.6.

(ii) If the final adverse benefit determination concerns:

(A) An admission, availability of care, continued stay or health care service for which the covered person received emergency services, but has not been discharged from a facility, the covered person or the covered person's authorized representative may request an expedited external review under section 2164.6.

(B) A denial of coverage based on a determination that the recommended or requested health care service is experimental or investigational, the covered person or covered person's authorized representative may file a request for a standard external review to be conducted under section 2164.7.

(C) A written certification by the treating health care provider that the recommended or requested health care service that is the subject of the request would be significantly less effective if not promptly initiated, the covered person or the

covered person's authorized representative may request an expedited external review to be conducted under section 2164.7.

(4) A copy of the description of both the standard and expedited external review procedures required by section 2136.1 that highlights the provisions in the external review procedures regarding the opportunity to submit additional information and any forms used to process an external review.

(5) An authorization form, or other document approved by the department that complies with the requirements of 45 CFR 164.508 (relating to uses and disclosures for which an authorization is required), by which the covered person, for purposes of conducting an external review under this subdivision, authorizes the insurer and the covered person's treating health care provider to disclose protected health information, including medical records, concerning the covered person, that are pertinent to the external review.

Section 2164.3. Request for external review.

(a) Form of request.--

(1) Except for a request for an expedited external review under section 2164.6, a request for external review shall be made in writing to the department.

(2) The department may prescribe by regulation the form and content of an external review request required to be submitted under this section.

(b) Permitted requests.--A covered person or the covered person's authorized representative may make a request for an external review of an adverse benefit determination or final adverse benefit determination.

Section 2164.4. Exhaustion of internal appeal process.

(a) Requirement to exhaust internal appeal process.--

(1) Except as provided in subsection (b), a request for external review under section 2164.5, 2164.6 or 2164.7 or a request for retrospective review under section 2164 may not be made until the covered person has exhausted the insurer's internal appeal process under section 2164.

(2) A covered person is considered to have exhausted the insurer's internal appeal process for purposes of this section if the covered person or the covered person's authorized representative:

(i) Has filed an appeal involving an adverse benefit determination under section 2164.

(ii) Except to the extent the covered person or the covered person's authorized representative requested or agreed to a delay, has not received a written decision on the appeal from the insurer within 30 days following the date the covered person or the covered person's authorized representative filed the appeal with the insurer.

(iii) The insurer waives its internal claim and appeal process and the requirement for a covered person

or covered person's authorized representative to exhaust the process before filing a request for an external review or an expedited external review.

(iv) The insurer has failed to comply with the requirements of the internal claim and appeal process unless the failure or failures are based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the covered person or covered person's authorized representative.

(b) Procedure for requesting expedited external review.--

(1) At the same time a covered person or the covered person's authorized representative files a request for expedited internal review of an adverse benefit determination under section 2164, the covered person or the covered person's authorized representative may file a request for an expedited external review of the adverse benefit determination:

(i) Under section 2164.6, if the covered person has a medical condition for which the time frame for completion of an expedited internal review of the adverse benefit determination under section 2164 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

(ii) Under section 2164.7, if the adverse benefit determination involves a denial of coverage based on a determination that the recommended or requested health care service is experimental or investigational, and the covered person's treating health care provider certifies in writing that the recommended or requested health care service that is the subject of the adverse benefit determination would be significantly less effective if not promptly initiated.

(2) Upon receipt of a request for an expedited external review under paragraph (1), the IRO conducting the external review under section 2164.6 or section 2164.7 shall determine whether the covered person is required to complete the expedited internal review process under section 2164 before the IRO conducts the expedited external review.

(c) Denial of request for expedited external review.--If the IRO determines that the covered person is required to first complete the internal expedited appeal process under section 2164, the IRO shall within 24 hours notify the covered person and, if applicable, the covered person's authorized representative, that the IRO may not proceed with the expedited external review under section 2164.6 until the insurer has completed the expedited review process and the covered person's adverse benefit determination appeal remains unresolved.

(d) Waiver of exhaustion requirement.--A request for external review of an adverse benefit determination may be made before the covered person has exhausted the insurer's internal

appeal procedures under section 2164, if the insurer agrees to waive the exhaustion requirement. At that time, the covered person or the covered person's authorized representative may file a request in writing for standard external review as provided in section 2164.5 or section 2164.7.

Section 2164.5. Standard external review.

(a) Request for review.--

(1) A covered person, or the covered person's authorized representative, may file a request for external review with the department within four months after the date of receipt of a notice of an adverse benefit determination or final adverse benefit determination under section 2164.2.

(2) The department shall send a copy of the request to the insurer within one business day of the date of receipt of a request for external review under paragraph (1).

(b) Preliminary review of request.--Within five business days of the date of receipt of the copy of the external review request received under subsection (a)(2), the insurer shall complete a preliminary review of the request to determine whether:

(1) The individual is or was a covered person under the health insurance policy at the time the health care service was requested or, in the case of a retrospective review, was a covered person under the health insurance policy at the time the health care service was provided.

(2) The health care service that is the subject of the adverse benefit determination or the final adverse benefit determination is a covered service under the covered person's health insurance policy, except for a determination by the insurer that the health care service is not covered because it does not meet the insurer's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness.

(3) The covered person has exhausted the insurer's internal appeal process under section 2164, unless the covered person is not required to exhaust the insurer's internal appeal process under section 2164.4.

(4) The covered person has not provided all the information and forms required to process an external review, including the release form provided under section 2164.2(b).

(c) Notice of initial determination.--

(1) Within one business day of completion of the preliminary review, the insurer shall notify the department and the covered person and, if applicable, the covered person's authorized representative, in writing whether the request is complete and eligible for external review. The following apply:

(i) If the request is not complete, the insurer shall inform the covered person and, if applicable, the covered person's authorized representative, and the department in writing and include in the notice what

information or materials are needed to make the request complete.

(ii) If the request is not eligible for external review, the insurer shall inform the covered person and, if applicable, the covered person's authorized representative, and the department in writing and include in the notice the reasons for the request's ineligibility.

