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
AS AMENDED BY
HOUSE AMENDMENT NO. 1

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, or 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 any pre-authorization in which the relevant data is provided as called for by the utilization review entity. Any request submitted by a provider or covered person that includes an unspecified, unclassified or miscellaneous code or data element to constitute a clean request shall also include appropriate supporting documentation or narrative which explains the unspecified, unclassified or miscellaneous code and describes the diagnosis and treatment rendered.

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LC : BCG : RAY:5351480088

(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.

(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. Electronic pre-authorization does not include any form of request that is transmitted to the utilization review entity through facsimile.

(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” or “medical necessity” 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 current version adopted by the United States Department of Health and Human Services.

(10) “Pre-authorization” means a requirement by a carrier or health insurance plan that providers 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. Pre-authorization lets the insured and provider know in advance which procedures and pharmaceuticals are considered by the insurer to be medically necessary.

(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 who are covered under a health benefit plan or health insurance policy or contract issued for delivery in this State or delivered in this State 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, managed care 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;

e. This definition does not include accident-only, credit, dental, vision, long-term care or disability income insurance, coverage issued as a supplement to liability insurance, worker's compensation or similar insurance or automobile medical payment insurance.

§ 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, and others with access to the website. Information from a utilization review entity that is not an insurer, health benefit plan, or health service corporation shall make this information available at an electronic pre-authorization portal that is accessible in real time. 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 practicing in the same clinical area.

(b) If an insurer, health benefit plan, or health service corporation intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, they shall ensure that the new or amended requirement is not implemented unless their 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 an insurer, health benefit plan, or health service corporation intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, they shall provide covered persons

who are currently authorized by the utilization review entity for coverage of the affected health care service and all contracted health care providers 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.

(d) Insurers, health benefit plans, and health service corporations utilizing pre-authorization shall report de-identified statistics regarding pre-authorization approvals, denials, and appeals to the Delaware Health Information Network in a format and frequency, no less than twice annually, of the Delaware Health Information Network's request. The Department may also request this data at any time. The statistics shall include, but may be expanded upon or further delineated by regulation, categories for all of the following:

(1) For denials, the aggregated reasons for denials such as, but not limited to, medical necessity or incomplete pre-authorization submission.

(2) For appeals:

a. Practitioner specialty;

b. Medication, diagnostic test, or diagnostic procedure;

c. Indication offered;

d. Reason for underlying denial; and

e. Number of 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's health care provider within 2 business days of obtaining a clean pre-authorization or of using services described in § 3377 of this title.

(b) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must grant a pre-authorization or issue an adverse determination and notify the covered person's health care provider of the determination within 8 business days of receipt of 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 grant a pre-authorization or issue an adverse determination and notify the covered person's health care provider of the determination within 5 business days of receipt of 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 and mandates as delineated in §§ 3349 and 3565 of this title.

§ 3375. Retrospective denial.

The utilization review entity may not revoke, limit, condition or restrict a pre-authorization on ground of medical necessity after the date the health care provider received the pre-authorization. Any language attempting to disclaim payment for services on the basis of changes to medical necessity that have been pre-authorized 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) A pre-authorization for pharmaceuticals 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 and except as otherwise set by evidence-based treatment protocol.

(b) A pre-authorization for a health care service shall be valid for a period of time that is reasonable and customary for the specific service, but no less than sixty days, 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, 2018, 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 issued or renewed after the effective date of this Act. 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.

§3380. Exemptions.

This subchapter shall not apply to policies or contracts designed for issuance to persons eligible for coverage under Titles XIX, Title XXI, and XVIII of the Social Security Act, known as Medicare, Medicaid, or any other similar coverage under state or federal governmental plans.

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, or 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 any pre-authorization in which the relevant data is provided as called for by the utilization review entity. Any request submitted by a provider or covered person that includes an unspecified, unclassified or miscellaneous code or data element to constitute a clean request shall also include appropriate supporting documentation or narrative which explains the unspecified, unclassified or miscellaneous code and describes the diagnosis and treatment rendered.

(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. Electronic pre-authorization does not include any form of request that is transmitted to the utilization review entity through facsimile.

(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” or “medical necessity” 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 current version adopted by the United States Department of Health and Human Services.

(10) “Pre-authorization” means a requirement by a carrier or health insurance plan that providers 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. Pre-authorization lets the insured and provider know in advance which procedures and pharmaceuticals are considered by the insurer to be medically necessary.

(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 who are covered under a health benefit plan or health insurance policy or contract issued for delivery in this State or delivered in this State 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, managed care 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;

e. This definition does not include accident-only, credit, dental, vision, long-term care or disability income insurance, coverage issued as a supplement to liability insurance, worker's compensation or similar insurance or automobile medical payment insurance.

§ 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, and others with access to the website. Information from a utilization review entity that is not an insurer, health benefit plan, or health service corporation shall make this information available at an electronic pre-authorization portal that is accessible in real time. 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 practicing in the same clinical area.

(b) If an insurer, health benefit plan, or health service corporation intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, they shall ensure that the new or amended requirement is not implemented unless their 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 an insurer, health benefit plan, or health service corporation intends either to implement a new pre-authorization requirement or restriction, or amend an existing requirement or restriction, they shall provide covered persons who are currently authorized by the utilization review entity for coverage of the affected health care service and all contracted health care providers 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.

(d) Insurers, health benefit plans, and health service corporations utilizing pre-authorization shall report de-identified statistics regarding pre-authorization approvals, denials, and appeals to the Delaware Health Information Network in a format and frequency, no less than twice annually, of the Delaware Health Information Network's request. The Department may also request this data at any time. The statistics shall include, but may be expanded upon or further delineated by regulation, categories for all of the following:

(1) For denials, the aggregated reasons for denials such as, but not limited to, medical necessity or incomplete pre-authorization submission.

(2) For appeals:

a. Practitioner specialty;

b. Medication, diagnostic test, or diagnostic procedure;

c. Indication offered;

d. Reason for underlying denial; and

e. Number of 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's health care provider within 2 business days of obtaining a clean pre-authorization or of using services described in § 3377 of this title.

(b) If a utilization review entity requires pre-authorization of a health care service, the utilization review entity must grant a pre-authorization or issue an adverse determination and notify the covered person's health care provider of the determination within 8 business days of receipt of 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 grant a pre-authorization or issue an adverse determination and notify the covered person's health care provider of the determination within 5 business days of receipt of 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 and mandates 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 medical necessity after the date the health care provider received the pre-authorization. Any language attempting to disclaim

payment for services on the basis of changes to medical necessity that have been pre-authorized 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.

§ 3586. Length of pre-authorization.

(a) A pre-authorization for pharmaceuticals 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 § 3582 of this title and except as otherwise set by evidence-based treatment protocol.

(b) A pre-authorization for a health care service shall be valid for a period of time that is reasonable and customary for the specific service, but no less than sixty days, 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 § 3582 of this title.

§ 3587. Electronic standards for pharmaceutical pre-authorization.

No later than January 1, 2018, 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 issued or renewed after the effective date of this Act. 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.

§ 3590. Exemptions.

This subchapter shall not apply to policies or contracts designed for issuance to persons eligible for coverage under Titles XIX, Title XXI, and XVIII of the Social Security Act, known as Medicare, Medicaid, or any other similar coverage under state or federal governmental plans.

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.