
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 225 Session of
2021

INTRODUCED BY MENTZER, ISAACSON, HOHENSTEIN, SCHLEGEL CULVER,
ZIMMERMAN, D. MILLER, GILLEN, THOMAS, KAUFFMAN, MARSHALL,
TOMLINSON, MALONEY, MALAGARI, OTTEN, O'MARA, EMRICK, MULLINS,
DUNBAR, KAUFER, KLUNK, SAYLOR, FEE, MIHALEK, ECKER, RAPP,
ORTITAY, DOWLING AND MARKOSEK, APRIL 1, 2021

REFERRED TO COMMITTEE ON INSURANCE, APRIL 1, 2021

AN ACT

1 Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An
2 act relating to insurance; amending, revising, and
3 consolidating the law providing for the incorporation of
4 insurance companies, and the regulation, supervision, and
5 protection of home and foreign insurance companies, Lloyds
6 associations, reciprocal and inter-insurance exchanges, and
7 fire insurance rating bureaus, and the regulation and
8 supervision of insurance carried by such companies,
9 associations, and exchanges, including insurance carried by
10 the State Workmen's Insurance Fund; providing penalties; and
11 repealing existing laws," in quality health care
12 accountability and protection, further providing for
13 definitions, for responsibilities of managed care plans,
14 providing for preauthorization standards and for
15 preauthorization costs, further providing for continuity of
16 care, providing for step therapy, further providing for
17 required disclosure, for operational standards and providing
18 for preauthorization and adverse determinations, for appeals,
19 for access requirements in service areas, for uniform
20 preauthorization form, for preauthorization exemptions and
21 for data collection and reporting; and making an editorial
22 change.

23 The General Assembly of the Commonwealth of Pennsylvania
24 hereby enacts as follows:

25 Section 1. The General Assembly finds that:

26 (1) Preauthorization of medical treatment, testing and

1 procedures was initially designed to reduce unnecessary cost
2 placed on insurers, insureds and providers.

3 (2) The process of preauthorization and the process to
4 appeal a preauthorization decision has not been updated in 20
5 years.

6 (3) The current preauthorization process has become
7 overly expansive, to the point where it is interfering with
8 the patient-provider relationship by inserting a third party
9 into the treatment decision-making process.

10 (4) The basic minimum requirements of this act are
11 necessary to ensure that the patient-provider relationship
12 remains paramount in making any decision on the course of
13 treatment.

14 Section 2. It is the intent of the General Assembly to
15 create clear definitions, notice requirements and processes for
16 the determination of authorizing insurance coverage for medical
17 treatment, procedures and testing prior to the patient receiving
18 the treatment, procedure and testing.

19 Section 3. The definitions of "emergency service,"
20 "enrollee," "grievance," "health care service," "prospective
21 utilization review," "retrospective utilization review,"
22 "utilization review" and "utilization review entity" in section
23 2102 of the act of May 17, 1921 (P.L.682, No.284), known as The
24 Insurance Company Law of 1921, are amended and the section is
25 amended by adding definitions to read:

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

29 * * *

30 "Administrative defect." Any deficiency, error, mistake or

1 missing information other than medical necessity that serves as
2 the basis of an adverse determination issued by a utilization
3 review entity as justification to deny preauthorization.

4 "Adverse determination." A decision made by a utilization
5 review entity from a preauthorization request that:

6 (1) the health care services furnished or proposed to an
7 insured are not medically necessary or result from an
8 administrative denial; or

9 (2) denies, reduces or terminates benefit coverage.

10 The term includes a decision to deny a step therapy exception
11 request under section 2118. The term does not include a decision
12 to deny, reduce or terminate services that are not covered for
13 reasons other than their medical necessity or experimental or
14 investigational nature.

15 * * *

16 "Appeal." A formal request, either orally or in writing, to
17 reconsider a determination not to authorize a health care
18 service prior to the service being provided. This does not
19 include a grievance filed under section 2161, relating to
20 reconsideration of a decision made after coverage has been
21 provided. The calculation of any deadline shall not commence
22 until written confirmation of an appeal is received. Nothing in
23 this definition precludes written confirmation of the appeal to
24 be submitted electronically or by facsimile.

25 "Appeal procedure." A formal process that permits an
26 insured, attending physician or his designee, facility or health
27 care practitioner on an insured's behalf to appeal an adverse
28 determination rendered by the utilization review entity or its
29 designee utilization review entity or agent.

30 "Authorization." A determination by a utilization review

1 entity that:

2 (1) A health care service has been reviewed and, based on
3 the information provided, satisfies the utilization review
4 entity's requirements for medical necessity.

5 (2) The health care service reviewed is a covered service.

6 (3) Payment will be made for the health care service.

7 * * *

8 "Clinical criteria." Policies, screening procedures,
9 determination rules, determination abstracts, clinical
10 protocols, practice guidelines and medical protocols that are
11 specified in a written document available for peer-to-peer
12 review by a peer within the same profession and specialty and
13 subject to challenge by an insured, a provider or a provider
14 organization when used as a basis to withhold preauthorization,
15 deny or otherwise modify coverage and that is used by a
16 utilization review entity to determine the medical necessity of
17 health care services. The criteria shall:

18 (1) Be based on nationally recognized standards.

19 (2) Be developed in accordance with the current standards of
20 national accreditation entities.

21 (3) Reflect community standards of care.

22 (4) Ensure quality of care and access to needed health care
23 services.

24 (5) Be evidence-based or based on generally accepted expert
25 consensus standards.

