

ACTION: Notice of Rulemaking Action
Title 28, California Code of Regulations

SUBJECT: Prescription Drug Prior Authorization or Step Therapy Exception Request Form Process; Amending section 1300.67.241 in Title 28, California Code of Regulations; Control No. 2016-5182.

PUBLIC PROCEEDINGS:

Notice is hereby given that the Director of the Department of Managed Health Care (Department) proposes to amend a regulation under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), section 1300.67.241, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form Process.”

This rulemaking action proposes to amend section 1300.67.241, in Title 28, California Code of Regulations. Before undertaking this action, the Director of the Department (Director) will conduct written public proceedings, during which time any interested person, or such person’s duly authorized representative, may present statements, arguments, or contentions relevant to the action described in this notice.

PUBLIC HEARING:

Pursuant to Health and Safety Code section 1367.241(d)(4), the Department and the California Department of Insurance will hold a joint public hearing regarding this regulation. The public hearing will start at **1:00 p.m.** and end no later than **5:00 p.m. on October 10, 2016** at:

**980 Ninth Street, 2nd Floor
Sacramento, CA 95814**

The facility is accessible to persons with mobility impairments. Persons with sight or hearing impairments are requested to notify the contact person for these hearings in order to make special arrangements. At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The Department requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

WRITTEN COMMENT PERIOD:

Any interested person, or his or her authorized representative, may submit written statements, arguments or contentions (hereafter referred to as comments) relating to the proposed regulatory action by the Department. Comments must be received by the Department, Office of Legal

Services, **by 5 p.m. on October 10, 2016**, which is hereby designated as the close of the written comment period.

Please address all comments to the Department of Managed Health Care, Office of Legal Services, Attention: Jennifer Willis, Senior Counsel. Comments may be transmitted by regular mail, fax, email or via the Department's website:

Website: <http://Department.ca.gov/regulations/>
Email: regulations@Department.ca.gov
Mail: Department of Managed Health Care
Office of Legal Services
Attn: Jennifer Willis, Senior Counsel
980 9th Street, Suite 500
Sacramento, CA 95814
Fax: (916) 322-3968

Please note: if comments are sent via the website, email or fax, there is no need to send the same comments by mail delivery. All comments, including via the website, email, fax or mail, should include the author's name and a U.S. Postal Service mailing address so the Department may provide commenters with notice of any additional proposed changes to the regulation text.

Please identify the action by using the Department's rulemaking title and control number, **Prescription Drug Prior Authorization or Step Therapy Exception Request Form Process, Control No. 2016-5182** in any of the above inquiries.

CONTACTS: Inquiries concerning the proposed adoption of these regulations may be directed to:

Jennifer Willis
Attorney IV
Department of Managed Health Care
Office of Legal Services
980 9th Street, Suite 500
Sacramento, CA 95814
(916) 324-9014
(916) 322-3968 fax
jwillis@Department.ca.gov

OR

Emilie Alvarez
Regulations Coordinator
Department of Managed Health Care
Office of Legal Services
980 9th Street, Suite 500
Sacramento, CA 95814
(916) 445-9960
(916) 322-3968 fax
ealvarez@Department.ca.gov

AVAILABILITY OF DOCUMENTS:

The Department has prepared and has available for public review the Initial Statement of Reasons, text of the proposed regulation and all information upon which the proposed regulation is based (rulemaking file). This information is available by request to the Department of

Managed Health Care, Office of Legal Services, 980 9th Street, Sacramento, CA 95814,
Attention: Regulations Coordinator.

The Notice of Proposed Rulemaking Action, the proposed text of the regulation, and the Initial Statement of Reasons are also available on the Department's website at <http://www.Department.ca.gov/LawsRegulations.aspx#open>.

You may obtain a copy of the final statement of reasons once it has been prepared by making a written request to the Regulation Coordinator named above.

AVAILABILITY OF MODIFIED TEXT:

The full text of any modified regulation, unless the modification is only non-substantial or solely grammatical in nature, will be made available to the public at least 15 days before the date the Department adopts the regulation. A request for a copy of any modified regulation(s) should be addressed to the Regulations Coordinator. The Director will accept comments via the Department's website, mail, fax or email on the modified regulation(s) for 15 days after the date on which the modified text is made available. The Director may thereafter adopt, amend or repeal the foregoing proposal substantially as set forth without further notice.

