

AMENDMENTS TO SENATE BILL NO. 225

Sponsor: REPRESENTATIVE PICKETT

Printer's No. 1837

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

4 in quality health care accountability and protection, further
5 providing for definitions, for responsibilities of managed
6 care plans, for financial incentives prohibition, for medical
7 gag clause prohibition, for emergency services, for
8 continuity of care, for procedures, for confidentiality, for
9 required disclosure and for internal complaint process,
10 providing for internal complaint process for enrollees,
11 further providing for appeal of complaint, for complaint
12 resolution, for certification and for operational standards,
13 providing for utilization review standards, further providing
14 for internal grievance process, for external grievance
15 process and for records, providing for adverse benefit
16 determinations, further providing for prompt payment of
17 claims, for health care provider and managed care plan
18 protection, for departmental powers and duties and for
19 penalties and sanctions, providing for regulations, further
20 providing for compliance with national accrediting standards
21 and for exceptions; making editorial changes; and making
22 repeals.

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

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

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

34 "Active clinical practice." The practice of clinical

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

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

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

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

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

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

30 (3) A rescission of coverage determination.

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

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

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

1 "Authorized representative." One of the following:

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

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

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

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

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

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

41 "Commissioner." The Insurance Commissioner of the
42 Commonwealth.

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

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

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

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

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

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

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

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

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

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

37 (2) serious impairment to bodily functions; or

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

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

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

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

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

1 (1) A general, special, psychiatric or rehabilitation
2 hospital.

3 (2) An ambulatory surgical facility.

4 (3) A cancer treatment center.

5 (4) A birth center.

6 (5) A skilled nursing center.

7 (6) An inpatient, outpatient or residential drug and alcohol
8 treatment facility.

9 (7) A laboratory, imaging, diagnostic or other outpatient
10 medical service or testing facility.

11 (8) A health care provider office or clinic.

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

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

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

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

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

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

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

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

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

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

- 12 (1) An accident only policy.
- 13 (2) A credit only policy.
- 14 (3) A long-term care or disability income policy.
- 15 (4) A specified disease policy.
- 16 (5) A Medicare supplement policy.
- 17 (6) A TRICARE policy, including a Civilian Health and
18 Medical Program of the Uniformed Services (CHAMPUS) supplement
19 policy.
- 20 (7) A fixed indemnity policy.
- 21 (8) A hospital indemnity policy.
- 22 (9) A dental only policy.
- 23 (10) A vision only policy.
- 24 (11) A workers' compensation policy.
- 25 (12) An automobile medical payment policy under 75 Pa.C.S.
26 (relating to vehicles).
- 27 (13) A homeowner's insurance policy.
- 28 (14) Any other similar policies providing for limited
29 benefits.

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

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

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

- 39 (1) This act, including section 630 and Article XXIV.
- 40 (2) The act of December 29, 1972 (P.L.1701, No.364), known
41 as the "Health Maintenance Organization Act."
- 42 (3) 40 Pa.C.S. Ch. 61 (relating to health plan corporations)
43 or 63 (relating to professional health services plan
44 corporations).

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

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

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

5 (1) Section 630.

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

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

10 (4) 40 Pa.C.S. Ch. 61 (relating to hospital plan
11 corporations).

12 (5) 40 Pa.C.S. Ch. 63 (relating to professional health
13 services plan corporations).

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

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

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

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

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

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

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

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

1 enrollee.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

32 (d) Nothing in this section shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 issued by a licensed health insurer.]

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

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

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

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

1 applicable for participating health care providers.

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

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

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

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

22 (1) Initial credentialing.

23 (2) Renewal of credentialing.

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

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

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

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

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

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

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

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

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

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

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

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

33 (2) Nothing in this section shall:

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

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

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

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

1 enrollees shall remain anonymous to the greatest extent
2 possible.

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

9 (f) Information for Covered
10 Persons and Enrollees.

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

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

25 For Insurers: This [managed care plan] health insurance
26 policy may not cover all your health care expenses. Read your
27 contract or member handbook carefully to determine which
28 health care services are covered.

