

**STATE OF CALIFORNIA
DEPARTMENT OF MANAGED HEALTH CARE
TITLE 28, CALIFORNIA CODE OF REGULATIONS
Section 1300.67.241**

INITIAL STATEMENT OF REASONS

**Amendments to the Prescription Drug Prior Authorization or Step Therapy Exception
Request Form Process**

(Control No. 2016-5182)

As required by section 11346.2 of the Government Code, the Director of the Department of Managed Health Care (Director) sets forth below the reasons for the amendment of section 1300.67.241 of title 28 of the California Code of Regulations (Regulations).

Authority

Pursuant to Health and Safety Code section 1341.9, the Department of Managed Health Care (Department) is vested with all duties, powers, purposes, responsibilities and jurisdiction as they pertain to health care service plans (health plans) and the health care service plan business.

Health and Safety Code section 1344 grants the Director authority to adopt, amend, and rescind regulations as necessary to carry out the provisions of the Knox-Keene Act, including rules governing applications and reports, and defining any terms as are necessary to carry out the provisions of the Knox-Keene Act.

Health and Safety Code section 1367.24 requires every health plan that provides prescription drug benefits to maintain an expeditious process by which prescribing providers may obtain authorization for non-formulary medically necessary prescription drugs. Section 1367.24 also requires every health plan that provides prescription drug benefits to provide the Department a description of its process, and requires the Department to review the health plans' performance in providing prescription benefits during periodic onsite medical surveys.

Health and Safety Code section 1367.241 requires the Department and the Department of Insurance (CDI) to jointly develop a prior authorization form for use by every health plan and health insurer that provides prescription drug benefits, except as specified.

Health and Safety Code section 1367.244 requires the Department and CDI to include a provision for a step therapy exception request in the prior authorization form developed pursuant to Health and Safety Code section 1367.241.

SPECIFIC PURPOSE/PROBLEM AND NECESSITY THAT REGULATION AMENDMENTS ADDRESS:

Specific Problems Addressed, and Necessity of Regulations

The Department has determined the adoption of this regulation is necessary in order to clarify and make specific the application of the law regarding prior authorization forms, prior authorization requirements, and step therapy exceptions and to comply with Health and Safety Code sections 1367.241 and 1367.244. Section 1367.241 requires that the Department, in collaboration with CDI, jointly develop a prior authorization form. The regulation is necessary to clarify other statutory requirements contained in section 1367.241. This regulatory amendment is also necessary to incorporate Health and Safety Code section 1367.244, which requires the Department and CDI to include a provision for a step therapy exception request in the prior authorization form developed pursuant to Health and Safety Code section 1367.241.

The previous law, enacted through Senate Bill (SB) 866 (Hernandez, Chapter 648, Statutes 2011), established a standardized prior authorization form and process developed by the Department and CDI to be utilized by health plans and health insurers, or their delegated representatives, for prescription drug prior authorization requests. While the intent of SB 866 was to streamline the prescription drug prior authorization process and improve enrollee access to prescription drugs, SB 866 did not account for new technology and alternative methods for transmitting prescription drug prior authorization requests. As a result, providers, health plans, and medical groups have expressed concern that alternative methods for transmitting prescription drug prior authorization requests, which may be more efficient than the standardized form, could be prohibited by current law.

Although prior authorization has been shown to be effective in controlling prescription drug costs, the lack of uniformity between health plans' and insurers' prior authorization processes ultimately delays and negatively impacts patient care. Specifically, the lack of uniformity in the prior authorization process results in providers spending excessive amounts of time completing prior authorization forms, thus spending less of their time on patient care, and patients often experience significant delays before receiving the prescription drugs. Additionally, varying health plan processes also leads to delay and confusion in the authorization and prescription process.