26 (6) Be sufficiently flexible to allow deviations from norms
27 when justified on a case-by-case basis.

28 (7) Be evaluated and updated if necessary at least annually.

29 "Clinical practice guidelines." A systematically developed
30 statement to assist in decision-making by health care providers

1 and enrollees relating to appropriate health care for specific
2 clinical circumstances and conditions.

3 * * *

4 "Emergency service." Any health care service provided to an
5 enrollee, including prehospital transportation or treatment by
6 emergency medical services providers, after the sudden onset of
7 a medical condition that manifests itself by acute symptoms of
8 sufficient severity or severe pain such that a prudent layperson
9 who possesses an average knowledge of health and medicine could
10 reasonably expect the absence of immediate medical attention to
11 result in:

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

15 (2) serious impairment to bodily functions; or

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

17 Emergency transportation and related emergency service provided
18 by a licensed ambulance service shall constitute an emergency
19 service.

20 ["Enrollee." Any policyholder, subscriber, covered person or
21 other individual who is entitled to receive health care services
22 under a managed care plan.]

23 "Expedited appeal." A formal request, either orally or in
24 writing, to reconsider an adverse determination not to authorize
25 emergency health care services or urgent health care services.

26 "Final adverse determination." An adverse determination that
27 has been upheld by a utilization review entity at the completion
28 of the utilization review entity's internal appeals process.

29 "Grievance." As provided in subdivision (i), a request by an
30 [enrollee] insured or a health care provider, with the written

1 consent of the [enrollee] insured, to have a managed care plan
2 or utilization review entity reconsider a decision solely
3 concerning the medical necessity and appropriateness of a health
4 care service after the service has been provided to the insured.

5 If the managed care plan is unable to resolve the matter, a
6 grievance may be filed regarding the decision that:

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

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

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

14 The term [does] shall not include a complaint.

15 * * *

16 "Health care service." Any [covered] treatment, admission,
17 procedure, test used to aid in diagnosis or the provision of the
18 applicable treatment, pharmaceutical product, medical supplies
19 and equipment or other services, including behavioral health[,
20 prescribed] or otherwise provided or proposed to be provided by
21 a health care provider to an enrollee under a managed care plan
22 contract.

23 * * *

24 "Medically necessary health care services." Health care
25 services that a prudent health care provider would provide to a
26 patient for the purpose of preventing, diagnosing or treating an
27 illness, injury, disease or its symptoms in a manner that is:

28 (1) in accordance with generally accepted standards of
29 medical practice based on clinical criteria;

30 (2) appropriate in terms of type, frequency, extent, site

1 and duration pursuant to clinical criteria; and
2 (3) not primarily for the economic benefit of the health
3 plans and purchasers or for the convenience of the patient,
4 treating physician or other health care provider.

5 "Medication assisted treatment" or "MAT." The use of
6 medications approved by the United States Food and Drug
7 Administration, including methadone, buprenorphine, alone or in
8 combination with naloxone, or naltrexone, in combination with
9 counseling and behavioral therapies, to provide a comprehensive
10 approach to the treatment of substance use disorders.

11 "NCPDP SCRIPT Standard." The National Council for
12 Prescription Drug 10 Programs SCRIPT Standard Version 201310,
13 the most recent standard adopted by the Department of Health and
14 Human Services or a subsequently related version, provided that
15 the new version is backward-compatible to the current version
16 adopted by the Department of Health and Human Services. The
17 NCPDP SCRIPT Standard applies to the provision of pharmaceutical
18 or pharmacological products.

19 "Nonurgent health care service." A health care service
20 provided to an enrollee that is not considered an emergency
21 service or an urgent health care service.

22 * * *

23 "Preauthorization." As follows:

24 (1) Formerly known as a prospective utilization review.

25 (2) The process by which a utilization review entity,
26 managed care organization or health care insurer determines the
27 medical necessity of otherwise covered health care services
28 prior to authorizing coverage and the rendering of the health
29 care services, including preadmission review, pretreatment
30 review, utilization and case management.

1 (3) The term includes a health insurer's or utilization
2 review entity's requirement that an insured or health care
3 practitioner notify the health insurer or utilization review
4 agent prior to providing a health care service. This
5 determination and any appeal therefrom shall be conducted prior
6 to the delivery or provision of a health care service and result
7 in a decision to approve or deny payment for the health care
8 service.

9 (4) The term may be used interchangeably with the term
10 "prior authorization."

11 * * *

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

17 * * *

18 "Retrospective utilization [review.] review" or
19 "retrospective review." A review by a utilization review entity
20 of all reasonably necessary supporting information which occurs
21 following delivery or provision of a health care service and
22 results in a decision to approve or deny payment for the health
23 care service[.], but may not be used to review a decision to
24 approve payment for health care services through
25 preauthorization.

26 * * *

27 "Step therapy exception." A step therapy protocol that is
28 overridden in favor of immediate coverage of the health care
29 provider's selected prescription drug.

30 "Step therapy protocol." A protocol, policy or program that

1 establishes the specific sequence in which medically appropriate
2 prescription drugs for a specified medical condition are used by
3 a particular patient and are covered by a managed care plan.

4 "Urgent health care service." A health care service deemed
5 by a provider to require expedited preauthorization review in
6 the event a delay may jeopardize life or health of the insured
7 or a delay in treatment could:

8 (1) negatively affect the ability of the insured to regain
9 maximum function; or

10 (2) subject the insured to severe pain that cannot be
11 adequately managed without receiving the care or treatment that
12 is the subject of the utilization review as quickly as possible.
13 The term does not include an emergency service or nonurgent
14 health care service.