AUTHORITY AND REFERENCE:

Pursuant to Health and Safety Code section 1341.9, the 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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

This rulemaking action clarifies and makes specific the application of the law regarding the Prescription Drug Prior Authorization or Step Therapy Exception Request Form, numbered 61-211 (Revised 04/16), which is incorporated by reference in the regulation, and the prescription drug prior authorization and step therapy process that must be followed by health plans.¹

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,

¹ The Prescription Drug Prior Authorization Request Form and the prior authorization process must also be followed by pharmacy benefit managers contracted with health plans and by risk-bearing organizations, physicians or physicians groups that are delegated the financial risk by health plans for prescription drugs and the prior authorization process.

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 authorizes 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 SCRIPTS standard. 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 less prescribing providers having to submit a prescription drug prior authorization form.

SB 282 seeks to take advantage of technological advances in electronic processing and allow the use of alternative third party programs and software to electronically transmit prescription drug prior authorization information. This could result in more efficiency, better coordination of care and a reduction in errors in the electronic prescription drug prior authorization process.

Except as specified, upon failure by a health plan to accept the prior authorization form or to respond to a prescribing provider within 72 hours for non-urgent or 24 hours for exigent circumstances, section 1367.241 deems the prior authorization request granted.

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.

The amended regulation and form proposed in this rulemaking action clarifies and makes specific the requirements within State law, specifically Health and Safety Code sections 1367.241 and 1367.244, incorporates the Prescription Drug Prior Authorization or Step therapy Exception Request Form by reference and delineates the process by which the form will be utilized and enforced.

BROAD OBJECTIVES AND BENEFITS OF THE REGULATION:

Pursuant to Government Code section 11346.5(a)(3)(C), the broad objectives and benefits of this regulation is that it updates the process for the submission of and response to a uniform prior authorization for the Prescription Drug Prior Authorization Request Form, the entities exempted from either use of the form or the regulation as a whole, the consequences for failing to respond to a request as required, and the Department's oversight and enforcement powers. The regulation incorporates the revised Prescription Drug Prior Authorization Request Form by reference. These updates are necessary pursuant to the passage of SB 282 and AB 374.

Specifically, amended subdivisions (a) and (b) delineate the parties subject to compliance with the regulation and Department oversight, and require use of the amended Prescription Drug Prior Authorization Request Form. Both the amended subdivisions and the amended form take 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. Section (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 drug prior authorizations and step therapy exception requests and is consistent with SB 282 and AB 374.

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. 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.

Subdivision (f) benefits health plans, providers and consumers by clarifying terms in a “Definition” portion of the amended regulation. Subdivision (g) benefits health plans, providers and consumers by clarifying the requirements for appealing a decision pursuant to the amended regulation and also clarifying that Medi-Cal managed care plans are not subject to this subdivision’s requirements.

Subdivisions (h), (i), (j) and (k) benefit the health plans, providers and consumers 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.

The broad benefit of subdivision (l) is to amend the regulation for consistency with the impacted entities under SB 282 and AB 374, to amend cites to subdivisions based on other amendments within the regulation, and to amend the timing requirements for issuing decisions on a prescription drug 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) has a broad benefit of amending the subdivision to clearly state that step therapy exceptions fall under the review and enforcement of the regulation, and that certain entities that have been exempted from the regulation requirements are not subject to review and enforcement.

Prior to the enactment of Health and Safety Code section 1367.241, health plans developed and utilized their own prior authorization forms for non-formulary prescription drugs. The result was that providers had to complete varying health plan-specific prior authorization forms each time a non-formulary prescription drug was prescribed, and comply with health plans’ individualized processes. By creating and requiring that all parties subject to Health and Safety Code section 1367.241 and the regulation utilize a uniform prescription authorization form, the impact on patient care and the delay in provision of non-formulary prescriptions will be minimized.

By specifying the process with which providers, health plans, pharmacy benefit managers, risk-bearing organizations, physicians, and physician groups must comply in the submission of and response to the Prescription Drug Prior Authorization Request Form, the Department will have oversight over the process and the ability to enforce the parties’ obligations, specifically through section (m) of this regulation.

BENEFITS OF THE CHANGES TO THE FORM INCORPORATED BY REFERENCE:

The broad benefits to the changes to the form is that it is compliant with current law as required by SB 282 and AB 374 and has also been updated to address questions and comments from stakeholders who were impacted by the previously adoption of the form. These changes include more precise language to prevent confusion, new terms included that are necessary because of the changes in law, and removal of outdated information.