Existing law, as enacted under SB 282 (Hernandez, Chapter 654, Statutes 2015) and revising previous SB 866, requires that every prescribing provider, as defined, when requesting prior authorization for prescription drugs, submit a standard prior authorization form to the health plan or health insurer, and requires those plans and insurers to utilize and accept only the standard prescription drug prior authorization form. The prior authorization form: (1) shall not exceed two pages (2) shall be made available electronically by the Department, CDI, and the health plan and health insurer; and (3) may be submitted electronically from the prescribing provider to the health plan or health insurer. SB 282 requires the Department and CDI to update the uniform prior authorization form on or before January 1, 2017, and requires prescribing providers to use, and health plans and health insurers to accept, only those forms or electronic process on or after July 1, 2017, or 6 months after the form is developed, whichever is later.

Pursuant to SB 282, the amendments to the regulation change the time limit for health plan review of prior authorization requests from two business days to 72 hours for non-urgent requests, and 24 hours if exigent circumstances exist.

Additionally, the amendments to the regulation, as required by SB 282 authorize a prescribing provider, as defined, to use prior authorization system utilizing the standardized form for prescription drug prior authorization or an electronic process developed specifically for transmitting prior authorization information that meets the NCPDP's SCRIPT standards. SB 282 also adds exemptions with respect to the use of the form for any contracted physician group that:

1. Is delegated the financial risk for prescription drugs by a health plan;
2. Uses its own internal prior authorization process rather than the health plan's prior authorization process for health plan enrollees; or
3. Is delegated a utilization management function by the health plan concerning any prescription drug, regardless of the delegation of financial risk.

The amendments to the regulation required by SB 282 will make it easier for prescribing providers to comply with prescription drug prior authorization requirements by permitting alternative electronic methods for submitting the prior authorization requests. This would result in more efficiency, better coordination of care and a reduction in errors in the electronic prescription drug prior authorization process. Furthermore, SB 282 expands the types of contracted physician groups exempt from compliance with the prescription drug prior authorization form requirements resulting in fewer prescribing providers having to submit a prescription drug prior authorization form.

The Department has also determined the adoption of this regulation is necessary in order to clarify and make specific the application of the law regarding prior authorization forms and prior authorization requirements to Medi-Cal managed care plans. Health and Safety Code section 1367.241, subdivision (b) specifies that the 72 and 24 hour deadlines for approval or disapproval of a prescription drug prior authorization request, and the consequence for a health plan's failure to comply with that provision, do not apply to contracts entered into under certain sections of the Welfare and Institutions Code: Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code. These contracts are described as Medi-Cal managed care plan contracts, but in the interest of clarity and consistency, the proposed amendments to the regulation also specifically reference the contracts in the manner they are identified in Health and Safety Code section 1367.241(b). The regulation is necessary to clarify the statutory requirements contained in section 1367.241 and to clearly indicate that certain subdivisions within the existing regulation do not apply to Medi-Cal managed care plans or any contracts entered into and identified in Health and Safety Code section 1367.241(b). The Welfare and Institutions Code already contains provisions that govern the timeframes and procedures with which Medi-Cal managed care plans shall comply when processing prescription prior authorizations (see Welfare and Institutions Code section 14456.5).

In addition to the amendments to the regulation and form required by SB 282, Assembly Bill (AB) 374 (Nazarian, Chapter 621, Statutes 2015) also requires amendments to the regulation and form to allow for a step therapy exception process. The regulation and form, as amended pursuant to AB 374, requires providers, except as specified, to utilize the amended form for step therapy exception requests and requires health plans to review all requests for step therapy exceptions to a health plan's step therapy process for prescription drugs within the same time periods as prior authorization requests. The bill would therefore assure timely review of physician requests for exceptions to a health plan's step therapy process and would provide clear patient protections.

SPECIFIC PURPOSE AND BENEFIT OF THE AMENDMENT TO SECTION 1300.67.241

Amended subdivision (a) clarifies and makes specific the parties subject to compliance with the regulation and Department oversight, and requires use of the amended Prescription Drug Prior Authorization or Step Therapy Exception Request Form. The amended subdivision takes into account the changes required by SB 282 and AB 374, thereby preventing confusion to health plans, providers and consumers and benefiting the health care marketplace. It also clarifies the scope of the exemption for certain contracted physician groups described in Health and Safety Code section 1367.241(f), as well as the applicability of the amended regulation to those contracted physician groups.

