SPONSOR: Rep. Baumbach & Sen. Henry
Reps. Bentz, J. Johnson, Q. Johnson, Kowalko, Mitchell, Paradee, Ramone, Smyk, Spiegelman, Viola, K. Williams; Sens. Hall-Long, Lopez, Sokola

HOUSE OF REPRESENTATIVES
148th GENERAL ASSEMBLY

# HOUSE BILL NO. 381

AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO PRE-AUTHORIZATION.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Title 18, Chapter 33 of the Delaware Code to add a new heading for Subchapter I and to add a new Subchapter II making deletions as shown by strike through and insertions as shown by underline as follows:

CHAPTER 33. HEALTH INSURANCE CONTRACTS

Subchapter I. General Provisions.

§ 3301 Scope of chapter.

Subchapter II. Pre-Authorization Transparency.

§ 3371. Definitions.

(a) In this section, the following words have the meanings indicated:

(1) "Adverse determination" means a benefit denial, reduction or termination, a denial of certification, a determination that an admission or continued stay, or course of treatment, or other covered health service does not satisfy the insurance policy's clinical requirements for appropriateness, necessity, health care setting and/or level of care.

(2) "Clean pre-authorization" means when a submission is made to satisfy pre-authorization in which the data for all relevant fields is provided and in the format called for by the utilization review entity.

(3) "Clinical criteria" means the written policies, written screening procedures, drug formularies or lists of covered drugs, determination rules, determination abstracts, clinical protocols, practice guidelines, medical protocols and any other criteria or rationale used by the utilization review entity to determine the necessity and appropriateness of health care services.

(4) "Covered person" means an individual and/or family who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into, with a carrier, pursuant to which the carrier provides health insurance for such person or persons.



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(5) “Electronic pre-authorization” means a submission of information via a website, the Delaware Health Information Network, or other method via the internet as delineated by regulation and as accepted by the utilization review entity.

(6) “Emergency health care services” means those services identified in §§ 3349 and 3565 of this title.

(7) “Health care service" means any services or supplies included in the furnishing to any individual of medical care, or hospitalization or incidental to the furnishing of such care or hospitalization, as well as the furnishing to any individual of any and all other services for the purpose of preventing, alleviating, curing or healing human illness, injury, disability or disease.

(8) “Medically necessary” means providing of health care services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, disease or its symptoms in a manner that is all of the following:

a. In accordance with generally accepted standards of medical practice;

b. Consistent with the symptoms or treatment of the condition;

c. Not solely for anyone’s convenience; and

d. Not including investigational or experimental health care services.

(9) “NCPDP SCRIPT standard**”** means the most recent standard adopted of the National Council for Prescription Drug Programs SCRIPT adopted by the United States Department of Health and Human Services. To fall within this definition, any version released subsequent to passage of this section must be compatible to the version in use in 2015.

(10) “Pre-authorization” means a requirement by a carrier or health insurance plan that states clinicians need to submit a treatment plan, service request, or other prior notification to the carrier for evaluation of appropriateness of the plan or if the service is medically necessary before treatment is rendered and thereby lets the insured and clinician know in advance which procedures and pharmaceuticals are covered.

(11) “Utilization review entity” means an individual or entity which performs pre-authorization for one or more of the following entities:

a. An employer with employees in Delaware who are covered under a health benefit plan or health insurance policy which does not fall under the Employee Retirement Income Security Act (ERISA);

b. An insurer, health benefit plan, or health service corporation that writes health insurance policies, performs pre-authorization, or entity to which these capabilities have been delegated;

c. A preferred provider organization, or health maintenance organization;

d. Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a health care provider in Delaware under a policy, plan, or contract.

§ 3372 Disclosure and review of pre-authorization requirements.

(a) A utilization review entity shall make any current pre-authorization requirements and restrictions readily accessible on its website and in written or electronic form upon request for covered persons, health care providers, government entities, and the general public. Requirements shall be described in detail but also in clear, easily-understandable language. Clinical criteria shall be described in language easily understandable by a health care provider.