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

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

23 (2) A health care provider's internal quality assurance or
24 utilization review process unless the review results in denial
25 of payment for a health care service.

26 "Utilization review entity." Any entity certified pursuant
27 to subdivision (h) that performs utilization review on behalf of
28 a managed care plan. The term includes any of the following:

29 (1) An employer with employes in this Commonwealth who are
30 covered under a health benefit plan or health insurance policy.

1 (2) An insurer that writes health insurance policies,
2 including preferred provider organizations defined in section
3 630.

4 (3) Pharmacy benefits managers responsible for managing
5 access of insureds to available pharmaceutical or
6 pharmacological care.

7 (4) Any other individual or entity that provides, offers to
8 provide or administers hospital, outpatient, medical or other
9 health benefits to an individual treated by a health care
10 provider in this Commonwealth under a policy, plan or contract.

11 (5) A health insurer if the health insurer performs
12 utilization review.

13 Section 4. Section 2111 of the act is amended by adding
14 paragraphs to read:

15 Section 2111. Responsibilities of Managed Care Plans.--A
16 managed care plan shall do all of the following:

17 * * *

18 (14) Make updates to its enrollment eligibility information
19 within thirty (30) days of receiving updated enrollment
20 information. Updates in enrollment eligibility may occur due to
21 new enrollments, coordination of benefits or termination of
22 benefits. If a managed care plan fails to update eligibility
23 information in a timely manner, the managed care plan may not
24 deny payment due to enrollment information being inaccurate for
25 a date of service if current eligibility information was
26 available. In the event of a retroactive termination or a
27 determination that an enrollee was ineligible for benefits, a
28 health plan may recover any payments made in error within ninety
29 (90) days of the date of service.

30 (15) When establishing rules pertaining to the timely filing

1 of health care provider claims, provide that a health care
2 provider's filing requirement will commence based on the
3 following, whichever occurs latest:

- 4 (i) the time of patient discharge; or
- 5 (ii) when authorization or approval is confirmed by the
6 managed care plan.

7 Section 5. The act is amended by adding sections to read:

8 Section 2114. Preauthorization Standards.--(a) No later
9 than one hundred eighty (180) days after the effective date of
10 this section, prior authorization requests shall be accessible
11 to health care providers and accepted by insurers, managed care
12 organizations and utilization review organizations
13 electronically through a secure electronic transmission
14 platform. The electronic preauthorization requirements under
15 this subsection do not apply:

16 (1) Under circumstances when electronic transmission is not
17 available to be issued or received due to a temporary
18 technological or electrical failure. In the instance of a
19 temporary technological failure, a practitioner shall, within
20 seventy-two (72) hours, seek to correct any cause for the
21 failure that is reasonably within the control of the
22 practitioner.

23 (2) When a practitioner or health care facility does not
24 have any of the following:

- 25 (i) Internet access.
- 26 (ii) An electronic health record system.
- 27 (b) NCPDP SCRIPT Standard shall be acceptable for
28 pharmaceutical or pharmacological care, subject to the terms and
29 limitations of subsection (a).

30 (c) Any restriction that a utilization review entity places

1 on the preauthorization of health care services shall be:

2 (1) based on the medical necessity of those services and on
3 clinical criteria;

4 (2) applied consistently; and

5 (3) disclosed by the managed care plan or utilization review
6 entity in accordance with section 2136.

7 (d) Adverse determinations and final adverse determinations
8 made by a utilization review entity or agent thereof shall be
9 based on clinical criteria.

10 (e) A utilization review entity shall not deny coverage of a
11 health care service solely based on the grounds that the health
12 care service does not meet clinical criteria.

13 (f) Preauthorization shall not be required:

14 (1) where a medication, including noncontrolled generic
15 medication or procedure prescribed for a patient is customary
16 and properly indicated or is a treatment for the clinical
17 indication as supported by peer-reviewed medical publications;
18 or

19 (2) for the provision of MAT for the treatment of an opioid-
20 use disorder.

21 (g) A managed care plan may not deny preauthorization for a
22 health care service for an insured currently managed with an
23 established treatment regimen or for continuity of care. The
24 continued care shall also not be subject to concurrent review if
25 the treatment regimen or continuity of care follows from a
26 previous preauthorization approval.

27 (h) If a provider contacts a utilization review entity
28 seeking preauthorization, a medically necessary health care
29 service and the utilization review entity, through any agent,
30 contractor, employe or representative informs the provider that

1 preauthorization is not required for the particular service that
2 is sought, coverage for the service shall be deemed approved.

3 (i) No later than one hundred eighty (180) days after the
4 effective date of this section, the payer shall accept and
5 respond to preauthorization requests under the pharmacy benefit
6 through a secure electronic transmission using the NCPDP SCRIPT
7 Standard ePA transactions.

8 Section 2115. Preauthorization Costs.--(a) In the event
9 that an insured is covered by more than one health plan that
10 requires preauthorization:

11 (1) If preauthorization for a health care service has been
12 approved by a primary insurer, a secondary insurer or defined
13 benefits plan shall not refuse payment for health care services
14 solely on the basis that the procedures of the secondary insurer
15 for preauthorization were not followed.

16 (2) Nothing in this section shall be construed to preclude a
17 secondary insurer or defined benefits plan from preauthorizing a
18 health care service that may have been denied preauthorization
19 by a primary insurer.