29 For MA or CHIP managed care plans: Your managed care plan may
30 not cover all your health care expenses. Read your member
31 handbook carefully to determine which health care services
32 are covered.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 (c) (1) An insurer shall include a description of the
12 insurer's external review procedures in or attached to the
13 policy, certificate, membership booklet, outline of coverage or
14 other evidence of coverage the insurer provides to covered
15 persons, including whether the insurer has complied with the
16 surprise billing and cost-sharing protections under the No
17 Surprises Act (Pub. L. 116-260, Div. BB, Title I, 134 Stat.
18 2758).

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

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

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

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

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

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

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

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

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

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

1 (2) The allowance of a written or oral complaint.
2 (3) The allowance of written data or other information.
3 (4) A review or investigation of the complaint which shall
4 be completed within thirty (30) days of receipt of the
5 complaint.

6 (5) A written notification to the [enrollee] covered person
7 regarding the decision of the initial review committee within
8 five (5) business days of the decision. Notice shall include the
9 basis for the decision and the procedure to file a request for a
10 second level review of the decision of the initial review
11 committee.

12 (c) The complaint process shall include a second level
13 review that includes all of the following:

14 (1) A review of the decision of the initial review committee
15 by a second level review committee consisting of three or more
16 individuals who did not participate in the initial review. At
17 least one third of the second level review committee shall not
18 be employed by the [managed care plan] insurer.

19 (2) A written notification to the [enrollee] covered person
20 of the right to appear before the second level review committee.

21 (3) A requirement that the second level review be completed
22 within forty-five (45) days of receipt of a request for such
23 review.

24 (4) A written notification to the [enrollee] covered person
25 regarding the decision of the second level review committee
26 within five (5) business days of the decision. The notice shall
27 include the basis for the decision and the procedure for
28 appealing the decision to the department [or the Insurance
29 Department].

30 Section 3. The act is amended by adding a section to read:

31 Section 2141.1. Internal Complaint Process for Enrollees.--

32 (a) An MA or CHIP managed care plan shall establish and
33 maintain an internal complaint process by which an enrollee or
34 the enrollee's authorized representative shall be able to file a
35 complaint.

36 (b) The complaint process shall consist of a review to
37 include all of the following:

38 (1) A review by a review committee consisting of one or more
39 employees of the MA or CHIP managed care plan.

40 (2) The allowance of a written or oral complaint.

41 (3) The allowance of written data or other information.

42 (4) Written notification to the enrollee of the decision of
43 the review committee within thirty (30) days of receipt of the
44 complaint, unless the time frame for deciding the complaint has
45 been extended by up to fourteen (14) days at the request of the
46 enrollee.

47 (5) The written notification of the decision shall include
48 the basis for the decision and the procedure to file a request
49 for a second level review of the decision of the review
50 committee, except as provided in paragraph (6).

51 (6) The written notification of the decision shall include

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

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

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

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

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

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

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

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

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

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

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

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

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

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

48 (a) The following shall apply:

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

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

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

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

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

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

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

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

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

37 (h) Utilization Review Entity Standards.

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

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

51 (c) The department may adopt a nationally recognized

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

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

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

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

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

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

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

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

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

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

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

36 (4.1) If performing a utilization review for a request for
37 health care services for an covered person or enrollee of an
38 insurer or MA or CHIP managed care plan, provide notification
39 within the following time frames:

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

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

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

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

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

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

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

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

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

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

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

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

42 (h.1) Utilization Review Standards.
43 Section 2153. Provider portal.

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

48 (1) Electronic submission of prior authorization
49 requests.

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

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

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

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

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

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

18 (c) Required use of provider portal.--

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

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

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

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

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

36 Section 2154. Medical policies and clinical review criteria.

37 (a) Medical policies.--

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

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

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

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

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

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

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

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

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

18 (b) Clinical review criteria.--

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

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

24 (ii) Be consistent with applicable governmental
25 guidelines.

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

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

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

38 Section 2155. Prior authorization review.

39 (a) General rule.--

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

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

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

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

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

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

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

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

16 (c) Information submission.--

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

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

41 (d) Clinical knowledge of reviewer.--

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

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

49 (ii) A licensed health care provider, in
50 consultation with an appropriately qualified third-party
51 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

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

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

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

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

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

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

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

23 (3) The following shall apply:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Section 2156. Step therapy considerations.

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

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

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

27 (i) Contraindications, including adverse reactions.

