

DEPARTMENT OF MANAGED HEALTH CARE

FINAL STATEMENT OF REASONS

Prescription Drug Prior Authorization or Step Therapy Exception Request Form

Title 28, Section 1300.67.241

Internal No. 2016-5182

Updated Informative Digest

There have been no changes in applicable laws or to the effect of the proposed regulation from the laws and effects described in the original Notice of Proposed Regulatory Action.

Update of Information Contained in the Initial Statement of Reasons

The Department has made the following non-substantive amendments:

- The Department revised the regulation and form to consistently use the full phrase “step therapy exception request” to ensure clarity.
- The Department changed the date of the form to clearly show the last time the form was updated.
- The Department has added the term “revised” in front of “Form 61-211” to clarify which version of the form must be posted electronically and made available and accepted when submitted by providers.
- The Department revised the regulation to consistently use the full phrase “contracted physician group” to prevent confusion as to applicability to providers.

The Department has made the following substantive amendments to the regulation and form:

- The Department clarified the language in the form instructions to state that the information entered on the form is protected health information under the Health Insurance Portability and Accountability Act (HIPAA).
- The Department revised the form under the section “Required clinical information” to request information related to exigent circumstances, if such circumstances exist.
- The Department has amended subdivision (a) to clarify that health plans shall utilize form 61-211 exception as specified in subdivisions (a)(1) through (a)(3). The newly amended language is more precise to allow health plans and providers a better understanding of their regulatory obligations under the regulation.
- The Department has amended subdivision (b) to clarify which provisions of the regulation apply to contracted physician groups to prevent confusion and misunderstandings with the application of the regulation.

- The Department has amended subdivision (c)(1) to clarify that a prescribing provider may use the SCRIPT standard in place of form 61-211 and in doing so, will be compliant with the regulation.
- The Department has amended subdivision (c)(2) to clarify that prescribing providers may use a contracted physician group's process for requests for those physician groups described in Health and Safety Code section 1367.241(f)(1) through (f)(3). This amendment will prevent confusion and/or misunderstanding of obligations under the regulation.

Update of Material Relied Upon

No material other than the public comments, the transcript of the public hearing, the Notice of Proposed Regulatory Action, the 15-day Comment Period documents, the Final Statement of Reasons, and the Final Text of the Regulations have been added to the rulemaking file since the time the rulemaking record was opened, and no additional material has been relied upon.

Mandate on Local School Agencies and School Districts

The Department has determined that the proposed regulation will not impose a mandate on local school agencies or school districts.

Comparable Federal Law

The Department has reviewed federal law and determined that there is no comparable federal law for this regulation.

Alternatives to the Proposed Regulation

As discussed in the Initial Statement of Reasons, various alternatives were considered by the Department, including other Prior Prescription Authorization forms (PA Forms), as well as not amending the existing prior authorization form. The Department determined that the alternatives considered would not be more effective in carrying out the purposes for which the regulation is proposed, would not be as effective and less burdensome to health plans and providers, required to utilize the PA Form, and would not be more cost-effective in implementing the requirement of the developing a standard form pursuant to Health and Safety Code section 1367.241.

Summary of and Responses to Comments

The Department's summary and responses to comments received are contained in Tabs I and M of the rulemaking record.