20 (b) An appeal of an adverse determination or external review
21 of a final adverse determination shall be provided without
22 charge to the insured or insured's health care provider.

23 Section 6. Section 2117 of the act is amended by adding
24 subsections to read:

25 Section 2117. Continuity of Care.--* * *

26 (g) If the appeal of an adverse determination of a
27 preauthorization request concerns ongoing health care services
28 that are being provided pursuant to an initially authorized
29 admission or course of treatment, the health care services shall
30 be continued to be paid and provided without liability to the

1 insured or insured's health care provider until the latest of:
2 (1) thirty (30) days following the insured or insured's
3 health care provider's receipt of a notice of final adverse
4 determination satisfying the requirements of this act, if the
5 decision on adverse determination has been appealed through an
6 external review proceeding;

7 (2) the duration of treatment; or

8 (3) sixty (60) days.

9 (h) The insured shall receive services for the longest
10 possible time calculated under this section.

11 (i) The insurer shall not be permitted to retroactively
12 review the decision to approve and provide health care services
13 through preauthorization, including preauthorizing for extending
14 the term or course of treatment.

15 (j) Notwithstanding any other provision of law, the insurer
16 shall not retroactively recover the cost of treatment either for
17 the initial period of treatment or the period of treatment
18 provided to the insured as part of the decision-making process
19 to authorize coverage of additional treatment periods.

20 Section 7. The act is amended by adding a section to read:

21 Section 2118. Step Therapy.--(a) Clinical review criteria
22 used to establish a step therapy protocol shall be based on
23 clinical practice guidelines that:

24 (1) Recommend that the prescription drugs be taken in the
25 specific sequence required by the step therapy protocol.

26 (2) Are developed and endorsed by a multidisciplinary panel
27 of experts that manages conflicts of interest among the members
28 of the writing and review groups by:

29 (i) Requiring members to disclose any potential conflict of
30 interest with an entity, including an insurer, health plan and

1 pharmaceutical manufacturer, and recuse themselves from voting
2 if they have a conflict of interest.

3 (ii) Using a methodologist to work with writing groups to
4 provide objectivity in data analysis and ranking of evidence
5 through the preparation of evidence tables and facilitating
6 consensus.

7 (iii) Offering opportunities for public review and comments.

8 (3) Are based on high-quality studies, research and medical
9 practice.

10 (4) Are created by an explicit and transparent process that:

11 (i) Minimizes biases and conflicts of interest.

12 (ii) Explains the relationship between treatment options and
13 outcomes.

14 (iii) Rates the quality of evidence supporting
15 recommendations.

16 (iv) Considers relevant patient subgroups and preferences.

17 (5) Are continually updated through a review of new
18 evidence, research and newly developed treatments.

19 (6) Use peer-reviewed publications in the absence of
20 clinical guidelines that meet the requirements of this act.

21 (b) When establishing a step therapy protocol, a utilization
22 review agent shall also take into account the needs of atypical
23 patient population and diagnoses when establishing clinical
24 review criteria.

25 (c) An insurer, pharmacy benefit manager or utilization
26 review organization shall:

27 (1) Upon written request, provide all specific written or
28 clinical review criteria relating to the particular condition or
29 disease, including clinical review criteria relating to a step
30 therapy protocol override determination.

1 (2) Make available clinical review criteria and other
2 clinical information on the publicly accessible Internet website
3 of the insurer, pharmacy benefit manager or utilization review
4 organization and to a health care professional on behalf of an
5 insured upon written request.

6 (d) This section shall not be construed to require an
7 insurer, health plan or the Commonwealth to establish a new
8 entity to develop clinical review criteria used for step therapy
9 protocols.

10 (e) When coverage of a prescription drug for the treatment
11 of a medical condition is restricted for use by an insurer,
12 health plan or utilization review organization through the use
13 of a step therapy protocol, the patient and prescribing
14 practitioner shall have access to a clear, readily accessible
15 and convenient process to request a step therapy exception. An
16 insurer, health plan or utilization review organization may use
17 its existing medical exceptions process to satisfy this
18 requirement. The process shall be made easily available on the
19 publicly accessible Internet website of the insurer, health plan
20 or utilization review organization. An insurer, health plan or
21 utilization review organization shall disclose all rules and
22 criteria related to the step therapy protocol upon request to
23 all prescribing practitioners, including the specific
24 information and documentation that must be submitted by a
25 prescribing practitioner or patient to be considered a complete
26 exception request.

27 (f) A step therapy exception shall be expeditiously granted
28 if:

29 (1) The required prescription drug is contraindicated or
30 likely will cause an adverse reaction by, or physical or mental

1 harm to, the patient.

2 (2) The required prescription drug is expected to be
3 ineffective based on the known clinical characteristics of the
4 patient and the known characteristics of the prescription drug
5 regimen.

6 (3) The patient has tried the required prescription drug
7 while under the current or a previous health insurance or health
8 benefit plan or another prescription drug in the same
9 pharmacologic class or with the same mechanism of action and the
10 prescription drug was discontinued due to lack of efficacy or
11 effectiveness, diminished effect or an adverse event.

12 (4) The required prescription drug is not in the best
13 interests of the patient based on medical necessity.

14 (5) The patient is stable on a prescription drug selected by
15 the patient's health care provider for the medical condition
16 under consideration while on a current or previous health
17 insurance or health benefit plan.

18 (g) Upon the granting of a step therapy exception, the
19 insurer, health plan or utilization review organization shall
20 authorize coverage for the prescription drug prescribed by the
21 patient's treating health care provider.

