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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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SENATE BILL

No. 225 Session of  
2021

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INTRODUCED BY PHILLIPS-HILL, MARTIN, J. WARD, MENSCH, COLLETT,  
MUTH, KANE, STEFANO, AUMENT, CAPPELLETTI AND BAKER,  
MARCH 18, 2021

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REFERRED TO BANKING AND INSURANCE, MARCH 18, 2021

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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 healthcare  
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 protocols, further providing  
17 for required disclosure, for operational standards and  
18 providing for preauthorization and adverse determinations,  
19 for appeals, for access requirements in service areas, for  
20 uniform preauthorization form, for preauthorization  
21 exemptions and for data collection and reporting; and making  
22 an editorial 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  
27 procedures was initially designed to reduce unnecessary cost

1 placed on insurers, insureds and providers.

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

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

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

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

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

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

28 \* \* \*

29 "Administrative defect." Any deficiency, error, mistake or  
30 missing information other than medical necessity that serves as

1 the basis of an adverse determination issued by a utilization  
2 review entity as justification to deny preauthorization.

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

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

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

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

14 \* \* \*

15 "Appeal." A formal request, either orally or in writing, to  
16 reconsider a determination not to authorize a health care  
17 service prior to the service being provided. This does not  
18 include a grievance filed under section 2161, relating to  
19 reconsideration of a decision made after coverage has been  
20 provided.

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

26 "Authorization." A determination by a utilization review  
27 entity that:

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

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

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

3 \* \* \*

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

14 (1) Be based on nationally recognized standards.

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

17 (3) Reflect community standards of care.

18 (4) Ensure quality of care and access to needed health care  
19 services.

20 (5) Be evidence-based or based on generally accepted expert  
21 consensus standards.

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

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

25 "Clinical practice guidelines." A systematically developed  
26 statement to assist in decision-making by health care providers  
27 and enrollees relating to appropriate health care for specific  
28 clinical circumstances and conditions.

29 \* \* \*

30 "Emergency service." Any health care service provided to an

1 enrollee, including prehospital transportation or treatment by  
2 emergency medical services providers, after the sudden onset of  
3 a medical condition that manifests itself by acute symptoms of  
4 sufficient severity or severe pain such that a prudent layperson  
5 who possesses an average knowledge of health and medicine could  
6 reasonably expect the absence of immediate medical attention to  
7 result in:

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

11 (2) serious impairment to bodily functions; or

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

13 Emergency transportation and related emergency service provided  
14 by a licensed ambulance service shall constitute an emergency  
15 service.

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

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

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

25 "Grievance." As provided in subdivision (i), a request by an  
26 [enrollee] insured or a health care provider, with the written  
27 consent of the [enrollee] insured, to have a managed care plan  
28 or utilization review entity reconsider a decision solely  
29 concerning the medical necessity and appropriateness of a health  
30 care service after the service has been provided to the insured.

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

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

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

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

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

11 \* \* \*

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

19 \* \* \*

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

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

26 (2) appropriate in terms of type, frequency, extent, site  
27 and duration pursuant to clinical criteria; and

28 (3) not primarily for the economic benefit of the health  
29 plans and purchasers or for the convenience of the patient,  
30 treating physician or other health care provider.

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

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

15 "Nonurgent health care service." A health care service  
16 provided to an enrollee that is not considered an emergency  
17 service or an urgent health care service.

18 \* \* \*

19 "Preauthorization" or "prior authorization." The process by  
20 which a utilization review entity managed care organization or  
21 health care insurer determines the medical necessity of  
22 otherwise covered health care services prior to authorizing  
23 coverage and the rendering of the health care services,  
24 including, but not limited to, preadmission review, pretreatment  
25 review, utilization and case management. The term includes a  
26 health insurer's or utilization review entity's requirement that  
27 an insured or health care practitioner notify the health insurer  
28 or utilization review agent prior to providing a health care  
29 service. This determination and any appeal therefrom shall be  
30 conducted prior to the delivery or provision of a health care

1 service and result in a decision to approve or deny payment for  
2 the health care service.

3 \* \* \*

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

9 \* \* \*

10 "Retrospective utilization [review.] review" or  
11 "retrospective review." A review by a utilization review entity  
12 of all reasonably necessary supporting information which occurs  
13 following delivery or provision of a health care service and  
14 results in a decision to approve or deny payment for the health  
15 care service[.], but may not be used to review a decision to  
16 approve payment for health care services through  
17 preauthorization.