(b) If a utilization review entity intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall ensure that the new or amended requirement is not implemented unless the utilization review entity's website has been updated to reflect the new or amended requirement or restriction. This shall not extend to expansion of coverage for new health care services.

(c) If a utilization review entity intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall provide covered persons who are currently using the affected health care service and all contracted health care practitioners who provide affected health care service or services of written notice of the new or amended requirement or amendment no less than 60 days before the requirement or restriction is implemented. Such notice may be delivered electronically or by other means as agreed to by the receiving entity.

(d) Entities utilizing pre-authorization shall make de-identified statistics available regarding pre-authorization approvals and denials on their website in a readily accessible format. The statistics shall include, but may be expanded upon or further delineated by regulation, categories for all of the following:

(1) Practitioner specialty;

(2) Medication, diagnostic test, or diagnostic procedure;

(3) Indication offered;

(4) Reasons for denial such as, but not limited to, medical necessity or incomplete pre-authorization submission; and

(5) Denials overturned upon appeal.

§ 3373 Utilization review entity's obligations with respect to pre-authorizations in non-emergency circumstances.

(a) If a utilization review entity requires pre-authorization of a pharmaceutical, the utilization review entity must complete its process or render an adverse determination and notify the covered person and the covered person's health care

provider within 2 business days of obtaining a clean pre-authorization or within 2 calendar days if using services described in § 3379 of this title.

(b) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must make a pre-authorization or adverse determination and notify the covered person and the covered person's health care provider of the pre-authorization or adverse determination within 5 calendar days of obtaining a clean pre-authorization not submitted through electronic pre-authorization. For purposes of this subsection, a clean pre-authorization includes the results of any face-to-face clinical evaluation or second opinion that may be required.

(c) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must make a pre-authorization or adverse determination and notify the covered person and the covered person's health care provider of the pre-authorization or adverse determination within 3 calendar days of obtaining a clean pre-authorization through electronic pre-authorization. For purposes of this subsection, a clean pre-authorization includes the results of any face-to-face clinical evaluation or second opinion that may be required.

§ 3374 Utilization review entity's obligations with respect to Pre-Authorization concerning emergency health care services.

A utilization review entity must follow all emergency procedures as delineated in §§ 3349 and 3565 of this title.

§ 3375 Retrospective denial.

(a) The utilization review entity may not revoke, limit, condition or restrict a pre-authorization on ground of medically necessary after the date the health care provider received the pre-authorization. Any language attempting to disclaim payment for services that have been pre-authorized as medically necessary and delivered while under coverage shall be null and void. A proper notification of policy changes validly delivered as per § 3372 of this title may void a pre-authorization if received after pre-authorization but before delivery of the service.

§ 3376 Length of pre-authorization.

A pre-authorization shall be valid for one year from the date the health care provider receives the pre-authorization, subject to confirmation of continued coverage and eligibility and to policy changes validly delivered as per § 3372 of this title.

§ 3377 Electronic standards for pharmaceutical pre-authorization.

No later than January 1, 2017, the insurer must accept and respond to pre-authorization requests under the pharmacy benefit through a secure electronic transmission using the NCPDP SCRIPT standard ePA transactions. Facsimile, proprietary payer portals, and electronic forms shall not be considered electronic transmission.

§ 3378 Health care services deemed preauthorized if a utilization review entity fails to comply with the requirements of this Subchapter.

Any failure by a utilization review entity to comply with the deadlines and other requirements specified in this Subchapter will result in any health care services subject to review to be automatically deemed preauthorized.

§ 3379 Waiver prohibited.

The provisions of this Subchapter cannot be waived by contract. Any contractual arrangement in conflict with the provisions of this Subchapter or that purports to waive any requirements of this Subchapter is null and void.

Section 2. Amend Title 18 to add a new Subchapter V to Chapter 35 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter V. Pre-Authorization Transparency.