(2) Notification under paragraph (1)(ii) shall be provided in a form as specified by the department and include a statement informing the covered person and, if applicable, the covered person's authorized representative that an insurer's initial determination that the external review request is ineligible for review may be appealed to the department.

(3) Notwithstanding an insurer's initial determination that the request is ineligible for review, the department may determine, based upon the terms of the covered person's health insurance policy, that a request is eligible for external review under subsection (b). The determination shall be binding on the insurer and the covered person and may be appealed to the commissioner. Consideration of the appeal may not delay or terminate the external review.

(d) Procedure for review of eligible requests.--

(1) Within one business day of the date of receipt of notice that a request is eligible for external review following the preliminary review conducted under subsection (c), the department shall:

(i) Assign an IRO to conduct the external review from the list of approved IROs compiled and maintained by the department under section 2164.9 and notify the insurer of the name of the assigned IRO.

(ii) Notify in writing the covered person and, if applicable, the covered person's authorized representative, of the request's eligibility and acceptance for external review. The notification shall include a statement that the covered person, or the covered person's authorized representative, may submit in writing to the assigned IRO, within 15 business days of the date of receipt of the notice provided under subparagraph (i), additional information that the IRO shall consider when conducting the external review. The IRO may accept and consider additional information submitted after five business days.

(2) The assigned IRO shall not be bound by a decision or conclusion reached during the insurer's internal claims and appeal process under section 2164.

(e) Forwarding of required documents.--

(1) Within five business days of the date of receipt of the notice provided under subsection (d)(1), the insurer, or a utilization review organization designated by the insurer,

shall provide to the assigned IRO the documents and information considered in making the adverse benefit determination or final adverse benefit determination.

(2) If the insurer, or a utilization review organization designated by the insurer, fails to provide documents and information within the time period specified in paragraph (1), the IRO may proceed with the review, terminate the external review and make a decision to reverse the adverse benefit determination or final adverse benefit determination. Within one business day of making the decision under paragraph (1), the IRO shall notify the department, the insurer, the covered person and, if applicable, the covered person's authorized representative.

(f) Review of information.--

(1) The assigned IRO shall review all of the information and documents received under subsection (e) and other information submitted in writing to the IRO by the covered person or the covered person's authorized representative under subsection (d)(1)(ii).

(2) Within one business day of receipt of information submitted by the covered person or the covered person's authorized representative, the assigned IRO shall forward the information to the insurer.

(g) Reconsideration by insurer.--

(1) Upon receipt of the information, if any, required to be forwarded under subsection (f)(2), the insurer may reconsider an adverse benefit determination or final adverse benefit determination that is the subject of the external review.

(2) Reconsideration by the insurer of an adverse benefit determination or final adverse benefit determination under paragraph (1) may not delay or terminate the external review.

(3) The external review may be terminated without an IRO determination only if the insurer decides, upon completion of the insurer's reconsideration, to reverse the insurer's adverse benefit determination or final adverse benefit determination and provide coverage or payment for the recommended health care service that is the subject of the external review.

(4) Within one business day of making the decision to reverse its adverse benefit determination or final adverse benefit determination, as provided in paragraph (3), the insurer shall notify the department, the assigned IRO, the covered person and, if applicable, the covered person's authorized representative, in writing of its decision.

(5) The assigned IRO shall terminate the external review upon receipt of the notice from the insurer sent under paragraph (4).

(h) Factors to be considered.--In addition to the documents and information provided under subsection (e), the assigned IRO, to the extent the information or documents are available and the

IRO considers them appropriate, shall consider the following information in reaching a decision:

(1) The covered person's medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, the covered person, the covered person's authorized representative or the covered person's treating provider.

(4) The terms of coverage under the covered person's health insurance policy to ensure that the IRO's decision is not contrary to the terms of coverage.

(5) The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include other practice guidelines developed by the Federal Government or national or professional medical societies, boards and associations.

(6) Applicable clinical review criteria developed and used by the insurer or a utilization review organization designated by the insurer.

(7) The option opinion of the IRO's clinical reviewer or reviewers after considering the information under paragraphs (1), (2), (3), (4), (5) and (6).

(i) Notice of decision.--

(1) Within 45 days of the date of receipt of the request for an external review, the assigned IRO shall provide written notice of the IRO's decision to uphold or reverse the adverse benefit determination or the final adverse benefit determination to:

(i) The covered person.

(ii) If applicable, the covered person's authorized representative.

(iii) The insurer.

(iv) The department.

(2) The IRO shall include in the notice under paragraph (1):

(i) A general description of the reason for the request for external review.

(ii) The date the IRO received the assignment from the department to conduct the external review.

(iii) The date the external review was conducted.

(iv) The date of the IRO's decision.

(v) The principal reason or reasons for the IRO's decision, including what applicable evidence-based standards were considered in reaching the IRO's decision.

(vi) The rationale for the IRO's decision.

(vii) References to the evidence or documentation, including evidence-based standards, considered in reaching the IRO's decision.

(3) Upon receipt of a notice of a decision under paragraph (1) reversing the adverse benefit determination or final adverse benefit determination, the insurer shall within

24 hours approve the coverage that was the subject of the adverse benefit determination or final adverse benefit determination.

(j) Assignment of IRO.--The department shall assign on a random basis an approved IRO from those qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse benefit determination or final adverse benefit determination, and shall consider the conflict-of-interest concerns under section 2164.10(d).

Section 2164.6. Expedited external review.

(a) Request for review.--Except as provided in subsection (f), a covered person or the covered person's authorized representative may make a request for expedited external review with the department at the time the covered person receives:

(1) An adverse benefit determination, if either of the following applies:

(i) The adverse benefit determination involves a medical condition of the covered person for which the time frame for completion of an expedited internal review under section 2164 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

(ii) The covered person or the covered person's authorized representative has filed a request for an expedited internal review of an adverse benefit determination under section 2164.