22 (h) The insurer, health plan or utilization review
23 organization shall grant or deny a step therapy exception
24 request or an appeal within seventy-two (72) hours of receipt.
25 In situations where exigent circumstances exist, the insurer,
26 health plan or utilization review organization shall respond
27 within twenty-four (24) hours of receipt. If a request for a
28 step therapy override exception is incomplete or additional
29 clinically relevant information is required, the insurer, health
30 plan or utilization review organization shall notify the

1 prescribing practitioner within seventy-two (72) hours of
2 submission, or twenty-four (24) hours in exigent circumstances,
3 of the additional or clinically relevant information required to
4 approve or deny the step therapy exception request or appeal
5 pursuant to the criteria disclosed in this section. Once the
6 requested information is submitted, the applicable time period
7 to grant or deny a step therapy exception request or appeal
8 shall apply. If a determination or request for incomplete or
9 clinically relevant information by an insurer, health plan or
10 utilization review organization is not received by the
11 prescribing practitioner within the time allotted, the exception
12 or appeal shall be deemed granted. In the event of a denial, the
13 insurer, health plan or utilization review organization shall
14 inform the patient of a potential appeal process.

15 (i) Any step therapy exception, as defined under this
16 section, shall be eligible for appeal by an insured.

17 (j) This section shall not be construed to prevent:

18 (1) An insurer, health plan or utilization review
19 organization from requiring a patient to try an AB-rated generic
20 equivalent or interchangeable biological product, as defined by
21 42 U.S.C. § 262(i)(3) (relating to regulation of biological
22 products), unless the requirement meets any of the criteria
23 under this section pursuant to a step therapy exception request
24 submitted under this section, prior to providing coverage for
25 the equivalent branded prescription drug.

26 (2) An insurer, health plan or utilization review
27 organization from requiring a pharmacist to effect substitutions
28 of prescription drugs consistent with State law.

29 (3) A health care provider from prescribing a prescription
30 drug that is determined to be medically appropriate.

1 (k) Notwithstanding any other provision of law, the
2 Insurance Department shall promulgate regulations necessary to
3 enforce this section.

4 (l) On an annual basis, an insurer, health plan or
5 utilization review organization shall report to the Insurance
6 Department, in a format prescribed by the Insurance Department,
7 the following:

8 (1) The number of step therapy exception requests received
9 by exception as provided in this section, including:

10 (i) The number that were denied and the reason for the
11 denial.

12 (ii) The number that were approved.

13 (iii) The number that were initially denied and then
14 appealed.

15 (iv) The number that were initially denied and then
16 subsequently reversed by internal appeal or external review.

17 (2) The type of health care providers or the medical
18 specialties of the health care providers submitting step therapy
19 exception requests.

20 (3) The medical conditions for which patients are granted
21 exceptions due to the likelihood that switching from the
22 prescription drug will likely cause an adverse reaction or
23 physical or mental harm to the insured.

24 (m) Notwithstanding any other definition under this act, as
25 used in this section, the following words and phrases shall have
26 the meanings given to them in this subsection:

27 "Clinical practice guidelines." A systematically developed
28 statement to assist decision making by health care providers and
29 patient decisions about appropriate health care for specific
30 clinical circumstances and conditions.

1 "Clinical review criteria." The written screening
2 procedures, decision abstracts, clinical protocols and practice
3 guidelines used by an insurer, health plan or utilization review
4 organization to determine the medical necessity and
5 appropriateness of health care services.

6 "Medically necessary." Health services and supplies that
7 under the applicable standard of care are appropriate:

8 (1) to improve or preserve health, life or function;
9 (2) to slow the deterioration of health, life or function;

10 or

11 (3) for the early screening, prevention, evaluation,
12 diagnosis or treatment of a disease, condition, illness or
13 injury.

14 "Step therapy exception." A step therapy protocol that
15 should be overridden in favor of immediate coverage of the
16 health care provider's selected prescription drug.

17 "Step therapy protocol." A protocol, policy or program that
18 establishes the specific sequence in which prescription drugs
19 for a specified medical condition and medically appropriate for
20 a particular patient are covered by an insurer or health plan.

21 "Utilization review organization." An entity that conducts
22 utilization review, other than insurer or health plan performing
23 utilization review for its own health benefit plans.

24 Section 8. Article XXI, Subdivision (f) subheading of the
25 act is amended to read:

26 (f) Information for Enrollees and Health Care Providers.

27 Section 9. Section 2136 of the act is amended by adding a
28 subsection to read:

29 Section 2136. Required Disclosure.--* * *

30 (c) If a utilization review entity intends to implement a

1 new preauthorization requirement or restriction or amend an
2 existing requirement or restriction, the utilization review
3 entity shall provide contracted health care providers and
4 insureds with written notice of the new or amended requirement
5 or amendment not less than sixty (60) days before the
6 requirement or restriction is implemented. The notice shall be
7 in writing. The requirement that the notice shall be in writing
8 may be satisfied by any of the following:

9 (1) Certified mail, return receipt requested.

10 (2) Electronic mail, read receipt requested.

11 (3) Publication on the website of the insurer with an
12 electronic mail message to providers and insureds that
13 identifies the location of the publication on the website.

14 (4) Web-exchange, provided that an electronic mail message
15 on how to access the web-exchange is sent to the providers and
16 insureds.

17 (5) Any other contractually agreed-upon method that
18 specifies the details of the communication which include some
19 proof of receipt by the providers and insureds.