COMPARISON WITH EXISTING REGULATIONS:

The regulation proposed in this rulemaking action is neither inconsistent nor incompatible with existing state regulations. The Department compared the following related existing regulation, California Code of Regulations, title 28, section 1300.67.24 and found no inconsistency or incompatibility with the proposed regulation.

ALTERNATIVES CONSIDERED:

Pursuant to Government Code section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or has otherwise been identified or brought to the attention of the Department would be more effective in carrying out the purpose for which the above action is proposed or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

The Department and the CDI drafted the proposed prior authorization form with input from stakeholder groups and jointly conducted pre-notice discussions pursuant to Government Code section 11346.45. Through written and verbal comments submitted during stakeholder workshops, the Department considered many alternative approaches and prior authorization forms presented by the stakeholders. Based on written and verbal comments from stakeholders, the Department and the CDI developed a revised prior authorization form that took into account the consumer and stakeholder input. The Department and the CDI finalized the prior authorization form after considering written comments from stakeholders. The final prior authorization form developed with substantial consumer and stakeholder input meets the demands of the individuals and businesses that will utilize the form on a daily basis.

The Department considered the following alternative forms:

Alternative #1: CMS Medicare Part D Coverage Determination Request Form

The federal Centers for Medicare and Medicaid Services (CMS) uses the Medicare Part D Coverage Determination Request Form. This form provides basic information to enrollees and prescribers requesting coverage determinations (including exception requests) from Medicare Part D drug plans. However, use of the form is optional and plan sponsors must accept any written request for a coverage determination. If the form is used, the Medicare drug plan may require additional information or documentation to support the request. The form contains a disclaimer specifying that it cannot be used to request certain medications.

The CMS form as a whole is not a reasonable alternative to the form proposed by this regulation. The biggest drawback of the CMS form is that it is specifically adapted for Medicare Part D determinations. Health and Safety Code section 1367.241 requires that the prior authorization form be used by every health plan that provides prescription drug benefits. The CMS form does

not offer sufficient flexibility in its format or information requested to be used as a standard form by all health plans.

However, the CMS form standard turnaround time for review is 72 hours, or 24 hours for expedited review. This is consistent with the new requirements under SB 282, and is therefore incorporated into the amended regulation.

Alternative #2: DHCS 50-1 Treatment Authorization Request Form (50-1 TAR):

Medical and pharmacy providers use the California Department of Health Care Services' (DHCS) DHCS 50-1 Treatment Authorization Request Form (50-1 TAR) when requesting authorization from Medi-Cal offices. Authorization requests are submitted to the local Medi-Cal field office or the appropriate regionalized field office, and accompanied by documentation supporting the medical necessity of the service(s). The authorization request must include: principal and significant associated diagnoses; the physician or licensed medical practitioner's signed prescription or inpatient doctor's order; the medical condition necessitating the services; and the type, number, and frequency of services to be rendered by each provider. The 50-1 TAR form must be submitted prior to dispensing refills.

The 50-1 TAR form is submitted only to Medi-Cal offices, whereas the proposed form will be submitted to all health plans when authorization is required. The 50-1 TAR form includes a procedure code and other fields that are not required by the proposed form. The 50-1 TAR also does not allow information on whether the patient has started using the requested medication or has tried other medications for the condition. There is no space to provide for additional clinical information. The biggest drawback of the 50-1 TAR form is that it is specifically designed for Medi-Cal determinations and does not offer sufficient flexibility in the format or information requested to be used as a standard form for all health plans.

The Department also considered the following National Standards:

Alternative #3: ICE Medication Prior Authorization Request Form

Industry Collaboration Effort ("ICE") uses its own medication prior authorization request form. The proposed form is more thorough than ICE's form in that it requires a plan or medical group phone number in addition to the plan or medical group facsimile number. The proposed form also requests a patient's secondary insurance information, if applicable. ICE's form requires prescribers to fill out all the fields on the form. The Department recognizes that not all the fields on the prior authorization request may be applicable, and the proposed form instructs a prescriber to fill out all *applicable* fields. For these reasons, the proposed form would provide health plans with more specific information than the ICE form provides.