(2) A final adverse benefit determination if either of the following apply:

(i) The covered person has a medical condition for which the time frame for completion of a standard external review under section 2164.5 would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function.

(ii) The final adverse benefit determination concerns an admission, availability of care, continued stay or health care service for which the covered person received emergency services but has not been discharged from a facility.

(b) Preliminary review of request.--

(1) Upon receipt of a request for an expedited external review, the department shall, within 24 hours, send a copy of the request to the insurer.

(2) Within 24 hours upon receipt of a request under paragraph (1), the insurer shall determine whether the request meets the requirements for review under section 2164.5(b). The insurer shall, within 24 hours, notify the department, the covered person and, if applicable, the covered person's authorized representative of the insurer's eligibility determination.

(3) Notification provided under paragraph (2) shall be provided in a form as specified by the department and include a statement informing the covered person and, if applicable, the covered person's authorized representative that an insurer's initial determination that the external review request is ineligible for review may be appealed to the department.

(4) Notwithstanding an insurer's initial determination that the request is ineligible for review, the department may decide, based upon the terms of the covered person's health insurance policy, that a request is eligible for external review under section 2164.5(b). The department's decision shall be binding on the insurer and the covered person and may be appealed to the commissioner. Consideration of an appeal may not delay or terminate the external review.

(5) Upon receipt of the notice that the request meets the requirements for review, the department shall, within 24 hours, assign an IRO to conduct the expedited external review from the list of approved IROs compiled and maintained by the department under section 2164.9. The department shall, within 24 hours, notify the insurer of the name of the assigned IRO.

(6) In reaching a decision in accordance with subsection (e), the assigned IRO shall not be bound by a decision or conclusion reached during the internal adverse benefit determination process for an insurer under section 2164.

(c) Forwarding of required documents.--Upon receipt of departmental notice of the name of the IRO assigned to conduct the expedited external review under subsection (b)(5), the insurer or an IRO designated by the insurer shall provide to the assigned IRO the documents and information considered in making the adverse benefit determination or final adverse benefit determination by one of the following methods:

(1) Electronically.

(2) By telephone.

(3) By facsimile.

(4) By any other available expeditious method.

(d) Factors to be considered.--In addition to the documents and information provided under subsection (c), the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, shall consider the following information in reaching a decision:

(1) The covered person's medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, the covered person, the covered person's authorized representative or the covered person's treating provider.

(4) The terms of coverage under the covered person's health insurance policy to ensure that the IRO'S decision is not contrary to the terms of coverage.

(5) The most appropriate practice guidelines, which

shall include applicable evidence-based standards and may include any other practice guidelines developed by the Federal Government or national or professional medical societies, boards and associations.

(6) Applicable clinical review criteria developed and used by the insurer or a utilization review organization designated by the insurer.

(7) The opinion of the IRO's clinical reviewer or reviewers after considering the information under paragraphs (1), (2), (3), (4), (5) and (6).

(e) Notice of decision.--

(1) As expeditiously as the covered person's medical condition or circumstances require, but in no event more than 72 hours after the date of receipt of the request for an expedited external review that meets the reviewability requirements under section 2164.5(b), the assigned IRO shall provide notice of the IRO's decision to uphold or reverse the adverse benefit determination or the final adverse benefit determination to:

(i) The covered person.

(ii) If applicable, the covered person's authorized representative.

(iii) The insurer.

(iv) The department.

(2) If the notice provided under paragraph (1) is not in writing, within 48 hours of the date of providing that notice, the assigned IRO shall provide written notice of the IRO's decision to uphold or reverse the adverse benefit determination or the final adverse benefit determination to:

(i) The covered person.

(ii) If applicable, the covered person's authorized representative.

(iii) The insurer.

(iv) The department.

(3) The IRO shall include in the notice under paragraph (2):

(i) A general description of the reason for the request for external review.

(ii) The date the IRO received the assignment from the department to conduct the external review.

(iii) The date the external review was conducted.

(iv) The date of the IRO's decision.

(v) The principal reason or reason for the IRO's decision, including applicable evidence-based standards considered in reaching the IRO's decision.

(vi) The rationale for the IRO's decision.

(vii) References to the evidence or documentation, including evidence-based standards, considered in reaching the IRO's decision.

(4) Upon receipt of a notice of a decision under paragraph (1) reversing the adverse benefit determination or

final adverse benefit determination, the insurer shall, within 24 hours, approve the coverage that was the subject of the adverse benefit determination or final adverse benefit determination.

(f) Prohibition of retrospective expedited external review.--An expedited external review may not be provided for retrospective adverse or final adverse benefit determinations.

(g) Assignment of IRO.--The department shall assign on a random basis an approved IRO among those qualified to conduct the particular external review based on the nature of the health care service that is subject of the adverse benefit determination or final adverse benefit determination, and shall consider the conflict-of-interest concerns under section 2164.10(d).

Section 2164.7. External review of experimental or investigational treatment adverse benefit determinations.

(a) Request for review.--

(1) Within four months of the date of receipt of a notice of an adverse benefit determination or final adverse benefit determination under section 2164.2 that involves a denial of coverage based on a determination that the health care services recommended or requested are experimental or investigational, a covered person, or the covered person's authorized representative, may file a request for external review with the department.

(2) A covered person, or the covered person's authorized representative, may make an oral request for expedited external review of the adverse benefit determination or final adverse benefit determination under paragraph (1) if the covered person's treating health care provider certificates in writing that the recommended or requested health care services that are the subject of the request would be significantly less effective if not promptly initiated. Upon receipt of a request for an expedited external review, the department shall notify the insurer within 24 hours.

(3) With respect to notice of an insurer's eligibility determination:

(i) Upon notice of the request for expedited external review, the insurer shall immediately determine whether the request meets the requirements for review under subsection (b). The insurer shall, within 24 hours, notify the department, the covered person and, if applicable, the covered person's authorized representative, of the insurer's eligibility determination.

(ii) The department may specify the form for the insurer's notice of initial determination under subparagraph (i) and any supporting information to be included in the notice.