20 Section 10. Section 2152(a)(4) and (6) of the act are
21 amended and the section is amended by adding subsections to
22 read:

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

25 * * *

26 (4) Conduct utilization reviews based on the medical
27 necessity and appropriateness of the health care service being
28 reviewed and provide notification within the following time
29 frames:

30 (i) A prospective utilization review decision shall be

1 communicated within two (2) business days of the receipt of all
2 supporting information reasonably necessary to complete the
3 review.

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

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

12 (iv) A utilization review entity shall allow an insured and
13 the insured's health care provider a minimum of one (1) business
14 day following an inpatient admission pursuant to an emergency
15 health care service or urgent health care service to notify the
16 utilization review entity of the admission and any health care
17 services performed.

18 * * *

19 (6) Provide all decisions in writing to include the basis
20 and clinical rationale for the decision. For adverse
21 determinations of preauthorization decisions, a utilization
22 review entity shall provide all decisions to the insured and the
23 insured's health care provider, which decisions shall also
24 include instructions concerning how an appeal may be perfected.
25 Utilization review entities may not retroactively review the
26 medical necessity of a preauthorization that has been previously
27 approved or granted.

28 * * *

29 (9) Post to the utilization review entity's publicly
30 accessible Internet website:

1 (i) A current list of services and supplies requiring
2 preauthorization.

3 (ii) Written clinical criteria for preauthorization
4 decisions.

5 (10) Ensure that a preauthorization shall be valid for one
6 hundred eighty (180) days or the duration of treatment,
7 whichever is greater, from the date the health care provider
8 receives the preauthorization so long as the insured is a member
9 of the plan. A duration of fewer than one hundred eighty (180)
10 days may be approved upon an agreement between a provider and
11 payer.

12 (11) When performing preauthorization, only request copies
13 of medical records if a difficulty develops in determining the
14 medical necessity of a health care service. In that case, the
15 utilization review agent may only request the necessary and
16 relevant sections of the medical record.

17 (12) Not deny preauthorization nor delay preauthorization
18 for administrative defects. In the event an administrative
19 defect is discovered, a managed care plan shall allow a health
20 care provider the opportunity to remedy the administrative
21 defect within thirty (30) days of receiving notice.

22 * * *

23 (e) Failure by a utilization review entity to comply with
24 deadlines and other requirements specified for preauthorization
25 shall result in the health care service subject to review to be
26 deemed preauthorized and paid by the managed care plan.

27 (f) A utilization review entity shall approve claims for
28 health care services for which a preauthorization was required
29 and received from the managed care plan prior to the rendering
30 of the health care services, unless one of the following occurs:

1 (1) The enrollee was not eligible for coverage at the time
2 the health care service was rendered. A managed care plan may
3 not deny payment for a claim on this basis if the enrollee's
4 coverage was retroactively terminated more than one hundred
5 twenty (120) days after the date of service, provided the claim
6 is submitted timely. If the claim is submitted after the timely
7 filing deadline, the managed care plan shall have no more than
8 thirty (30) days after the claim is received to deny the claim
9 on the basis the enrollee was not eligible for coverage on the
10 date of the health care service.

11 (2) The preauthorization was based on materially inaccurate
12 or incomplete information provided by the enrollee, the
13 enrollee's designee or the health care provider, such that if
14 the correct or complete information had been provided, the
15 preauthorization would not have been granted.

16 (3) There is a reasonable basis supported by material facts
17 available for review that the enrollee, the enrollee's designee
18 or the health care provider has engaged in fraud or abuse.

19 Section 11. The act is amended by adding sections to read:

20 Section 2161.1. Preauthorization and Adverse
21 Determinations.--(a) A utilization review entity shall ensure
22 that:

23 (1) Preauthorizations are made by a qualified licensed
24 health care provider who has knowledge of the items, services,
25 products, tests or procedures submitted for preauthorization.

26 (2) Adverse determinations are made by a physician. The
27 reviewing physician must possess a current and valid
28 nonrestricted license to practice medicine in this Commonwealth
29 and be board certified. However, the insurer shall make
30 available a physician in a like specialty if the review requires

1 a peer-to-peer review in the specialty or sub-specialty or the
2 review is requested by the submitting provider. A utilization
3 review entity may seek approval from the Insurance Commissioner
4 to use a reviewing physician that is not board-certified due to
5 unavailability or difficulty in finding a board-certified
6 reviewing physician in a given specialty. The Insurance
7 Commissioner shall develop a form and parameters for the
8 requests and shall transmit all requests as notices to the
9 Legislative Reference Bureau for publication in the Pennsylvania
10 Bulletin. The Insurance Commissioner shall provide at least ten
11 (10) days for comment before rendering a decision, which
12 decision shall be transmitted to the Legislative Reference
13 Bureau as a separate notice for publication in the Pennsylvania
14 Bulletin.

15 (b) Notification of a preauthorization shall be accompanied
16 by a unique preauthorization number and indicate:

17 (1) The specific health care services preauthorized.

18 (2) The next date for review.

19 (3) The total number of days approved.

20 (4) The date of admission or initiation of services, if
21 applicable.

22 (c) Neither the utilization review entity nor the payer or
23 health insurer that has retained the utilization review entity
24 may retroactively deny coverage for emergency or nonemergency
25 care that had been preauthorized when the care was provided, if
26 the information provided was accurate.