18 \* \* \*

19 "Urgent health care service." A health care service deemed  
20 by a provider to require expedited preauthorization review in  
21 the event a delay may jeopardize life or health of the insured  
22 or a delay in treatment could:

23 (1) negatively affect the ability of the insured to regain  
24 maximum function; or

25 (2) subject the insured to severe pain that cannot be  
26 adequately managed without receiving the care or treatment that  
27 is the subject of the utilization review as quickly as possible.

28 The term shall not include an emergency service or nonurgent  
29 health care service.

30 "Utilization review." A system of prospective, concurrent or



1 retrospective utilization review performed by a utilization  
2 review entity of the medical necessity and appropriateness of  
3 health care services prescribed, provided or proposed to be  
4 provided to an enrollee. The term includes preauthorization, but  
5 does not include any of the following:

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

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

11 "Utilization review entity." Any entity certified pursuant  
12 to subdivision (h) that performs utilization review on behalf of  
13 a managed care plan. The term includes:

14 (1) an employer with employes in this Commonwealth who are  
15 covered under a health benefit plan or health insurance policy;

16 (2) an insurer that writes health insurance policies,  
17 including preferred provider organizations defined in section  
18 630;

19 (3) pharmacy benefits managers responsible for managing  
20 access of insureds to available pharmaceutical or  
21 pharmacological care;

22 (4) any other individual or entity that provides, offers to  
23 provide or administers hospital, outpatient, medical or other  
24 health benefits to an individual treated by a health care  
25 provider in this Commonwealth under a policy, plan or contract;  
26 or

27 (5) a health insurer if the health insurer performs  
28 utilization review.

29 Section 4. Section 2111 of the act is amended by adding  
30 paragraphs to read:

1 Section 2111. Responsibilities of Managed Care Plans.--A

2 managed care plan shall do all of the following:

3 \* \* \*

4 (14) Make updates to its enrollment eligibility information  
5 within thirty (30) days of receiving updated enrollment  
6 information. Updates in enrollment eligibility may occur due to  
7 new enrollments, coordination of benefits or termination of  
8 benefits. If a managed care plan fails to update eligibility  
9 information in a timely manner, the managed care plan may not  
10 deny payment due to enrollment information being inaccurate for  
11 a date of service if current eligibility information was  
12 available. In the event of a retroactive termination or a  
13 determination that an enrollee was ineligible for benefits, a  
14 health plan may recover any payments made in error within thirty  
15 (30) days of the date of service.

16 (15) When establishing rules pertaining to the timely filing  
17 of health care provider claims, provide that a health care  
18 provider's filing requirement will commence based on the  
19 following, whichever occurs latest:

20 (i) the time of patient discharge; or

21 (ii) when authorization or approval is confirmed by the  
22 managed care plan.

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

24 Section 2114. Preauthorization Standards.--(a) No later  
25 than one hundred eighty (180) days after the effective date of  
26 this section, preauthorization requests shall be accessible to  
27 health care providers and accepted by insurers, managed care  
28 organizations and utilization review organizations  
29 electronically through a secure electronic transmission  
30 platform. The electronic preauthorization requirements under

1 this subsection shall not apply:

2 (1) under circumstances when electronic transmission is not  
3 available to be issued or received due to a temporary  
4 technological or electrical failure and, in the instance of a  
5 temporary technological failure, a practitioner shall, within  
6 seventy-two (72) hours, seek to correct any cause for the  
7 failure that is reasonably within the practitioner's control.

8 (2) when a practitioner who or health care facility that  
9 does not have either of the following:

10 (i) Internet access; or

11 (ii) an electronic health record system.

12 (b) NCPDP SCRIPT Standard shall be acceptable for  
13 pharmaceutical or pharmacological care, subject to the terms and  
14 limitations under subsection (a).

15 (c) Any restriction that a utilization review entity places  
16 on the preauthorization of health care services shall be:

17 (1) based on the medical necessity of those services and on  
18 clinical criteria;

19 (2) applied consistently; and

20 (3) disclosed by the managed care plan or utilization review  
21 entity pursuant to section 2136.