§ 3581. Definitions.

For purposes of this Subchapter, the following definitions apply:

(1) "Adverse determination" means a benefit denial, reduction or termination, a denial of certification, a determination that an admission or continued stay, or course of treatment, or other covered health service does not satisfy the insurance policy's clinical requirements for appropriateness, necessity, health care setting and/or level of care.

(2) "Clean pre-authorization" means when a submission is made to satisfy pre-authorization in which the data for all relevant fields is provided and in the format called for by the utilization review entity.

(3) "Clinical criteria" means the written policies, written screening procedures, drug formularies or lists of covered drugs, determination rules, determination abstracts, clinical protocols, practice guidelines, medical protocols and any other criteria or rationale used by the utilization review entity to determine the necessity and appropriateness of health care services.

(4) "Covered person" means an individual or family, or both, who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into, with a carrier, pursuant to which the carrier provides health insurance for such person.

(5) "Electronic pre-authorization" is a submission of information via a website, the Delaware Health Information Network, or other method via the internet as delineated by regulation and as accepted by the utilization review entity.

(6) "Emergency health care services" means those services identified in §§ 3349 and 3565 of this title.

(7) “Health care service" means any services or supplies included in the furnishing to any individual of medical care, or hospitalization or incidental to the furnishing of such care or hospitalization, as well as the furnishing to any individual of any and all other services for the purpose of preventing, alleviating, curing or healing human illness, injury, disability or disease.

(8) “Medically necessary” means providing of health care services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, disease or its symptoms in a manner that is all of the following:

a. In accordance with generally accepted standards of medical practice;

b. Consistent with the symptoms or treatment of the condition;

c. Not solely for anyone’s convenience; and

d. Not including investigational or experimental health care services.

(9) “NCPDP SCRIPT standard**”** means the most recent standard adopted of the National Council for Prescription Drug Programs SCRIPT adopted by the United States Department of Health and Human Services. To fall within this definition, any version released subsequent to passage of this section must be compatible to the version in use in 2015.

(10) “Pre-authorization” means a requirement by a carrier or health insurance plan that states clinicians need to submit a treatment plan, service request, or other prior notification to the carrier for evaluation of appropriateness of the plan or if the service is medically necessary before treatment is rendered. It lets the insured and clinician know in advance which procedures and pharmaceuticals are covered.

(11) “Utilization review entity” means an individual or entity which performs pre-authorization for one or more of the following entities:

a. An employer with employees in Delaware who are covered under a health benefit plan or health insurance policy which does not fall under the Employee Retirement Income Security Act (ERISA);

b. An insurer, health benefit plan, or health service corporation that writes health insurance policies, performs pre-authorization, or entity to which these capabilities have been delegated;

c. A preferred provider organization, or health maintenance organization;

d. Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a health care provider in Delaware under a policy, plan, or contract.

§ 3582 Disclosure and review of pre-authorization requirements.

(a) A utilization review entity shall make any current pre-authorization requirements and restrictions readily accessible on its website and in written or electronic form upon request for covered persons, health care providers, government entities, and the general public. Requirements shall be described in detail but also in clear, easily-understandable language. Clinical criteria shall be described in language easily understandable by a health care provider.

(b) If a utilization review entity intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall ensure that the new or amended requirement is not implemented unless the utilization review entity's website has been updated to reflect the new or amended requirement or restriction. This shall not extend to expansion of coverage for new health care services.

(c) If a utilization review entity intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, the utilization review entity shall provide covered persons who are currently using the affected health care service and all contracted health care practitioners who provide affected health care service or services of written notice of the new or amended requirement or amendment no less than 60 days before the requirement or restriction is implemented. Such notice may be delivered electronically or by other means as agreed to by the receiving entity.