New subdivision (b) clarifies the type of entity that is not subject to the requirements of the regulation to prevent confusion and mistaken use of the form or process by impacted entities when not required.

New subdivision (c), as added to the regulation, permits a prescribing provider to utilize either the Department's prior authorization and step therapy exception form or a form compliant with the National Council for Prescription Drug Programs' SCRIPT standard (SCRIPT standard). This gives both providers and health plans more options in processing prescription prior authorizations and step therapy exception requests and is consistent with SB 282 and AB 374. New subdivision (c)(2) aligns with the statute to give the contracted physician groups identified in section 1367.241(f)(1)-(3) the option to use their own prior authorization request process, consistent with section 1367.241(h)(3). This clarifies that the identified physician groups are not required to use the department's form, and this flexibility will reduce the administrative burden to those groups.

Amended subdivision (d) clarifies the parties subject to the use of Form No. 61-211 or the SCRIPT standard when the process has been contracted to a pharmacy benefit manager (PBM). This amendment is consistent with SB 282 and AB 374 and benefits health plans, providers and consumers by clarifying the prescription drug prior authorization and step therapy exception request process when there is a contracted PBM.

Amended subdivision (e) benefits health plans, providers and consumers by clarifying the effective date of the amended regulation and form and other specific requirements, including electronic availability of the form, information required to be in an approval or a disapproval of a prescription drug prior authorization or step therapy exception request, required times for processing non-urgent and exigent requests, and that Medi-Cal managed care plans are not required to meet the required times for processing non-urgent and exigent requests. The amended subdivision takes into account the changes required by SB 282 and AB 374, thereby preventing confusion to health plans, providers and consumers and benefiting the health care marketplace. Specifically:

- Subdivision (e)(1) requires that health plans or PBMs make amended Form 61-211 electronically available;
- Subdivision (e)(2) requires that health plans or PBMs accept Form 61-211 or a form compliant with the SCRIPTS standard through any reasonable means of transmission;
- Subdivision (e)(3) clarifies that step therapy is included in the subdivision as required by AB 374 and that a form compliant with the SCRIPTS standard is also included in this subdivision; and,
- Subdivision (e)(4) clarifies the mandatory timeframes for processing a non-urgent or exigent request and the information that must be contained in a denial of such a request. This subdivision also clarifies that (e)(4) does not apply to Medi-Cal managed care plans.

Amended subdivision (f) benefits health plans, providers and consumers by clarifying terms in a “Definition” portion of the amended regulation to prevent confusion amongst health plans, providers and consumers impacted by the regulation when processing requests.

New subdivision (g) benefits health plans, providers and consumers by clarifying the requirements for appealing a decision pursuant to the amended regulation as required by federal law and also clarifying that Medi-Cal managed care plans are not subject to this subdivision’s requirements.

Amended subdivisions (h) clarifies the law by amending the existing text to note that the subdivision now applies to step therapy exception requests, that the SCRIPTS standard may be used in lieu of Form 61-211, and amending cites to subdivisions based on the other amendments contained within the regulation.

Amended subdivision (i) clarifies the law by amending the existing text to note that the subdivision now applies to step therapy exception requests, and that the SCRIPTS standard may be used in lieu of Form 61-211.

Amended subdivision (j) clarifies the law by amending the existing text to note that the subdivision now applies to step therapy exception requests..

Amended subdivision (k) clarifies the law by amending the existing text to note that the subdivision now applies to step therapy exception requests, and amending cites to subdivisions based on the other amendments contained within the regulation.

Amended subdivision (l) clarifies the impacted entities required to send a notice of disapproval, and amends the timing requirements for issuing decisions on a prescription prior authorization or step therapy request for non-urgent or exigent circumstances and to clearly state what occurs if these timing requirements are not met by the appropriate party. This subdivision also clearly states that it does not apply to Medi-Cal managed care plans.