(iii) The notice of initial determination under

subparagraph (i) shall include a statement informing the covered person and, if applicable, the covered person's authorized representative, of an insurer's initial determination that the external review request is ineligible for review and that the external review request may be appealed to the department.

(3) Notwithstanding an insurer's initial determination, the department may decide that a request is eligible for external review under paragraph (2) and require that the request be referred for external review. The department's decision shall be made in accordance with the terms of the covered person's health insurance policy and shall be subject to all applicable provisions of this subdivision. The department's decision shall be binding on the insurer and the covered person and may be appealed to the commissioner. Consideration of an appeal may not delay or terminate the external review.

(4) Upon receipt of a notice under paragraph (2), the department shall, within 24 hours, assign an IRO to review the expedited request from the list of approved IROs compiled and maintained by the department under section 2164.9 and notify the insurer of the name of the assigned IRO. The insurer, or a utilization review organization designated by the insurer, shall then provide or transmit all necessary documents and information considered in making the adverse benefit determination or final adverse benefit determination to the assigned IRO:

(i) Electronically.

(ii) By telephone.

(iii) By facsimile.

(iv) By any other available expeditious method.

(b) Preliminary review request.--

(1) Except for a request for an expedited external review made under subsection (a)(2), within one business day of the date of receipt of the request for external review, the department shall notify the insurer of the department's receipt of the request.

(2) Within five business days of the date of receipt of the notice sent under paragraph (1), the insurer shall conduct and complete a preliminary review of the request to determine whether:

(i) The individual is or was a covered person under the health insurance policy at the time the health care services were recommended or requested or, in the case of a retrospective review, was a covered person under the health insurance policy at the time the health care services were provided.

(ii) The recommended or requested health care service that is the subject of the adverse benefit determination or final adverse benefit determination:

(A) Is a covered benefit under the covered

person's health insurance policy, except for the insurer's determination that the health care service is experimental or investigational for a particular medical condition.

(B) Is not explicitly listed as an excluded benefit under the covered person's health insurance policy.

(iii) The covered person's treating health care provider has certified that one of the following situations is applicable:

(A) Standard health care services have not been effective in improving the condition of the covered person.

(B) Standard health care services are not medically appropriate for the covered person.

(C) There are no available standard health care services covered under the health insurance policy that are more beneficial than the recommended or requested health care services described in subparagraph (iv).

(iv) The covered person's treating health care provider either:

(A) Has recommended health care services that the health care provider certifies, in writing, are likely to be more beneficial to the covered person, in the health care provider's opinion, than available standard health care services.

(B) Has certified in writing that scientifically valid studies using accepted protocols demonstrate that the health care services requested by the covered person who is the subject of the adverse benefit determination or final adverse benefit determination, are likely to be more beneficial to the covered person than any available standard health care services, when the treating health care provider is a licensed, board-certified or board-eligible physician qualified to practice in the area of medicine appropriate to treat the covered person's condition.

(v) The covered person has exhausted the insurer's internal claims and appeal process under section 2164, unless the covered person is not required to exhaust the insurer's internal appeal process under section 2164.4.

(vi) The covered person has provided all the information and forms required by the department that are necessary to process an external review, including the release form provided under section 2164.2(b).

(c) Notice of initial determination.--

(1) Within one business day of completion of the preliminary review, the insurer shall notify the department and covered person and, if applicable, the covered person's

authorized representative, in writing whether the request is complete and eligible for external review.

(2) If the request:

(i) Is not complete, the insurer shall inform the covered person and, if applicable, the covered person's authorized representative and the department in writing and include in the notice what information or materials are needed to make the request complete.

(ii) Is not eligible for external review, the insurer shall inform the covered person and, if applicable, the covered person's authorized representative and the department in writing and include in the notice the reasons for the request's ineligibility.

(3) Notification provided under paragraph (2) shall be provided in a form specified by the department and include a statement informing the covered person and, if applicable, the covered person's authorized representative of an insurer's initial determination that the request is ineligible for external review and that the external review request may be appealed to the department.

(4) Notwithstanding an insurer's initial determination that the request is ineligible for review, the department may determine, based upon the terms of the covered person's health insurance policy, that the request is eligible for external review under section 2164.5. The determination shall be binding on the insurer and the covered person and may be appealed to the commissioner. Consideration of the appeal may not delay or terminate the external review.

(5) When a request is determined to be eligible for external review, the insurer shall notify the department, the covered person and, if applicable, the covered person's authorized representative.

(d) Procedure for review of requests eligible for external review.--

(1) Within one business day of the date of receipt of notice that a request is eligible for external review following the preliminary review conducted under subsection (c), the department shall:

(i) Assign an IRO to conduct the external review from the list of approved IROs compiled and maintained by the department under section 2164.9 and notify the insurer of the name of the assigned IRO.

(ii) Notify in writing the covered person and, if applicable, the covered person's authorized representative of the request's eligibility and acceptance for external review. The notification shall include a statement that the covered person, or the covered person's authorized representative, may submit in writing to the assigned IRO, within five business days of the date of receipt of the notice provided under

subparagraph (i), additional information that the IRO shall consider when conducting the external review. The IRO may accept and consider additional information submitted after five business days.

(2) Within one business day of the receipt of the notice of assignment to conduct the external review under paragraph (1), the assigned IRO shall:

(i) Select one or more clinical reviewers under paragraph (3) to conduct the external review.

(ii) Based on the opinion or opinions of the clinical reviewer or reviewers, make a decision to uphold or reverse the adverse benefit determination or final adverse benefit determination.

(3) In selecting a clinical reviewer, the assigned IRO shall select a physician or other health care provider who meets the minimum qualifications described in section 2611.1 and, through clinical experience in the past three years, has expertise in the treatment of the covered person's condition and is knowledgeable about the recommended or requested health care service. The covered person, the covered person's authorized representative and, if applicable, the insurer may not choose or control the choice of the physician or other health care provider to be selected to conduct the external review.