27 (d) In the event a health care provider obtains
28 preauthorization for one (1) service but the service provided is
29 not an exact match to the service that was preauthorized, but
30 the service does not materially depart from the service that was

1 preauthorized, a health plan shall not deny payment for the
2 service only if:

3 (1) the date of service differs by less than thirty (30)
4 days;

5 (2) the physician or health care provider rendering the
6 service differs from the physician or health care provider that
7 was indicated on the preauthorization, but is otherwise licensed
8 and qualified to provide the preauthorized service; or

9 (3) the service provided is different than what was
10 preauthorized but is commonly and appropriately a substitute
11 based on common procedural terminology.

12 (e) If the denial of preauthorization is conditioned upon
13 incomplete information or administrative error, the health plan
14 shall allow the health care provider to resubmit the claim with
15 corrected information for appropriate reimbursement within
16 thirty (30) days of receiving notice.

17 (f) (1) If a utilization review entity questions the
18 medical necessity of a health care service, the utilization
19 review entity shall notify the insured's health care provider
20 that medical necessity is being questioned and provide the basis
21 of the challenge in sufficient detail to allow the provider to
22 meaningfully address the concern of the utilization review
23 entity prior to issuing an adverse determination.

24 (2) The insured's health care provider or the health care
25 provider's designee and the insured or insured's designee shall
26 have the right to discuss the medical necessity of the health
27 care service with the utilization review physician.

28 (3) A utilization review entity questioning medical
29 necessity of a health care service which may result in an
30 adverse determination shall make the reviewing physician or a

1 physician who is part of a team making the decision available
2 telephonically between the hours of seven (7) o'clock
3 antemeridian and seven (7) o'clock postmeridian.

4 (g) When making a determination based on medical necessity,
5 a utilization review entity shall base the determination on an
6 insured's presenting symptoms, diagnosis and information
7 available through the course of treatment or at the time of
8 admission or presentation at the emergency department.

9 (h) In the event a utilization review entity determines an
10 alternative level of care is appropriate, the utilization review
11 entity shall provide and cite the specific criteria used as the
12 basis for the level of care determination to the health care
13 provider, prior to denial to enable a meaningful peer-to-peer
14 review. If, after the peer-to-peer review has been completed,
15 denial remains the determination, the health care provider shall
16 have the right to appeal the determination.

17 (i) A utilization review entity may not issue an adverse
18 determination for a procedure due to lack of preauthorization if
19 the procedure is medically necessary or clinically appropriate
20 for the patient's medical condition and rendered at the same
21 time as a related procedure for which preauthorization was
22 required and received.

23 (j) A utilization review entity shall make a
24 preauthorization or adverse determination and notify the insured
25 and the insured's health care practitioner as follows:

26 (1) For nonurgent health care services, within seventy-two
27 (72) hours of obtaining all the necessary information to make
28 the preauthorization or adverse determination.

29 (2) For urgent health care services, within twenty-four (24)
30 hours of obtaining all the necessary information to make the

1 preauthorization or adverse determination.

2 (k) No utilization review entity may require
3 preauthorization for an emergency service, including
4 postevaluation and poststabilization services.

5 Section 2161.2. Appeals.--(a) An insured or the insured's
6 health care provider may request an expedited appeal of an
7 adverse determination via telephone, facsimile, electronic mail
8 or other expeditious method. Within one (1) day of receiving an
9 expedited appeal and all information necessary to decide the
10 appeal, the utilization review entity shall provide the insured
11 and the insured's health care provider written confirmation of
12 the expedited review determination.

13 (b) An appeal shall be reviewed only by a physician who
14 satisfies any of the following conditions:

15 (1) Is board certified in the same specialty as a health
16 care practitioner who typically manages the medical condition or
17 disease.

18 (2) Is currently in active practice, provided that if
19 circumstances so justify or the provider seeking
20 preauthorization specifically requests a health care provider
21 actively engaged in the specialty who typically manages the
22 medical condition or disease, such a physician shall be made
23 available for the review.

24 (3) Is knowledgeable of, and has experience in, providing
25 the health care services under appeal.

26 (4) Is under contract with a utilization review entity to
27 perform reviews of appeals and payment of fees due under the
28 contract, but the performance and payment is not subject to or
29 contingent upon the outcome of the appeal.

30 The physician may also be subject to a provider agreement

1 with the insurer as a provider, but may not receive any other
2 fee or compensation from the insurer. The physician's receipt of
3 compensation from the utilization review entity shall not be
4 considered by the physician in determining the conclusion
5 reached by the physician. The physician shall at all times
6 render independent and accurate medical judgment in reaching an
7 opinion or conclusion. Failure to comply with this provision
8 shall render the physician subject to licensure disciplinary
9 action by the appropriate State licensing board.

10 (5) Not involved in making the adverse determination.

11 (6) Familiar with all known clinical aspects of the health
12 care services under review, including all pertinent medical
13 records provided to the utilization review entity by the
14 insured's health care provider and any relevant record provided
15 to the utilization review entity by a health care facility.

16 (c) The utilization review entity shall ensure that appeal
17 procedures satisfy the following requirements:

18 (1) The insured and the insured's health care provider may
19 challenge the adverse determination and have the right to appear
20 in person before the physician who reviews the adverse
21 determination.

22 (2) The utilization review entity shall provide the insured
23 and the insured's health care provider with written notice of
24 the time and place concerning where the review meeting will take
25 place. Notice shall be given to the insured's health care
26 provider at least fifteen (15) days in advance of the review
27 meeting.

28 (3) If the insured or the insured's health care provider
29 appear in person, the utilization review entity shall offer the
30 insured or insured's health care provider the opportunity to

1 communicate with the reviewing physician, at the utilization
2 review entity's expense, by conference call, videoconferencing
3 or other available technology.