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

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

28 (f) Preauthorization shall not be required:

29 (1) where a medication, including noncontrolled generic  
30 medication or procedure prescribed for a patient is customary

1 and properly indicated or is a treatment for the clinical  
2 indication as supported by peer-reviewed medical publications;  
3 or

4 (2) for the provision of MAT for the treatment of an opioid-  
5 use disorder.

6 (f.1) A managed care plan may not deny preauthorization for  
7 a health care service for an insured currently managed with an  
8 established treatment regimen or for continuity of care. The  
9 continued care may not be subject to concurrent review if the  
10 treatment regimen or continuity of care follows from a previous  
11 preauthorization approval.

12 (g) If a provider contacts a utilization review entity  
13 seeking preauthorization, a medically necessary health care  
14 service and the utilization review entity, through any agent,  
15 contractor, employe or representative informs the provider that  
16 preauthorization is not required for the particular service that  
17 is sought, coverage for the service shall be deemed approved.

18 (h) No later than one hundred eighty (180) days after the  
19 effective date of this section, the payer shall accept and  
20 respond to preauthorization requests under the pharmacy benefit  
21 through a secure electronic transmission using the NCPDP SCRIPT  
22 Standard ePA transactions.

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

26 (1) If preauthorization for a health care service has  
27 been approved by a primary insurer, then a secondary insurer  
28 or defined benefits plan may not refuse payment for health  
29 care services solely on the basis that the procedures of the  
30 secondary insurer for preauthorization were not followed.

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

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

8           Section 6. Section 2117 of the act is amended by adding  
9           subsections to read:

10          Section 2117. Continuity of Care.--\* \* \*

11          (g) If the appeal of an adverse determination of a  
12          preauthorization request concerns ongoing health care services  
13          that are being provided pursuant to an initially authorized  
14          admission or course of treatment, the health care services shall  
15          be continued to be paid and provided without liability to the  
16          insured or insured's health care provider until the latest of:

17          (1) thirty (30) days following the insured or insured's  
18          health care provider's receipt of a notice of final adverse  
19          determination satisfying the requirements of this act, if the  
20          decision on adverse determination has been appealed through an  
21          external review proceeding;

22          (2) the duration of treatment; or

23          (3) sixty (60) days.

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

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

30          (j) Notwithstanding any other provision of law, the insurer

1 shall not retroactively recover the cost of treatment either for  
2 the initial period of treatment or the period of treatment  
3 provided to the insured as part of the decision-making process  
4 to authorize coverage of additional treatment periods.

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

6 Section 2118. Step Therapy.--(a) The following shall apply:

7 (1) Clinical review criteria used to establish a step  
8 therapy protocol shall be based on clinical practice guidelines  
9 that:

10 (i) Recommend that the prescription drugs be taken in the  
11 specific sequence required by the step therapy protocol.

12 (ii) Are developed and endorsed by a multidisciplinary panel  
13 of experts that manages conflicts of interest among the members  
14 of the writing and review groups by:

15 (A) Requiring members to disclose any potential conflict of  
16 interests with entities, including insurers, health plans and  
17 pharmaceutical manufacturers and recuse themselves from voting  
18 if the member has a conflict of interest.

19 (B) Using a methodologist to work with writing groups to  
20 provide objectivity in data analysis and ranking of evidence  
21 through the preparation of evidence tables and facilitating  
22 consensus.

23 (C) Offering opportunities for public review and comments.

24 (iii) Are based on high quality studies, research and  
25 medical practice.

26 (iv) Are created by an explicit and transparent process  
27 that:

28 (A) minimizes biases and conflicts of interest;

29 (B) explains the relationship between treatment options and  
30 outcomes;

1 (C) rates the quality of the evidence supporting  
2 recommendations; and

3 (D) considers relevant patient subgroups and preferences.

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

6 (2) In the absence of clinical guidelines that meet the  
7 requirements under paragraph (1), peer reviewed publications may  
8 be substituted.

9 (3) When establishing a step therapy protocol, a utilization  
10 review agent shall also take into account the needs of atypical  
11 patient populations and diagnoses when establishing clinical  
12 review criteria.