(4) In accordance with subsection (e), each clinical reviewer shall provide a written opinion to the assigned IRO regarding whether the recommended or requested health care service should be covered.

(5) The assigned clinical reviewer is not bound by a decision or conclusion reached during the insurer's internal claims and appeal process under section 2164.

(e) Forwarding of required documents.--

(1) Within five business days of the date of receipt of the notice provided under subsection (d)(1), the insurer, or a utilization review organization designated by the insurer, shall provide to the assigned IRO the documents and information considered in making the adverse benefit determination or the final adverse benefit determination.

(2) Except as provided in paragraph (3), failure by the insurer, or by a utilization review organization designated by the insurer, to provide the documents and information within the time period specified in paragraph (1) may not delay the conduct of the external review.

(3) If the insurer, or a utilization review organization designated by the insurer, fails to provide the documents and information within the time period specified in paragraph (1), the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final adverse benefit determination. Within 24 hours upon making the decision, the IRO shall notify the department, the insurer, the covered person, and, if applicable, the covered

person's authorized representative.

(f) Review of information.--

(1) Each clinical reviewer selected under subsection (d) shall review all of the information and documents received under subsection (e) and other information submitted in writing by the covered person or covered person's authorized representative under subsection (d)(1)(ii).

(2) Within one business day of receipt of information submitted by the covered person or covered person's authorized representative under subsection (d)(1)(ii), the assigned IRO shall forward the information to the insurer.

(g) Reconsideration by insurer.--

(1) Upon receipt of the information, if any, required to be forwarded under subsection (f)(2), the insurer may reconsider an adverse benefit determination or final adverse benefit determination that is the subject of the external review.

(2) Reconsideration by the insurer of an adverse benefit determination or final adverse benefit determination under paragraph (1) may not delay or terminate the external review.

(3) The external review may be terminated without an IRO determination only if the insurer decides, upon completion of reconsideration, to reverse the adverse benefit determination or final adverse benefit determination and provide coverage or payment for the recommended health care service that is the subject of the external review.

(4) Within one business day of making the decision to reverse the insurer's adverse benefit determination or final adverse benefit determination, as provided in paragraph (3), the insurer shall notify the department, the assigned IRO, the covered person, and, if applicable, the covered person's authorized representative, in writing of the insurer's decision.

(5) The assigned IRO shall terminate the external review upon receipt of the notice from the insurer under paragraph (4).

(h) Clinical review process.--

(1) Except as provided in paragraph (3), within 20 days of being selected in accordance with subsection (d) to conduct the external review, each clinical reviewer shall provide an opinion to the assigned IRO regarding whether the recommended or requested health care service should be covered.

(2) Except for an opinion provided under paragraph (3), a clinical reviewer's opinion shall be in writing and include the following information:

(i) A description of the covered person's medical condition.

(ii) A description of the indicators relevant to determining whether there is sufficient evidence to demonstrate that:

(A) The recommended or requested health care service is more likely than not to be beneficial to the covered person than any available standard health care service.

(B) The adverse risks of the recommended or requested health care service would not be substantially increased over the adverse risks of available standard health care service.

(iii) A description and analysis of medical or scientific evidence considered in reaching the opinion.

(iv) A description and analysis of an evidence-based standard.

(v) Information on whether the reviewer's rationale for the opinion is based on subsection (i)(5)(i) or (ii).

(3) The following shall apply:

(i) For an expedited external review, a clinical reviewer shall provide an opinion orally or in writing to the assigned IRO as expeditiously as the covered person's medical condition or circumstances require, but in no event more than five calendar days after being selected in accordance with subsection (d).

(ii) If the opinion provided under subparagraph (i) is not in writing, within 48 hours of the date the opinion was provided, the clinical reviewer shall provide written confirmation of the opinion to the assigned IRO and include the information required under paragraph (2).

(i) Factors to be considered.--In addition to the documents and information provided under subsection (a)(2) or (e), a clinical reviewer selected under subsection (d), to the extent the information or documents are available and the reviewer considers appropriate, shall consider the following in reaching an opinion under subsection (h):

(1) The covered person's medical records.

(2) The attending health care provider's recommendation.

(3) Consulting reports from appropriate health care providers and other documents submitted by the insurer, the covered person, and, if applicable, the covered person's authorized representative or treating provider.

(4) The terms of coverage under the covered person's health insurance policy to ensure that the IRO's decision is not contrary to the terms.

(5) Whether either of the following is satisfied:

(i) The recommended or requested health care service has been approved by the United States Food and Drug Administration, if applicable, for the condition.

(ii) Medical or scientific evidence or evidence-based standards demonstrate that:

(A) The expected benefit of the recommended or requested health care service is more likely than not to be beneficial to the covered person than any available standard health care service.

(B) The adverse risks of the recommended or requested health care service would not be substantially increased over the adverse risks of an available standard health care service.

(j) Notice of decision.--

(1) Within 20 days of the date the assigned IRO receives the opinion of a clinical reviewer, the assigned IRO shall provide written notice of the assigned IRO's decision to uphold or reverse the adverse benefit determination to:

(i) The covered person.

(ii) If applicable, the covered person's authorized representative.

(iii) The insurer.

(iv) The department.

(2) If a majority of the clinical reviewers recommend that:

(i) The recommended or requested health care service be covered, the IRO shall make a decision to reverse the insurer's adverse benefit determination or final adverse benefit determination.

(ii) The recommended or requested health care service not be covered, the IRO shall make a decision to uphold the insurer's adverse benefit determination or final adverse benefit determination.

(3) If the clinical reviewers are evenly divided as to whether the recommended or requested health care service should be covered:

(i) The IRO shall obtain the opinion of an additional clinical reviewer in order for the IRO to make a decision based on the opinions of a majority of the clinical reviewers.

(ii) The additional clinical reviewer selected shall use the same information to reach an opinion as the clinical reviewers who have already submitted their opinion.

(iii) The selection of the additional clinical reviewer may not extend the time within which the assigned IRO is required to make a decision.