Subdivision (m) clarifies that a step therapy exceptions falls under the review and enforcement of the regulation, and amends the subdivision to clearly who which entities are exempted from the regulation requirements and not subject to review and enforcement by the Department. Specifically:

- Former subdivision (m)(1) has been deleted because it is no longer applicable due to the changes in law;
- New subdivision (m)(1) clarifies which entities shall have a provision within their contracts requiring the PBM to comply with the regulation and Section 1367.241 of the Act;
- Amended subdivision (m)(2) makes specific which entities are subject to having written policies and procedures and amended to include the step therapy exception;
- Amended subdivision (m)(3) makes specific that health plans do not waive their responsibilities to comply with Section 1367.241 when they contract with a PBM and that the step therapy exception also falls within this requirement;
- Amended subdivision (m)(4) clarifies which entities are subject to the enforcement and penalty provisions within the Knox-Keene Act and also amends the subdivision to specifically cite to the prescription drug prior authorization and step therapy process;
- Amended subdivision (m)(5) clarifies and makes specific which entities are subject to the enforcement and penalty provisions within the Knox-Keene Act and that failure to comply with the regulation and Section 1367.241 constitutes a basis for disciplinary action by the Department.

CHANGES TO THE FORM INCORPORATED BY REFERENCE:

Form 61-211 has been renamed to clarify that it includes the step therapy requirement of AB 374 and is now titled, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form.”

The “Instructions” box on page 1 has been clarified to include the step therapy exception information and to also state that the information in the form must be HIPAA compliant.

The “Patient Information” box on page 1 has been amended and clarified to delete duplicative information regarding HIPAA compliance that is not contained in the “Instructions” box.

The “Medication/Medical and Dispensing Information” box on page 1 has been clarified to include a step therapy check box as required by AB 374.

The “Medication/Medical and Dispensing Information” has a non-substantive change in the third line to remove a wrong colored parenthesis and replace it in the correct color.

The “Instructions” box on page 2 has been clarified to clearly state that the instructions regarding required information should be followed for a step therapy exception request.

Box Number 2 on page 2 has been clarified to delete the reference to ICD-9, which is no longer allowable pursuant to federal law.

Box Number 3 on page 2 has been clarified to indicate that it now also applies to step therapy exception requests.

Box Number 3 on page 2 has been made specific to indicate that the clinical information should contain information related to a determination of “exigent circumstances” and to removing the formulary tier exception information which is no longer relevant because of the step therapy inclusion in the form.

The prescriber signature section on page 2, now clarifies that an Electronic I.D. Verification may be used in place of a signature by the prescribing provider. This new terminology is defined in the “Definition” portion of the regulation.

The word “Insurer” has been added on page 2 for clarification that this part of the form only needs to be filled out by the plan or insurer once a form is submitted.

The requirement that the plan or insurer include the “Date/Time Request was Received by Plan/Insurer” has been added to clarify that this information must be included for Department or CDI oversight to ensure that required timeframes are being met.

The requirement that the plan or insurer include the time of the decision in has been added to clarify that this information must be included for Department or CDI oversight to ensure that required timeframes are being met.

DOCUMENTS RELIED UPON

- Knox-Keene Act, Section 1367.241;
- Senate Bill 866 (Hernandez, Chapter 648, Statutes 2011);
- Senate Bill 282 (Hernandez, Chapter 654, Statutes 2015);
- Assembly Bill 374 (Nazarian, Chapter 621, Statutes 2015);
- Centers for Medicare and Medicaid Services Part D Coverage Determination Request Form;
- Department of Health Care Services 50-1 Treatment Authorization Request (TAR) Form;
- Industry Collaborative Effort (ICE) Medication Prior Authorization Form;
- Rx America Prior Authorization Form;’
- Prescription Solutions Medication Prior Authorization Request Form;
- AB 374, Assembly Floor Bill Analysis, As Amended 9/2/2015;
- Minnesota Uniform Form for Prescription Drug Prior Authorization Requests and Formulary Exceptions; and,
- National Council for Prescription Drug Programs’ SCRIPT standard, NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA), Fact Sheet.