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

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

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

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

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

46 Section 2157. Medication assisted treatment.

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

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

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

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

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

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

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

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

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

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

47 (1) A review of the decision issued pursuant to subsection

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

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

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

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

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

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

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

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

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

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

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

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

1 following requirements:

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

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

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

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

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

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

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

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

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

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

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

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

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

48 Section 2163. Records.--Records regarding grievances filed
49 under this subdivision that result in decisions adverse to
50 enrollees shall be maintained by the MA or CHIP managed care
51 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.

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

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

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

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

19 (i) If the covered person has a medical condition
20 for which the time frame for completion of an expedited
21 review of an adverse benefit determination under section
22 2164 would seriously jeopardize the life or health of the
23 covered person or would jeopardize the covered person's
24 ability to regain maximum function, the covered person,
25 or the covered person's authorized representative, may
26 file a request for an expedited external review at the
27 same time as a request for an expedited review of an
28 adverse benefit determination under section 2164. The IRO
29 assigned to conduct the expedited external review shall
30 determine whether the covered person is required to
31 complete the expedited review of the adverse benefit
32 determination prior to conducting the expedited external
33 review. The request may be filed under section 2164.6 or
34 2164.7 if:

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

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

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

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

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

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

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

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

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

31 (ii) If the final adverse benefit determination
32 concerns:

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

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

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

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

4 (4) A copy of the description of both the standard and
5 expedited external review procedures required by section
6 2136.1 that highlights the provisions in the external review
7 procedures regarding the opportunity to submit additional
8 information and any forms used to process an external review.

9 (5) An authorization form, or other document approved by
10 the department that complies with the requirements of 45 CFR
11 164.508 (relating to uses and disclosures for which an
12 authorization is required), by which the covered person, for
13 purposes of conducting an external review under this
14 subdivision, authorizes the insurer and the covered person's
15 treating health care provider to disclose protected health
16 information, including medical records, concerning the
17 covered person, that are pertinent to the external review.
18 Section 2164.3. Request for external review.

19 (a) Form of request.--

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

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

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

30 Section 2164.4. Exhaustion of internal appeal process.

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

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

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

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

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

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

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

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

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

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

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

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

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

40 (c) Denial of request for expedited external review.--If the
41 IRO determines that the covered person is required to first
42 complete the internal expedited appeal process under section
43 2164, the IRO shall within 24 hours notify the covered person
44 and, if applicable, the covered person's authorized
45 representative, that the IRO may not proceed with the expedited
46 external review under section 2164.6 until the insurer has
47 completed the expedited review process and the covered person's
48 adverse benefit determination appeal remains unresolved.

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

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

7 (a) Request for review.--

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

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

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

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

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

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

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

41 (c) Notice of initial determination.--

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

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

1 information or materials are needed to make the request
2 complete.

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

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

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

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

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

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

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

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

48 (e) Forwarding of required documents.--

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

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

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

14 (f) Review of information.--

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

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

24 (g) Reconsideration by insurer.--

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

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

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

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

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

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

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

3 (1) The covered person's medical records.

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

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

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

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

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

20 (7) The option opinion of the IRO's clinical reviewer or
21 reviewers after considering the information under paragraphs
22 (1), (2), (3), (4), (5) and (6).

23 (i) Notice of decision.--

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

29 (i) The covered person.

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

32 (iii) The insurer.

33 (iv) The department.

34 (2) The IRO shall include in the notice under paragraph
35 (1):

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

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

40 (iii) The date the external review was conducted.

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

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

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

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

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

1 24 hours approve the coverage that was the subject of the
2 adverse benefit determination or final adverse benefit
3 determination.

4 (j) Assignment of IRO.--The department shall assign on a
5 random basis an approved IRO from those qualified to conduct the
6 particular external review based on the nature of the health
7 care service that is the subject of the adverse benefit
8 determination or final adverse benefit determination, and shall
9 consider the conflict-of-interest concerns under section
10 2164.10(d).

11 Section 2164.6. Expedited external review.

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

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

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

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

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

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

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

41 (b) Preliminary review of request.--

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

45 (2) Within 24 hours upon receipt of a request under
46 paragraph (1), the insurer shall determine whether the
47 request meets the requirements for review under section
48 2164.5(b). The insurer shall, within 24 hours, notify the
49 department, the covered person and, if applicable, the
50 covered person's authorized representative of the insurer's
51 eligibility determination.