13 (4) An insurer, pharmacy benefit manager or utilization  
14 review organization shall:

15 (i) upon written request, provide all specific written  
16 clinical review criteria relating to the particular condition or  
17 disease, including clinical review criteria relating to a step  
18 therapy protocol override determination; and

19 (ii) make the clinical review criteria and other clinical  
20 information available on its publicly accessible Internet  
21 website and to a health care professional on behalf of an  
22 insured upon written request.

23 (5) This subsection shall not be construed to require  
24 insurers, health plans or the Commonwealth to set up a new  
25 entity to develop clinical review criteria used for step therapy  
26 protocols.

27 (b) The following shall apply:

28 (1) When coverage of a prescription drug for the treatment  
29 of any medical condition is restricted for use by an insurer,  
30 health plan or utilization review organization through the use

1 of a step therapy protocol, the patient and prescribing  
2 practitioner shall have access to a clear, readily accessible  
3 and convenient process to request a step therapy exception. An  
4 insurer, health plan or utilization review organization may use  
5 its existing medical exceptions process to satisfy this  
6 requirement. The process shall be made easily accessible on the  
7 publicly accessible Internet website of the insurer, health plan  
8 or utilization review organization. An insurer, health plan or  
9 utilization review organization must disclose all rules and  
10 criteria related to the step therapy protocol upon request to  
11 all prescribing practitioners, including the specific  
12 information and documentation that must be submitted by a  
13 prescribing practitioner or patient to be considered a complete  
14 exception request.

15 (2) A step therapy exception shall be granted if:

16 (i) The required prescription drug is contraindicated or  
17 will likely cause an adverse reaction by or physical or mental  
18 harm to the patient.

19 (ii) The required prescription drug is expected to be  
20 ineffective based on the known clinical characteristics of the  
21 patient and the known characteristics of the prescription drug  
22 regimen.

23 (iii) The patient has tried the required prescription drug  
24 while under the patient's current or previous health insurance  
25 or health benefit plan, or another prescription drug in the same  
26 pharmacologic class or with the same mechanism of action, and  
27 the prescription drug was discontinued due to lack of efficacy  
28 or effectiveness, diminished effect or an adverse event.

29 (iv) The required prescription drug is not in the best  
30 interest of the patient, based on medical necessity.



1 (v) The patient is stable on a prescription drug selected by  
2 the patient's health care provider for the medical condition  
3 under consideration while on a current or previous health  
4 insurance or health benefit plan.

5 (3) Upon the granting of a step therapy exception, the  
6 insurer, health plan or utilization review organization shall  
7 authorize coverage for the prescription drug prescribed by the  
8 patient's treating health care provider.

9 (4) The insurer, health plan or utilization review  
10 organization shall grant or deny a step therapy exception  
11 request or an appeal within seventy-two (72) hours of receipt.  
12 The following shall apply:

13 (i) In cases where exigent circumstances exist, an insurer,  
14 health plan or utilization review organization shall respond  
15 within twenty-four (24) hours of receipt.

16 (ii) If a request for a step therapy override exception is  
17 incomplete or additional clinically relevant information is  
18 required, the insurer, health plan or utilization review  
19 organization shall notify the prescribing practitioner within  
20 seventy-two (72) hours of submission, or twenty-four (24) hours  
21 in exigent circumstances, what additional or clinically relevant  
22 information is required in order to approve or deny the step  
23 therapy exception request or appeal under this section.

24 (iii) Once the requested information is submitted, the  
25 applicable time period to grant or deny a step therapy exception  
26 request or appeal shall apply.

27 (iv) Should a determination or request for incomplete or  
28 clinically relevant information by an insurer, health plan or  
29 utilization review organization not be received by the  
30 prescribing practitioner within the time allotted, the exception

1 or appeal shall be deemed granted.

2 (v) In the event of a denial, the insurer, health plan or  
3 utilization review organization must inform the patient of a  
4 potential appeal process.

5 (5) Any step therapy exception under this subsection shall  
6 be eligible for appeal by an insured.

7 (6) This subsection shall not be construed to prevent:

8 (i) An insurer, health plan or utilization review  
9 organization from requiring a patient to try an AB-rated generic  
10 equivalent or interchangeable biological product, as defined in  
11 42 U.S.C. § 262(i)(3) (relating to regulation of biological  
12 products), unless the requirement meets any of the criteria  
13 under this subsection for a step therapy exception request,  
14 prior to providing coverage for the equivalent branded  
15 prescription drug;

16 (ii) An insurer, health plan or utilization review  
17 organization from requiring a pharmacist to effect substitutions  
18 of prescription drugs consistent with the laws of this  
19 Commonwealth.