REASONABLE ALTERNATIVES TO THE REGULATION

The Department and the CDI drafted a proposed prior authorization or step therapy exception form and jointly conducted pre-notice discussions pursuant to Government Code section 11346.45. The Department and CDI jointly conducted two semi-public pre-notice discussions with stakeholders and interested parties on February 23rd and 25th, 2016.

Through written and verbal comments submitted during stakeholder workshops, the Department considered many different alternative approaches and prior authorization or step therapy exception forms presented by the stakeholders. Based on written and verbal comments from stakeholders, the Department and the CDI developed a revised prior authorization or step therapy exception form. The Department and the CDI finalized the prior authorization or step therapy exception form referenced in this ISOR after considering written comments from stakeholders. The final prior authorization form meets the demands of the individuals and businesses that will utilize the form on a daily basis. Further, the Department has demonstrated in the “Documents Relied Upon” portion of this ISOR that it has complied with the statutory requirement contained in Health and Safety Code section 1367.241

The Department will consider all reasonable alternatives submitted by members of the public during the comment period.

ECONOMIC IMPACT

The Department has determined that the regulation amendments will not have a statewide adverse economic impact directly affecting businesses because the amendments to the regulation and the form are incorporating current law, as revised by Senate Bill 282 and Assembly Bill 374 and will benefit health plans, providers and consumers by making specific the requirements under the law.

ECONOMIC IMPACT ANALYSIS

Creation or Elimination of Jobs Within the State of California

The amended regulation and form is designed to assist prescribing providers, health plans, physicians, and physician groups in the prior authorization and step therapy exception process. Prior authorization and step therapy exception processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization and step therapy exception request form. Because the amendments and additions to the regulation only clarify and make specific the updated laws for the health care industry and impacted enrollees, the Department has determined that this amendment will not create or eliminate jobs within the State of California, and in fact, will benefit persons with jobs by updating obsolete provisions and making clear what is required under current law. Therefore, in clarifying and interpreting California Health and Safety Code section 1367.241, no jobs in California will be created or eliminated.

Creation of New Businesses or Elimination of Existing Businesses Within the State of California

The amended regulation and form is designed to assist prescribing providers, health plans, physicians, and physician groups in the prior authorization and step therapy exception process. Prior authorization and the step therapy exception processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization and step therapy exception request form. Because the amendments and additions to the regulation only clarify and make specific the updated laws for the health care industry and impacted enrollees, the Department has determined that this amendment will not create new businesses or eliminate existing businesses within the State of California. However, it will benefit health care businesses by updating obsolete provisions and making clear what is required under current law. Therefore, in clarifying and interpreting California Health and Safety Code section 1367.241, no new businesses in California will be created or existing businesses eliminated.

Expansion of Businesses Currently Doing Businesses Within the State of California

The amended regulation and form is designed to assist prescribing providers, health plans, physicians, and physician groups in the prior authorization and step therapy exception process. Prior authorization and the step therapy exception processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization and step therapy exception request form. Because the amendments and additions to the regulation only clarify and make specific the updated laws for the health care industry and impacted enrollees, the Department has determined that this amendment will not expand businesses currently doing business within the State of California. However, it will benefit health care businesses by updating obsolete provisions and making clear what is required under current law. Therefore, in clarifying and interpreting California Health and Safety Code section 1367.241, no existing businesses in California will be expanded.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment

This amended regulation and form is designed to assist prescribing providers, health plans, physicians, and physician groups in the prior authorization and step therapy exception process. Prior authorization and step therapy exception processes are currently being performed by existing health plans, physicians, and physician groups. This regulation may improve the health and welfare of California residents by reducing delays in requesting medications, controlling prescription drug costs, and ensuring that prior authorizations and step therapy exception requests are done in a timely manner. This regulation will not adversely affect the health and welfare of California residents, worker safety, or California's environment.

Therefore, as described in the paragraphs above, the ultimate benefits to the health and welfare of residents of California from these amendments is increased protection of the public health and safety through a more uniform prescription drug prior authorization and step therapy process, as well as increased transparency in business and business practices.