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

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

16 (5) Upon receipt of the notice that the request meets
17 the requirements for review, the department shall, within 24
18 hours, assign an IRO to conduct the expedited external review
19 from the list of approved IROs compiled and maintained by the
20 department under section 2164.9. The department shall, within
21 24 hours, notify the insurer of the name of the assigned IRO.

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

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

33 (1) Electronically.

34 (2) By telephone.

35 (3) By facsimile.

36 (4) By any other available expeditious method.

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

42 (1) The covered person's medical records.

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

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

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

51 (5) The most appropriate practice guidelines, which

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

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

8 (7) The opinion of the IRO's clinical reviewer or
9 reviewers after considering the information under paragraphs
10 (1), (2), (3), (4), (5) and (6).

11 (e) Notice of decision.--

12 (1) As expeditiously as the covered person's medical
13 condition or circumstances require, but in no event more than
14 72 hours after the date of receipt of the request for an
15 expedited external review that meets the reviewability
16 requirements under section 2164.5(b), the assigned IRO shall
17 provide notice of the IRO's decision to uphold or reverse the
18 adverse benefit determination or the final adverse benefit
19 determination to:

20 (i) The covered person.

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

23 (iii) The insurer.

24 (iv) The department.

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

30 (i) The covered person.

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

33 (iii) The insurer.

34 (iv) The department.

35 (3) The IRO shall include in the notice under paragraph
36 (2):

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

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

41 (iii) The date the external review was conducted.

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

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

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

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

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

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

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

8 (g) Assignment of IRO.--The department shall assign on a
9 random basis an approved IRO among those qualified to conduct
10 the particular external review based on the nature of the health
11 care service that is subject of the adverse benefit
12 determination or final adverse benefit determination, and shall
13 consider the conflict-of-interest concerns under section
14 2164.10(d).

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

18 (a) Request for review.--

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

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

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

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

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

51 (iii) The notice of initial determination under

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

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

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

28 (i) Electronically.

29 (ii) By telephone.

30 (iii) By facsimile.

31 (iv) By any other available expeditious method.

32 (b) Preliminary review request.--

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

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

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

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

51 (A) Is a covered benefit under the covered

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

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

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

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

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

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

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

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

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

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

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

48 (c) Notice of initial determination.--

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

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

3 (2) If the request:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

32 (e) Forwarding of required documents.--

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

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

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

1 person's authorized representative.

2 (f) Review of information.--

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

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

12 (g) Reconsideration by insurer.--

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

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

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

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

34 (5) The assigned IRO shall terminate the external review
35 upon receipt of the notice from the insurer under paragraph
36 (4).

37 (h) Clinical review process.--

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

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

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

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

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

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

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

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

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

15 (3) The following shall apply:

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

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

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

33 (1) The covered person's medical records.

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

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

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

42 (5) Whether either of the following is satisfied:

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

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

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

1 (B) The adverse risks of the recommended or
2 requested health care service would not be
3 substantially increased over the adverse risks of an
4 available standard health care service.
5 (j) Notice of decision.--
6 (1) Within 20 days of the date the assigned IRO receives
7 the opinion of a clinical reviewer, the assigned IRO shall
8 provide written notice of the assigned IRO's decision to
9 uphold or reverse the adverse benefit determination to:
10 (i) The covered person.
11 (ii) If applicable, the covered person's authorized
12 representative.
13 (iii) The insurer.
14 (iv) The department.
15 (2) If a majority of the clinical reviewers recommend
16 that:
17 (i) The recommended or requested health care service
18 be covered, the IRO shall make a decision to reverse the
19 insurer's adverse benefit determination or final adverse
20 benefit determination.
21 (ii) The recommended or requested health care
22 service not be covered, the IRO shall make a decision to
23 uphold the insurer's adverse benefit determination or
24 final adverse benefit determination.
25 (3) If the clinical reviewers are evenly divided as to
26 whether the recommended or requested health care service
27 should be covered:
28 (i) The IRO shall obtain the opinion of an
29 additional clinical reviewer in order for the IRO to make
30 a decision based on the opinions of a majority of the
31 clinical reviewers.
32 (ii) The additional clinical reviewer selected shall
33 use the same information to reach an opinion as the
34 clinical reviewers who have already submitted their
35 opinion.
36 (iii) The selection of the additional clinical
37 reviewer may not extend the time within which the
38 assigned IRO is required to make a decision.
39 (4) The IRO shall include the following in the notice
40 provided under paragraph (1):
41 (i) A general description of the reason for the
42 request for external review.
43 (ii) The written opinion of each clinical reviewer,
44 including the recommendation of each clinical reviewer as
45 to whether the recommended or requested health care
46 service should be covered and the rationale for the
47 reviewer's recommendation.
48 (iii) The date the IRO was assigned by the
49 department to conduct the external review.
50 (iv) The date of the external review.
51 (v) The date of the IRO's decision.