(4) The IRO shall include the following in the notice provided under paragraph (1):

(i) A general description of the reason for the request for external review.

(ii) The written opinion of each clinical reviewer, including the recommendation of each clinical reviewer as to whether the recommended or requested health care service should be covered and the rationale for the reviewer's recommendation.

(iii) The date the IRO was assigned by the department to conduct the external review.

(iv) The date of the external review.

(v) The date of the IRO's decision.

(vi) The principal reason or reasons for the IRO's decision.

(vii) The rationale for the IRO's decision.

(5) Upon receipt of a notice of a decision under paragraph (1) reversing the adverse benefit determination or final adverse benefit determination, the insurer shall, within 24 hours, approve the coverage that was the subject of the adverse benefit determination or final adverse benefit determination.

(k) Assignment of IRO.--The department shall assign, on a random basis, an approved IRO among those qualified to conduct the particular external review based on the nature of the health care service that is the subject of the adverse benefit determination or final adverse benefit determination, and shall consider the conflict-of-interest concerns under section 2164.10(d).

Section 2164.8. Binding nature of external review decision.

(a) Binding on insurer.--An external review decision shall be binding on the insurer, except to the extent the insurer has other remedies available under applicable State law.

(b) Binding on covered person.--An external review decision shall be binding on a covered person, except to the extent the covered person has other remedies available under applicable Federal and State law.

(c) Finality of decision.--Neither the covered person nor the covered person's authorized representative may file a subsequent request for external review involving the same adverse benefit determination or final adverse benefit determination for which the covered person has already received an external review decision under this subarticle.

Section 2164.9. Department approval of independent review organizations.

(a) General rule.--The department may approve an IRO eligible to be assigned to conduct external reviews under this subdivision.

(b) Eligibility requirements.--To be eligible for approval by the department under this section to conduct external reviews under this subdivision, an IRO must:

(1) Except as otherwise provided in this section, be accredited by a nationally recognized private accrediting entity that the department has determined to possess IRO accreditation standards that are equivalent to or exceed the minimum qualifications for the IROs established under section 2611.1.

(2) Submit an application for approval in accordance with subsection (d).

(3) Identify the IRO's proposed fees for external reviews.

(c) Form of application.--The department shall develop an application form for initially approving and for renewing the approval of IROs to conduct external reviews.

(d) Consideration of application.--

(1) An IRO seeking approval to conduct external reviews under this subdivision shall submit the application form and include with the form all documentation and information necessary for the department to determine whether the IRO satisfies the minimum qualifications established under section 2164.10.

(2) The department may approve an IRO that is not accredited by a nationally recognized private accrediting entity if there are no acceptable nationally recognized private accrediting entities providing IRO accreditation.

(3) The department may charge the IRO an application fee to be submitted with an application for approval or for renewal.

(4) The department may decline to certify an IRO if the IRO's proposed fees for external reviews are determined by the department to be unreasonable.

(e) Duration of approval.--

(1) An approval shall be valid for two years unless the department determines before the approval expires that the IRO no longer satisfies the minimum qualifications established under section 2164.10.

(2) If the department determines that an IRO is no longer accredited or no longer satisfies the minimum requirements established under section 2164.10, the department may terminate the approval of the IRO and remove the IRO from the list of IROs approved to conduct external reviews under this subdivision.

(f) List of approved IROs.--The department shall maintain and periodically update a list of approved IROs. The department shall periodically transmit notice a list of approved IROs to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

(g) No prohibition.--Nothing in this section or in section 2164.10 shall prohibit an entity certified as a utilization review entity from being approved as an IRO.

Section 2164.10. Minimum qualifications for independent review organizations.

(a) Requirements for department approval.--To be approved under section 2164.9 to conduct external reviews and external grievances, an IRO must establish and maintain written policies and procedures that govern all aspects of both the standard and expedited adverse benefit determination external review and external grievance review required by sections 2162, 2162.6 and 2162.7 that include, at a minimum:

(1) A quality assurance mechanism in place that ensures:

(i) That an external review is conducted within the specified time period and that required notices are provided in a timely manner.

(ii) The selection of qualified and impartial clinical reviewers to conduct external review on behalf

of the IRO, and suitable matching of reviewers to specific cases.

(iii) That an IRO employs or contracts with an adequate number of clinical reviewers to suitably match reviewers to specific cases.

(iv) The confidentiality of medical and treatment records and clinical review criteria.

(v) That a person employed by or under contract with the IRO adheres to the requirements of this subdivision.

(vi) That the IRO and its assigned clinical reviewers are unbiased in the conduct of an external review.

(2) A toll-free telephone service to receive information 24 hours per day, 7 days per week, related to external reviews, that is capable of accepting, recording or providing appropriate instruction to incoming telephone callers during other-than-normal business hours.

(3) An agreement to maintain and provide to the department the information described in section 2164.12.

(b) Qualifications of clinical reviewer.--A clinical reviewer assigned by an IRO to conduct external review must be a physician or other appropriate health care provider who meets the following minimum qualifications:

(1) Has expertise in the treatment of the covered person's or enrollee's medical condition that is the subject of the external review.

(2) Is knowledgeable about the recommended health care service through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person or enrollee.

(3) Holds a nonrestricted license in a state or commonwealth of the United States and, for a physician, a current certification from a recognized American medical specialty board in the area or areas of medicine appropriate to the subject of the external review.

(4) Has no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by a hospital, governmental agency or unit or regulatory body that raise a substantial question as to the clinical reviewer's physical, mental or professional competence or moral character.

(c) Prohibited relationships.--In addition to the requirements under subsection (a), an IRO may not own or control, be a subsidiary of or in any way be owned or controlled by or exercise control with an insurer or MA or CHIP managed care plan, a national, State or local trade association of insurers or MA or CHIP managed care plans, or health care providers.