20 (iii) A health care provider from prescribing a prescription  
21 drug that is determined to be medically appropriate.

22 (c) Notwithstanding any provision of law to the contrary,  
23 the Insurance Department shall promulgate any regulations  
24 necessary to enforce this section.

25 (d) An insurer, health plan or a utilization review  
26 organization shall annually report to the Insurance Department,  
27 in a format prescribed by the Insurance Department:

28 (i) the number of step therapy exception requests received  
29 by exception;

30 (ii) the type of health care providers or the medical

1 specialties of the health care providers submitting step therapy  
2 exception requests;

3 (iii) the number of step therapy exception requests by  
4 exception that were denied and the reasons for the denials;

5 (iv) the number of step therapy exception requests by  
6 exception that were approved;

7 (v) the number of step therapy exception requests by  
8 exception that were initially denied and then appealed;

9 (vi) the number of step therapy exception requests by  
10 exception that were initially denied and then subsequently  
11 reversed by internal appeals or external reviews; and

12 (vii) the medical conditions for which patients are granted  
13 exceptions due to the likelihood that switching from the  
14 prescription drug will likely cause an adverse reaction by or  
15 physical or mental harm to the insured.

16 (e) As used in this section, the following words and phrases  
17 shall have the meanings given to them in this subsection unless  
18 the context clearly indicates otherwise:

19 "Clinical practice guidelines." A systematically developed  
20 statement to assist decision making by health care providers and  
21 patient decisions about appropriate healthcare for specific  
22 clinical circumstances and conditions.

23 "Clinical review criteria." The written screening  
24 procedures, decision abstracts, clinical protocols and practice  
25 guidelines used by an insurer, health plan or utilization review  
26 organization to determine the medical necessity and  
27 appropriateness of healthcare services.

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

30 (1) to improve or preserve health, life or function;

1           (2) to slow the deterioration of health, life or  
2           function; or  
3           (3) for the early screening, prevention, evaluation,  
4           diagnosis or treatment of a disease, condition, illness or  
5           injury.

6           "Step therapy exception." When a step therapy protocol  
7           should be overridden in favor of immediate coverage of the  
8           health care provider's selected prescription drug.

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

13           "Utilization review organization." An entity that conducts  
14           utilization review, other than an insurer or health plan  
15           performing utilization review for its own health benefit plans.

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

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

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

21           Section 2136. Required Disclosure.--\* \* \*

22           (c) If a utilization review entity intends to implement a  
23           new preauthorization requirement or restriction or amend an  
24           existing requirement or restriction, the utilization review  
25           entity shall provide contracted health care providers and  
26           insureds with written notice of the new or amended requirement  
27           or amendment not less than sixty (60) days before the  
28           requirement or restriction is implemented. The notice shall be  
29           in writing which may be satisfied by any of the following:

30           (1) certified mail return receipt requested;

- 1           (2) electronic mail read receipt requested;  
2           (3) publication on the publicly accessible Internet  
3           website of the insurer with an electronic mail message to  
4           providers and insureds that identifies the location of the  
5           publication on the website;  
6           (4) web-exchange, provided that an electronic mail  
7           message on how to access the web-exchange is sent to the  
8           providers and insured; or  
9           (5) any other contractually agreed upon method,  
10           specifying the details of the communication which include  
11           some proof of receipt by the providers and insureds.

12       Section 10. Section 2152(a)(4) and (6) of the act are  
13 amended and the section is amended by adding subsections to  
14 read:

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

17       \* \* \*

18       (4) Conduct utilization reviews based on the medical  
19 necessity and appropriateness of the health care service being  
20 reviewed and provide notification within the following time  
21 frames:

22       (i) A prospective utilization review decision shall be  
23 communicated within two (2) business days of the receipt of all  
24 supporting information reasonably necessary to complete the  
25 review.

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

30       (iii) A retrospective utilization review decision shall be

1 communicated within thirty (30) days of the receipt of all  
2 supporting information reasonably necessary to complete the  
3 review.

4 (iv) A utilization review entity shall allow an insured and  
5 the insured's health care provider a minimum of one (1) business  
6 day following an inpatient admission pursuant to an emergency  
7 health care service or urgent health care service to notify the  
8 utilization review entity of the admission and any health care  
9 services performed.