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

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

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

10 (k) Assignment of IRO.--The department shall assign, on a
11 random basis, an approved IRO among those qualified to conduct
12 the particular external review based on the nature of the health
13 care service that is the subject of the adverse benefit
14 determination or final adverse benefit determination, and shall
15 consider the conflict-of-interest concerns under section
16 2164.10(d).

17 Section 2164.8. Binding nature of external review decision.

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

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

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

31 Section 2164.9. Department approval of independent review
32 organizations.

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

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

39 (1) Except as otherwise provided in this section, be
40 accredited by a nationally recognized private accrediting
41 entity that the department has determined to possess IRO
42 accreditation standards that are equivalent to or exceed the
43 minimum qualifications for the IROs established under section
44 2611.1.

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

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

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

1 (d) Consideration of application.--

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

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

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

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

18 (e) Duration of approval.--

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

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

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

34 (g) No prohibition.--Nothing in this section or in section
35 2164.10 shall prohibit an entity certified as a utilization
36 review entity from being approved as an IRO.
37 Section 2164.10. Minimum qualifications for independent review
38 organizations.

39 (a) Requirements for department approval.--To be approved
40 under section 2164.9 to conduct external reviews and external
41 grievances, an IRO must establish and maintain written policies
42 and procedures that govern all aspects of both the standard and
43 expedited adverse benefit determination external review and
44 external grievance review required by sections 2162, 2162.6 and
45 2162.7 that include, at a minimum:

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

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

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

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

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

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

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

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

13 (2) A toll-free telephone service to receive information
14 24 hours per day, 7 days per week, related to external
15 reviews, that is capable of accepting, recording or providing
16 appropriate instruction to incoming telephone callers during
17 other-than-normal business hours.

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

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

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

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

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

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

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

50 (d) Conflicts of interest.--

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

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

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

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

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

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

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

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

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

31 (e) Accreditation.--

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

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

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

1 private accrediting entity that is not reviewed by the NAIC.
2 Section 2164.11. Hold harmless for independent review
3 organizations.

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

12 Section 2164.12. External review reporting requirements.

13 (a) Recordkeeping by IROs.--

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

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

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

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

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

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

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

40 (v) The number of external reviews under sections
41 2164.5 and 2164.7 that were terminated as the result of a
42 reconsideration by the insurer of the adverse benefit
43 determination or final adverse benefit determination
44 after the receipt of additional information from the
45 covered person or the covered person's authorized
46 representative.

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

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

51 (b) Recordkeeping by insurers.--

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

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

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

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

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

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

19 (4) The insurer shall retain the written records
20 required under this subsection for at least three years.
21 Section 2164.13. Funding of external review.

22 (a) Cost.--The insurer against which a request for standard
23 external review or expedited external review under section
24 2164.5, 2164.6 or 2164.7 is filed shall pay the cost of the IRO
25 to conduct the external review.

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

31 (c) No fee.--A covered person or the covered person's
32 authorized representative may not be charged a fee in order to
33 file a request for external review.
34 Section 2164.14. Availability of forms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 * * *

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

16 Section 11. Repeals are as follows:

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

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

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

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

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

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

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

32 Section 12. Continuation is as follows:

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

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

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

49 Section 13. This act shall take effect as follows:

50 (1) The following provisions shall take effect
51 immediately:

1 (i) Section 12 of this act.
2 (ii) Section 13 of this act
3 (iii) This section.
4 (2) The addition of section 2153 of the act shall take
5 effect January 1, 2023.
6 (3) The remainder of this act shall take effect January
7 1, 2024.