(d) Conflicts of interest.--

(1) In addition to the requirements under this section,

to be approved under sections 2162, 2162.6 or 2162.7 to conduct an external review of a specified case, neither the IRO selected to conduct the external review nor a clinical reviewer assigned by the IRO to conduct the external review may have a material professional, familial or financial conflict of interest with any of the following:

(i) The insurer or MA or CHIP managed care plan that is the subject of the external review.

(ii) The covered person or enrollee whose treatment is the subject of the external review or the covered person's or enrollee's authorized representative.

(iii) An officer, director or management employee of the insurer or MA or CHIP managed care plan that is the subject of the external review.

(iv) The health care provider, the health care provider's medical group or independent practice association recommending the health care service that is the subject of the external review.

(v) The facility at which the recommended health care service would be provided.

(vi) The developer or manufacturer of the principal drug, device, procedure or other therapy being recommended for the covered person or enrollee whose treatment is the subject of the external review.

(2) In determining whether an IRO or clinical reviewer of the IRO has a material professional, familial or financial conflict of interest for purposes of paragraph (1), the department shall take into consideration situations where an apparent conflict of interest under paragraph (1) is not material.

(e) Accreditation.--

(1) An IRO that is accredited by a nationally recognized private accrediting entity that possesses independent review accreditation standards that the department has determined are equivalent to or exceed the minimum qualifications of this section shall be presumed to be in compliance with this section to be eligible for approval under section 2164.9.

(2) The department shall initially and periodically review the IRO accreditation standards of a nationally recognized private accrediting entity to determine whether the entity's standards are, and continue to be, equivalent to or exceeding the minimum qualifications established under this section. The department may accept a review conducted by the NAIC for the purposes of the determination under this paragraph.

(3) Upon request, a nationally recognized private accrediting entity shall make its current IRO accreditation standards available to the department or the NAIC in order for the department to determine if the entity's standards exceed or are equivalent to the minimum qualifications established under this section. The department may exclude a

private accrediting entity that is not reviewed by the NAIC.

Section 2164.11. Hold harmless for independent review organizations.

No IRO, clinical reviewer working on behalf of an IRO or an employee, agent or contractor of an IRO may be held liable for damages to a person for an opinion rendered, or act or omission performed, within the scope of the organization's or person's duties under the law during or upon completion of an external review conducted under this subdivision, unless the opinion was rendered, or act or omission performed, in bad faith or involved gross negligence.

Section 2164.12. External review reporting requirements.

(a) Recordkeeping by IROs.--

(1) An IRO assigned under this subdivision to conduct an external review shall maintain written records in the aggregate for the entire Commonwealth and for each insurer or MA or CHIP managed care plan, on all requests for which the IRO conducted an external review during a calendar year.

(2) An IRO required to maintain written records under paragraph (1) on all requests for external review for which the IRO was assigned to conduct an external review shall submit to the department, upon request, a report in the format specified by the department.

(3) The report shall include in the aggregate, for the entire Commonwealth and for each insurer or MA or CHIP managed care plan:

(i) The total number of requests for external review.

(ii) The number of requests for external review resolve and, of those resolved, the number resolved upholding the adverse benefit determination or final adverse benefit determination and the number resolved reversing the adverse benefit determination or final adverse benefit determination.

(iii) The average length of time for external review request resolution.

(iv) A summary of the types of coverages or cases for which an external review was sought, provided in a format specified by the department.

(v) The number of external reviews under sections 2164.5 and 2164.7 that were terminated as the result of a reconsideration by the insurer of the adverse benefit determination or final adverse benefit determination after the receipt of additional information from the covered person or the covered person's authorized representative.

(vi) Other information the department may request or require.

(4) The IRO shall retain the written records required under this subsection for at least three years.

(b) Recordkeeping by insurers.--

(1) An insurer shall maintain written records in the aggregate, for the entire Commonwealth, for each type of health insurance policy offered by the insurer, on all requests for external review as to which the insurer receives notice from the department under this subarticle.

(2) An insurer required to maintain written records under paragraph (1) shall submit to the department, upon request, a report in the format specified by the department.

(3) The report shall include in the aggregate, for the entire Commonwealth and for each type of health insurance policy offered by the insurer:

(i) The total number of requests for external review.

(ii) Of the total number of requests for external review reported under subparagraph (i), the number of requests determined eligible for external review.

(iii) Other information the department may request or require.

(4) The insurer shall retain the written records required under this subsection for at least three years.

Section 2164.13. Funding of external review.

(a) Cost.--The insurer against which a request for standard external review or expedited external review under section 2164.5, 2164.6 or 2164.7 is filed shall pay the cost of the IRO to conduct the external review.

(b) Fees.--The fees charged by an IRO shall be reasonable and customary. The department shall annually transmit notice of the fees for the types of adverse benefit determinations under review to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

(c) No fee.--A covered person or the covered person's authorized representative may not be charged a fee in order to file a request for external review.

Section 2164.14. Availability of forms.

(a) General rule.--The department shall make available, in an electronic format and, upon request, in print format, any applicable forms adopted by the department related to an adverse benefit determination request, notice of initial determination by insurer, health care provider certification for expedited review, insurer annual report, IRO internal report and other forms specified by this subdivision.

(b) Location of forms.--Forms described in subsection (a) shall be posted on the department's publicly accessible Internet website.

(c) Amendment and revision.--If forms described in subsection (a) are amended or revised, the department shall transmit notice of the changes to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

Section 8. Section 2166, Subdivision (k) heading of Article XXI and sections 2171, 2181 and 2182 of the act are amended to read:

Section 2166. Prompt Payment of Claims.--(a) [A licensed] An insurer or [a] MA or CHIP managed care plan shall pay a clean claim submitted by a health care provider or covered person within forty-five (45) days of receipt of the clean claim.

(b) If [a licensed] an insurer or [a] MA or CHIP managed care plan fails to remit the payment as provided under subsection (a), interest at ten per centum (10%) per annum shall be added to the amount owed on the clean claim. Interest shall be calculated beginning the day after the required payment date and ending on the date the claim is paid. The [licensed] insurer or MA or CHIP managed care plan shall not be required to pay any interest calculated to be less than two ($2) dollars.