10 \* \* \*

11 (6) Provide all decisions in writing to include the basis  
12 and clinical rationale for the decision. For adverse  
13 determinations of preauthorization decisions, a utilization  
14 review entity shall provide all decisions to the insured and the  
15 insured's health care provider, which decisions shall also  
16 include instructions concerning how an appeal may be perfected.  
17 Utilization review entities may not retroactively review the  
18 medical necessity of a preauthorization that has been previously  
19 approved or granted.

20 \* \* \*

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

23 (i) A current list of services and supplies requiring  
24 preauthorization.

25 (ii) Written clinical criteria for preauthorization  
26 decisions.

27 (10) Ensure that a preauthorization shall be valid for no  
28 less than one hundred eighty (180) days or the duration of  
29 treatment, whichever is greater, from the date the health care  
30 provider receives the preauthorization so long as the insured is

1 a member of the plan. A duration of less than one hundred and  
2 eighty (180) days may be approved upon an agreement between a  
3 provider and payer.

4 (11) When performing preauthorization, only request copies  
5 of medical records if a difficulty develops in determining the  
6 medical necessity of a health care service. In that case, the  
7 utilization review agent may only request the necessary and  
8 relevant sections of the medical record.

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

14 \* \* \*

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

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

23 (1) The enrollee was not eligible for coverage at the time  
24 the health care service was rendered. A managed care plan may  
25 not deny payment for a claim on this basis if the enrollee's  
26 coverage was retroactively terminated more than one hundred  
27 twenty (120) days after the date of service, provided the claim  
28 is submitted timely. If the claim is submitted after the timely  
29 filing deadline, the managed care plan shall have no more than  
30 thirty (30) days after the claim is received to deny the claim

1 on the basis the enrollee was not eligible for coverage on the  
2 date of the health care service.

3 (2) The preauthorization was based on materially inaccurate  
4 or incomplete information provided by the enrollee, the  
5 enrollee's designee or the health care provider, such that if  
6 the correct or complete information had been provided, the  
7 preauthorization would not have been granted.

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

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

12 Section 2161.1. Preauthorization and Adverse  
13 Determinations.--(a) A utilization review entity shall ensure  
14 that:

15 (1) Preauthorization is made by a qualified licensed health  
16 care provider who has knowledge of the items, services,  
17 products, tests or procedures submitted for preauthorization.

18 (2) Adverse determinations are made by a physician. The  
19 reviewing physician must possess a current and valid  
20 nonrestricted license to practice medicine in this Commonwealth  
21 and be board certified. The insurer shall make available a  
22 physician in a like specialty if the review requires a peer-to-  
23 peer review in the specialty or subspecialty or a review is  
24 requested by the submitting provider. A utilization review  
25 entity may seek approval from the Insurance Commissioner to use  
26 a reviewing physician that is not board-certified due to  
27 unavailability or difficulty in finding a board-certified  
28 reviewing physician in a given specialty. The Insurance  
29 Commissioner shall develop a form and parameters for the  
30 requests and shall transmit all requests as notices to the



1 Legislative Reference Bureau for publication in the Pennsylvania  
2 Bulletin. The Insurance Commissioner shall provide at least ten  
3 (10) days for comment before rendering a decision, which  
4 decision shall be transmitted to the Legislative Reference  
5 Bureau as a separate notice for publication in the Pennsylvania  
6 Bulletin.

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

9 (1) The specific health care services preauthorized.

10 (2) The next date for review.

11 (3) The total number of days approved.

12 (4) The date of admission or initiation of services, if  
13 applicable.

14 (c) Neither the utilization review entity nor the payer or  
15 health insurer that has retained the utilization review entity  
16 may retroactively deny coverage for emergency or nonemergency  
17 care that had been preauthorized when the care was provided, if  
18 the information provided was accurate.