(d) Entities utilizing pre-authorization shall make de-identified statistics available regarding pre-authorization approvals and denials on their website in a readily accessible format. The statistics shall include, but may be expanded upon or further delineated by regulation, categories for all of the following:

(1) Practitioner specialty;

(2) Medication, diagnostic test, or diagnostic procedure;

(3) Indication offered;

(4) Reasons for denial such as, but not limited to, medical necessity or incomplete pre-authorization submission; and

(5) Denials overturned upon appeal.

§ 3583 Utilization review entity's obligations with respect to pre-authorizations in non-emergency circumstances.

(a) If a utilization review entity requires pre-authorization of a pharmaceutical, the utilization review entity must complete its process or render an adverse determination and notify the covered person and the covered person's health care provider within 2 business days of obtaining a clean pre-authorization or within 2 calendar days if using services described in § 3382 of this title.

(b) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must make a pre-authorization or adverse determination and notify the covered person and the covered person's health care

provider of the pre-authorization or adverse determination within 5 calendar days of obtaining a clean pre-authorization not submitted through electronic pre-authorization. For purposes of this subsection, a clean pre-authorization includes the results of any face-to-face clinical evaluation or second opinion that may be required.

(c) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must make a pre-authorization or adverse determination and notify the covered person and the covered person's health care provider of the pre-authorization or adverse determination within 3 calendar days of obtaining a clean pre-authorization through electronic pre-authorization. For purposes of this subsection, a clean pre-authorization includes the results of any face-to-face clinical evaluation or second opinion that may be required.

§ 3584 Utilization review entity's obligations with respect to pre-authorization concerning emergency health care services.

A utilization review entity must follow all emergency procedures as delineated in §§ 3349 and 3565 of this title.

§ 3585 Retrospective denial.

The utilization review entity may not revoke, limit, condition or restrict a pre-authorization on ground of medically necessary after the date the health care provider received the pre-authorization. Any language attempting to disclaim payment for services that have been pre-authorized as medically necessary and delivered while under coverage shall be null and void. A proper notification of policy changes validly delivered as per § 3582 of this title may void a pre-authorization if received after pre-authorization but before delivery of the service.

§ 3586 Length of pre-authorization.

A pre-authorization shall be valid for one year from the date the health care provider receives the pre-authorization, subject to confirmation of continued coverage and eligibility and to policy changes validly delivered as per § 3382 of this title.

§ 3587 Electronic standards for pharmaceutical pre-authorization.

No later than January 1, 2017, the insurer must accept and respond to pre-authorization requests under the pharmacy benefit through a secure electronic transmission using the NCPDP SCRIPT standard ePA transactions. Facsimile, proprietary payer portals, and electronic forms shall not be considered electronic transmission.

§ 3588 Health care services deemed preauthorized if a utilization review entity fails to comply with the requirements of this Subchapter.

Any failure by a utilization review entity to comply with the deadlines and other requirements specified in this Subchapter will result in any health care services subject to review to be automatically deemed preauthorized.

§ 3589 Waiver Prohibited.

The provisions of this Subchapter cannot be waived by contract. Any contractual arrangement in conflict with the provisions of this Subchapter or that purports to waive any requirements of this Subchapter is null and void.

Section 3. This Act shall take effect on January 1, 2017.

Section 4. Severability. If any provision of this Act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and to this end the provisions of this Act are declared to be severable.

SYNOPSIS

Patients struggle every day to receive necessary care, suffering symptoms longer than appropriate and encountering unnecessary stress factors as they engage in the complicated system of health insurance. One such factor is Pre-Authorization, a tool designed to save the money by making sure that care is necessary. For years patients and clinicians have been put through arduous appeals processes being told that they are necessary to keep costs down or worse, told after the fact that their care won't be paid for even when previously told otherwise. Yet, anecdotally, appeals to these decisions are nearly always granted after hours of staff and clinician time. Reliable data is difficult, if not impossible, to come by to evaluate if programs are worth the costs of time that they shift to the patient and clinician. This legislation requires greater transparency, efficiency, and fairness in pre-authorization programs.