(k) [Health Care Provider and Managed Care Plan Protection] Conscience Protection.

Section 2171. [Health Care Provider and Managed Care Plan] Conscience Protection.--(a) [A] An insurer or MA or CHIP managed care plan shall not exclude, discriminate against or penalize any health care provider for its refusal to allow, perform, participate in or refer for health care services when the refusal of the health care provider is based on moral or religious grounds and that provider makes adequate information available to [enrollees] covered persons enrollees or, if applicable, prospective [enrollees] covered persons.

(b) No public institution, public official or public agency may take disciplinary action against, deny licensure or certification or penalize any person, association or corporation attempting to establish a [plan] health are coverage arrangement or operating, expanding or improving an existing insurer or MA or CHIP managed care plan because the person, association or corporation refuses to provide any particular form of health care services or other services or supplies covered by other insurers or MA or CHIP managed care plans when the refusal is based on moral or religious grounds.

Section 2181. Departmental Powers and Duties.--(a) [The department shall require that records] Records and documents submitted to [a] an insurer or MA or CHIP managed care plan or utilization review entity as part of any complaint [or], grievance, internal appeals or adverse benefit determination shall be made available to the department, upon request, for purposes of enforcement or compliance with this article.

(b) The department shall compile data received from [a] an insurer or MA or CHIP managed care plan on an annual basis regarding the number, type and disposition of complaints [and], grievances, internal appeals and adverse benefits determinations filed with [a] an insurer or MA or CHIP managed care plan under this article.

(c) The department shall issue guidelines identifying those provisions of this article that exceed or are not included in the "Standards for the Accreditation of Managed Care Organizations" published by the National Committee for Quality Assurance. These guidelines shall be published in the

Pennsylvania Bulletin and updated as necessary. Copies of the guidelines shall be made available to insurers, MA or CHIP managed care plans, health care providers and covered persons and enrollees upon request.

(d) The department [and the Insurance Department] shall ensure compliance with this article. The [appropriate] department [shall] may investigate potential violations of the article based upon information received from covered persons, enrollees, health care providers and other sources [in order to ensure compliance with this article].

[(e) The department and the Insurance Department shall promulgate such regulations as may be necessary to carry out the provisions of this article.]

(f) The department [in cooperation with the Insurance Department] shall submit an annual report to the General Assembly regarding the implementation, operation and enforcement of this article.

Section 2182. Penalties and Sanctions.--(a) The department [or the Insurance Department, as appropriate,] may impose a civil penalty of up to five thousand ($5,000) dollars for a violation of this article.

(b) [A] An insurer or MA or CHIP managed care plan shall be subject to the act of July 22, 1974 (P.L.589, No.205), known as the "Unfair Insurance Practices Act."

(c) The department [or the Insurance Department] may maintain an action in the name of the Commonwealth for an injunction to prohibit any activity which violates the provisions of this article.

(d) The department may issue an order temporarily prohibiting [a] an insurer or MA or CHIP managed care plan which violates this article from enrolling new [members] covered persons or enrollees.

(e) The department may require [a] an insurer or MA or CHIP managed care plan to develop and adhere to a plan of correction approved by the department. The department shall monitor compliance with the plan of correction. The plan of correction shall be available to covered persons or enrollees of the insurer or MA or CHIP managed care plan upon request.

[(f) In no event shall the department and the Insurance Department impose a penalty for the same violation.]

Section 9. The act is amended by adding a section to read:

Section 2184. Regulations.--The department may promulgate regulations as necessary and appropriate to carry out the provisions of this article.

Section 10. Sections 2191 and 2192(4) of the act are amended to read:

Section 2191. Compliance with National Accrediting Standards.--Notwithstanding any other provision of this article to the contrary, the department shall give consideration to [a] an insurer's or MA or CHIP managed care plan's demonstrated compliance with the standards and requirements set forth in the

"Standards for the Accreditation of Managed Care Organizations" published by the National Committee for Quality Assurance or other department-approved quality review organizations in determining compliance with the same or similar provisions of this article. The insurer or MA or CHIP managed care plan, however, shall remain subject to and shall comply with any other provisions of this article that exceed or are not included in the standards of the National Committee for Quality Assurance or other department-approved quality review organizations.

Section 2192. Exceptions.--This article shall not apply to any of the following:

* * *

(4) The fee-for-service programs operated by the Department of [Public Welfare] Human Services under Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1396 et seq.).

Section 11. Repeals are as follows:

(1) The General Assembly declares that the repeals under paragraph (2) are necessary to effectuate this act.

(2) The following acts and parts of acts are repealed to the extent specified:

(i) Section 630(e) and (f) of the act, insofar as they are inconsistent with this act.

(ii) The act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act, insofar as it is inconsistent with this act.

(iii) 40 Pa.C.S. Ch. 61, insofar as it is inconsistent with the this act.

(iv) 40 Pa.C.S. Ch. 63, insofar as it is inconsistent with the this act.

(v) All other parts of this act are repealed insofar as they are inconsistent with this act.

Section 12. Continuation is as follows:

(1) Except as otherwise required to comply with this act, activities initiated under Article XXI of the act prior to the effective date of this section shall continue and remain in full force and effect and may be completed under Article XXI of the act on and after the effective date of this section.

(2) Contracts and obligations entered into under Article XXI of the act prior to the effective date of this section shall not be affected or impaired by this act.

(3) Orders, regulations, rules and decisions of the Department of Health which were made under Article XXI of the act prior to the effective date of this section and which are in effect on the effective date of this section shall remain in full force and effect and shall be enforced by the department until revoked, vacated or modified by the department under Article XXI of the act.

Section 13. This act shall take effect as follows:

(1) The following provisions shall take effect immediately:

(i) Section 12 of this act.
(ii) Section 13 of this act
(iii) This section.
(2) The addition of section 2153 of the act shall take effect January 1, 2023.
(3) The remainder of this act shall take effect January 1, 2024.