19 (d) In the event a health care provider obtains  
20 preauthorization for one (1) service but the service provided is  
21 not an exact match to the service that was preauthorized, but  
22 the service does not materially depart from the service that was  
23 preauthorized, a health plan shall not deny payment for the  
24 service only if:

25 (1) the date of service differs by less than thirty (30)  
26 days;

27 (2) the physician or health care provider rendering the  
28 service differs from the physician or health care provider that  
29 was indicated on the preauthorization, but is otherwise licensed  
30 and qualified to provide the preauthorized service; or

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

4 (e) If the denial of preauthorization is conditioned upon  
5 incomplete information or administrative error, the health plan  
6 shall allow the health care provider to resubmit the claim with  
7 corrected information for appropriate reimbursement up to thirty  
8 (30) days after receiving notice.

9 (f) (1) If a utilization review entity questions the  
10 medical necessity of a health care service, the utilization  
11 review entity shall notify the insured's health care provider  
12 that medical necessity is being questioned and provide the basis  
13 of the challenge in sufficient detail to allow the provider to  
14 meaningfully address the concern of the utilization review  
15 entity prior to issuing an adverse determination.

16 (2) The insured's health care provider or the health care  
17 provider's designee and the insured or insured's designee shall  
18 have the right to discuss the medical necessity of the health  
19 care service with the utilization review physician.

20 (3) A utilization review entity questioning medical  
21 necessity of a health care service which may result in an  
22 adverse determination shall make the reviewing physician or a  
23 physician who is part of a team making the decision available  
24 telephonically between the hours of seven (7) o'clock  
25 antemeridian and seven (7) o'clock postmeridian.

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

1 (h) In the event a utilization review entity determines an  
2 alternative level of care is appropriate, the utilization review  
3 entity shall provide and cite the specific criteria used as the  
4 basis for the level of care determination to the health care  
5 provider, prior to denial to enable a meaningful peer-to-peer  
6 review. If, after the peer-to-peer has been completed, denial  
7 remains the determination, the health care provider shall have  
8 the right to appeal the determination.

9 (i) A utilization review entity may not issue an adverse  
10 determination for a procedure due to lack of preauthorization if  
11 the procedure is medically necessary or clinically appropriate  
12 for the patient's medical condition and rendered at the same  
13 time as a related procedure for which preauthorization was  
14 required and received.

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

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

21 (2) For urgent health care services, within twenty-four (24)  
22 hours of obtaining all the necessary information to make the  
23 preauthorization or adverse determination.

24 (k) No utilization review entity may require  
25 preauthorization for an emergency service, including  
26 postevaluation and poststabilization services.

27 Section 2161.2. Appeals.--(a) An insured or the insured's  
28 health care provider may request an expedited appeal of an  
29 adverse determination via telephone, facsimile, electronic mail  
30 or other expeditious method. Within one (1) day of receiving an

1 expedited appeal and all information necessary to decide the  
2 appeal, the utilization review entity shall provide the insured  
3 and the insured's health care provider written confirmation of  
4 the expedited review determination.

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

7 (1) Is board certified in the same specialty as a health  
8 care practitioner who typically manages the medical condition or  
9 disease.

10 (2) Is currently in active practice, provided that in events  
11 where circumstances justify it or where the provider seeking  
12 preauthorization specifically requests a health care provider  
13 actively engaged in the specialty who typically manages the  
14 medical condition or disease, the physician shall be made  
15 available for the review.

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

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

22 The physician may also be subject to a provider agreement  
23 with the insurer as a provider, but may not receive any other  
24 fee or compensation from the insurer. The physician's receipt of  
25 compensation from the utilization review entity shall not be  
26 considered by the physician in determining the conclusion  
27 reached by the physician. The physician shall at all times  
28 render independent and accurate medical judgment in reaching an  
29 opinion or conclusion. Failure to comply with this provision  
30 shall render the physician subject to licensure disciplinary

1 action by the appropriate State licensing board.

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

3 (6) Familiar with all known clinical aspects of the health  
4 care services under review, including, but not limited to, all  
5 pertinent medical records provided to the utilization review  
6 entity by the insured's health care provider and any relevant  
7 record provided to the utilization review entity by a health  
8 care facility.

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

11 (1) The insured and the insured's health care provider may  
12 challenge the adverse determination and have the right to appear  
13 in person before the physician who reviews the adverse  
14 determination.

15 (2) The utilization review entity shall provide the insured  
16 and the insured's health care provider with written notice of  
17 the time and place concerning where the review meeting will take  
18 place. Notice shall be given to the insured's health care  
19 provider at least fifteen (15) days in advance of the review  
20 meeting.