Alternative #4: Rx America Prior Authorization Request Form

Rx America's form is specific to Rx America, and for insurance information, requests only the patient's identification number. The form does not request any information regarding the patient's secondary insurance, if applicable. The form also lacks specificity in the requested information related to a medication authorization determination; it does not request information regarding whether the medication is a new medication or a renewal, any previous authorizations for the medication, the administration method, the administration location, and the ICD-9/ICD-10 code for diagnoses.

The fields on the Rx America form are too broad in their requests for information related to the authorization. This practice would not work when uniformly applied to all health plans. The Rx America form offers too much variability and little instruction as to the information that a prescriber must provide when requesting authorization.

Alternative #5: Prescription Solutions Medication Prior Authorization Request Form

Prescription Solutions' (A UnitedHealth Group Company) form is specific to Prescription Solutions, and requests only the patient's Prescription Solutions member identification number for insurance information. The form does not require information about the patient's gender, height, weight, and allergies.

The Prescription Solutions form is not specific enough to be used as a standard form for all health plans. The form requires "directions for use" of the medication, but does not include important fields for specifying the frequency, length of therapy, number of refills, quantity, administration method, and administration location. Providers would interpret "directions for use" differently and provide differing degrees of information. The form also does not allow the provision of additional clinical information to support the authorization request, and does not require sufficient information. For these reasons, the Prescription Solutions form is not a reasonable alternative to the regulation.

Alternative #6: Minnesota Uniform Form for Prescription Drug Prior Authorization Requests and Formulary Exceptions

The Minnesota Uniform Form for Prescription Drug Prior Authorization Requests and Formulary Exceptions is a form that can be used for prior authorization requests, formulary exceptions, or "unsure/unknown." The form does not allow information for a patient's secondary insurance information, if applicable, and does not require information regarding the administration location. The form also does not include an attestation clause or the option of including attachments, and does not even require a prescriber's signature. The form is not solely for prior authorization requests and does not require sufficient information for all health plans to make authorization request determinations.

The Department invites interested persons to present statements or arguments with respect to alternatives to the requirements of the proposed regulations during the written comment period.

PURPOSE OF THE REGULATION:

Prior to the enactment of Health and Safety Code section 1367.241, health plans developed and utilized their own prior authorization forms for non-formulary prescription drugs. The result was that providers had to complete varying health plan-specific prior authorization forms each time a non-formulary prescription drug was prescribed, and comply with health plans' individualized processes. By creating and requiring that all parties subject to Health and Safety Code sections 1367.241 and 1367.244 utilize a uniform prescription drug prior authorization and step therapy exception form, the impact on patient care and the delay in provision of non-formulary prescriptions will be minimized.

By specifying the process with which providers, health plans, pharmacy benefit managers, risk-bearing organizations, physicians, and physician groups must comply in the submission of and response to the prescription drug prior authorization and step therapy exception form and process, the Department will have oversight over the process and the ability to enforce the parties' obligations, specifically through section (m) of this regulation.

SUMMARY OF FISCAL IMPACT:

- Mandate on local agencies and school districts: None
- Cost or Savings to any State Agency: None
- Direct or Indirect Costs or Savings in Federal Funding to the State: None
- Cost to Local Agencies and School Districts Required to be Reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None
- Costs to private persons or businesses directly affected: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- Effect on Housing Costs: None
- Other non-discretionary cost or savings imposed upon local agencies: None

DETERMINATIONS:

The Department has made the following initial determinations:

The Department has determined the regulation will not impose a mandate on local agencies or school districts, nor are there any costs requiring reimbursement by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Department has determined the regulation will have no significant effect on housing costs.

The Department has determined the regulation does not affect small businesses. Health care

service plans are not considered a small business under Government Code Section 11342.610(b) and (c).

The Department has determined the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Department has determined that this regulation will have no cost or savings in federal funding to the state.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS (Government Code section 11346.3(b)):

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 process. Prior authorization and step therapy processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization request form. 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 process. Prior authorization and step therapy processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization request form. 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 Business 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 or step therapy process. Prior authorization and step therapy processes are currently being performed by existing health plans, physicians, and physician groups; the regulation creates the statutorily required uniform prior authorization request form. In clarifying and interpreting California Health and Safety Code section 1367.241, no existing businesses will be expanded that are currently doing business in the State of California.

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 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.

BUSINESS REPORT:

These amendments to the existing regulation and form update the information contained within the regulation and form to be consistent with current law to better inform health plans, providers and consumers of their health care rights. The amendments to this regulation and form are necessary for the health, safety or welfare of the people of the state that the regulation applies to businesses.