4 (4) The physician performing the review of the appeal shall
5 consider all information, documentation or other material
6 submitted in connection with the appeal without regard to
7 whether the information was considered in making the adverse
8 determination.

9 (d) The following deadlines shall apply to the utilization
10 review entities:

11 (1) A utilization review entity shall decide an expedited
12 appeal and notify the insured and the insured's health care
13 provider of the determination within three (3) days after
14 receiving a notice of expedited appeal by the insured or the
15 insured's health care provider and all information necessary to
16 decide the appeal.

17 (2) A utilization review entity shall issue a written
18 determination concerning a nonexpedited appeal not later than
19 thirty (30) days after receiving a notice of appeal from an
20 insured or insured's health care provider and all information
21 necessary to decide the appeal.

22 (e) Written notice of final adverse determinations shall be
23 provided to the insured and the insured's health care provider.

24 (f) If the insured or the insured's health care provider or
25 a designee on behalf of either the insured or the insured's
26 health care provider has satisfied all necessary requirements
27 for the appeal of an adverse determination through the
28 preauthorization process and the appeal has resulted in a
29 continued adverse determination either based on lack of medical
30 necessity or an administrative defect, the insured, the

1 insured's health care provider or a designee on behalf of either
2 the insured or the insured's health care provider or a designee
3 may file a consumer complaint with the Insurance Department. The
4 complaint shall be adjudicated without unnecessary delay and a
5 determination shall be issued by the Insurance Department with
6 appropriate sanctions, if applicable, pursuant to the authority
7 given to the Insurance Department.

8 (g) To the extent that an insured, an insured's health care
9 provider or a designee on behalf of either the insured or the
10 insured's health care provider or a designee files a consumer
11 complaint with the department or the Office of Attorney General
12 pursuant to their authority to receive such complaints, a copy
13 of the complaint filed with either the department or the Office
14 of Attorney General shall be forwarded to the Insurance
15 Department and the copy shall serve as a new consumer complaint
16 to be adjudicated pursuant to the terms of this section and all
17 other applicable law.

18 (h) Nothing in this section shall be construed to preclude
19 the ability of an insured or an insured's designee to file a
20 separate consumer complaint with the Insurance Department for
21 failure to comply with the requirements of this act as it
22 applies to preauthorization processes or denial of health
23 insurance coverage generally.

24 Section 2195. Access Requirements in Service Areas.--If a
25 patient's safe discharge is delayed for any reason, including
26 lack of available posthospitalization services such as skilled
27 nursing facilities, home health services and postacute
28 rehabilitation, the managed care plan shall reimburse the
29 hospital for each subsequent date of service at the greater of
30 the contracted rate with the managed care plan for the current

1 level of care and service or the full diagnostic related group
2 payment divided by the mean length of stay for the particular
3 diagnostic related group.

4 Section 2196. Uniform Preauthorization Form.--(a) Within
5 three (3) months of the effective date of this section, the
6 Insurance Department shall convene a panel to develop a uniform
7 preauthorization form that all health care providers in this
8 Commonwealth shall use to request preauthorization and that all
9 health insurers shall accept as sufficient to request
10 preauthorization of health care services.

11 (b) The panel shall consist of not fewer than ten (10)
12 persons. Equal representation shall be afforded to the
13 physician, health care facility, employer, health insurer and
14 consumer protection communities within this Commonwealth.

15 (c) Within one (1) year of the effective date of this
16 section, the panel shall conclude development of the uniform
17 preauthorization form and the Insurance Department shall make
18 the uniform preauthorization form available to health care
19 providers in this Commonwealth and utilization review entities
20 and agents.

21 Section 2197. Preauthorization Exemptions.--A health care
22 service that has been provided following approval through the
23 preauthorization procedures provided by the insurer or which
24 have been disclosed as not subject to preauthorization
25 procedures shall not be subject to retrospective review or
26 concurrent review based on medical necessity related to the
27 preauthorization.

28 Section 2198. Data Collection and Reporting.--(a) The
29 Insurance Department shall maintain and collect data on the
30 number of appeals filed by enrollees, enrollee designees and

1 health care providers with utilization review entities.

2 (b) The Insurance Department shall, on an annual basis,
3 publish a report, which shall be posted on the department's
4 publicly accessible Internet website. The Insurance Department
5 shall serve a copy of the report on the Banking and Insurance
6 Committee of the Senate and the Insurance Committee of the House
7 of Representatives. The report shall identify the following data
8 elements by place and type of service:

9 (1) The total number of appeals filed against utilization
10 review entities.

11 (2) The number and percentage of appeals filed against each
12 utilization review entity.

13 (3) The total number of appeals found in favor of
14 utilization review entities.

15 (4) The number and percentage of appeals found in favor of
16 each managed care plan.

17 (5) The total number of appeals found in favor of the
18 enrollee, designee or health care provider.

19 (6) The number and percentage of appeals found in favor of
20 the enrollee, designee or health care provider against each
21 managed care plan.

22 (c) The Insurance Department shall evaluate, monitor and
23 track health plan statistics per the information gathered in
24 subsection (a) and investigate negative trends and outliers and
25 shall facilitate meetings between health care providers and
26 managed care plans to discuss and resolve disputes.

27 Section 12. Nothing in this act shall be construed to
28 preclude an insurer from developing a program exempting a health
29 care provider from preauthorization protocols.

30 Section 13. This act shall take effect in 60 days.