21 (3) If the insured or the insured's health care provider  
22 appear in person, the utilization review entity shall offer the  
23 insured or insured's health care provider the opportunity to  
24 communicate with the reviewing physician, at the utilization  
25 review entity's expense, by conference call, video conferencing  
26 or other available technology.

27 (4) The physician performing the review of the appeal shall  
28 consider all information, documentation or other material  
29 submitted in connection with the appeal without regard to  
30 whether the information was considered in making the adverse

1 determination.

2 (d) The following deadlines shall apply to the utilization  
3 review entities:

4 (1) A utilization review entity shall decide an expedited  
5 appeal and notify the insured and the insured's health care  
6 provider of the determination within three (3) days after  
7 receiving a notice of expedited appeal by the insured or the  
8 insured's health care provider and all information necessary to  
9 decide the appeal.

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

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

17 (f) If the insured or the insured's health care provider or  
18 a designee on behalf of either the insured or the insured's  
19 health care provider has satisfied all necessary requirements  
20 for the appeal of an adverse determination through the  
21 preauthorization process and the appeal has resulted in a  
22 continued adverse determination either based on lack of medical  
23 necessity or an administrative defect, the insured, the  
24 insured's health care provider or a designee on behalf of either  
25 the insured or the insured's health care provider or a designee  
26 may file a consumer complaint with the Insurance Department. The  
27 complaint shall be adjudicated without unnecessary delay and a  
28 determination issued by the Insurance Department with  
29 appropriate sanctions, if applicable, pursuant to the authority  
30 given to the Insurance Department.

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

11 (h) Nothing in this section shall be construed to preclude  
12 an insured or an insured's designee the ability to file a  
13 separate consumer complaint with the Insurance Department for  
14 failure to comply with the requirements of this act as it  
15 applies to preauthorization processes or denial of health  
16 insurance coverage generally.

17 Section 2195. Access Requirements in Service Areas.--If a  
18 patient's safe discharge is delayed for any reason, including  
19 lack of available posthospitalization services, including, but  
20 not limited to, skilled nursing facilities, home health services  
21 and postacute rehabilitation, the managed care plan shall  
22 reimburse the hospital for each subsequent date of service at  
23 the greater of the contracted rate with the managed care plan  
24 for the current level of care and service or the full diagnostic  
25 related group payment divided by the mean length of stay for the  
26 particular diagnostic related group.

27 Section 2196. Uniform Preauthorization Form.--(a) Within  
28 three (3) months of the effective date of this section, the  
29 Insurance Department shall convene a panel to develop a uniform  
30 preauthorization form that all health care providers in this

1 Commonwealth shall use to request preauthorization and that all  
2 health insurers shall accept as sufficient to request  
3 preauthorization of health care services.

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

8 (c) Within one (1) year of the effective date of this  
9 section, the panel shall conclude development of the uniform  
10 preauthorization form and the Insurance Department shall make  
11 the uniform preauthorization form available to health care  
12 providers in this Commonwealth and utilization review entities  
13 and agents.

14 Section 2197. Preauthorization Exemptions.--A health care  
15 service that has been provided following approval through the  
16 preauthorization procedures provided by the insurer or which  
17 have been disclosed as not subject to preauthorization  
18 procedures shall not be subject to retrospective review or  
19 concurrent review based on medical necessity related to the  
20 preauthorization.

21 Section 2198. Data Collection and Reporting.--(a) The  
22 Insurance Department shall maintain and collect data on the  
23 number of appeals filed by enrollees, enrollee designees and  
24 health care providers with utilization review entities.

25 (b) The Insurance Department shall, on an annual basis,  
26 publish a report made accessible on the department's publicly  
27 accessible Internet website and serve a copy of the report on  
28 the Banking and Insurance Committee of the Senate and the  
29 Insurance Committee of the House of Representatives that  
30 identifies the following data elements by place and type of



1 service:

2 (1) The total number of appeals filed against utilization  
3 review entities.

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

6 (3) The total number of appeals found in favor of  
7 utilization review entities.

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

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

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

15 (c) The Insurance Department shall evaluate, monitor and  
16 track health plan statistics per the information gathered in  
17 subsection (a) and investigate negative trends and outliers and  
18 shall facilitate meetings between health care providers and  
19 managed care plans to discuss and resolve disputes.

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

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