

FINAL STATEMENT OF REASONS

Standard Prescription Drug Formulary Template

Adding Section 1300.67.205 to Title 28, California Code of Regulations

(Control No. 2017-5229)

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 Notice of Proposed Regulatory Action date September 28, 2018.

Update of Information Contained in the Initial Statement of Reasons

- The Department amended section 1300.67.205, subdivision (a)(3), the definition of “established name,” in order to further clarify and define the term by cross referencing applicable and relevant law in the Health and Safety Code. The Department determined that citing to relevant law in the Health and Safety Code, rather than federal law, would prevent confusion with possible misapplication of the term to the health plan formularies and benefit the stakeholders by providing a consistent and understood term to be used in the formulary.
- The Department amended subdivision (a)(7), the definition of “nonformulary drug,” to remove information about when a drug that is not on a formulary may be obtained through an exception request. The Department determined this information was unnecessary and potentially confusing in this definition area of the formulary template because it does not add any meaning to the definition of the term in question and, in fact, relates to a different method of obtaining a drug through the enrollee’s health plan. Information regarding exception requests is instead contained in section (d)(2)(G) of the formulary template.
- The Department amended subdivision (a)(8), the definition of “Prescription Drug” or “drug” for clarity. The term “self-administered” was eliminated because it caused confusion regarding its relation to inpatient care versus outpatient care and stakeholder comments indicated that certain drugs could be administered in a clinical setting or could be administered by providers and still fall within the definition of a “prescription drug.” In addition, the Department clarified that the definition includes over-the-counter drugs since the inclusion of over-the-counter drugs in the definition was previously unclear and over-the-counter drugs may be considered “prescription drugs” for purposes of copays and deductibles in a health plan formulary. Therefore, in order to ensure the definition did not conflict

with application of over-the-counter drugs in these types of situations, they were added to the definition to prevent confusion and provide clarity to stakeholders.

- The Department deleted the reference to the Uniform Provider Directory Standards in subdivision (c)(3). This amendment is necessary because the Uniform Provider Directory Standards are an evolving document and have not been adopted pursuant to the Administrative Procedures Act. Health and Safety Code section 1367.27(k)(1) exempts the Department from the Administrative Procedures Act regarding the Uniform Provider Directory Standards but the exemption will expire on January 1, 2021. The current Uniform Provider Directory standards will require change once the Department begins the rulemaking process and inclusion of a reference to these standards in the original definition was premature and caused confusion with the stakeholders. Therefore, the Department made the policy decision to remove this reference.
- The Department deleted the reference to “non-formulary” in section 1300.67.205, subdivision (d)(2)(G) in order to avoid confusion and potential misinformation regarding the exception request process. The term “non-formulary” inadvertently narrowed the instances where an enrollee can request an exception request since an exception request can be made for a formulary drug as well as a non-formulary drugs. Other non-substantive, grammatical changes were also made to this subdivision.
- The Department deleted the reference to “non-formulary” in subdivision (d)(2)(P) to prevent confusion and provide necessary clarity in certain situations concerning obtaining formulary drugs. There are instances where prior-authorization is required even if the drug is listed on a health plan’s formulary. This is because a prior-authorization can be required for both formulary drugs and non-formulary drugs. It was necessary to remove the reference to “non-formulary” to prevent enrollees from being given misinformation and thereby potentially misunderstanding the health plan prior authorization process.
- The Department deleted the reference to Rule 1300.67.241(f)(2) in subdivision (d)(2)(Q). Although this Rule does apply to step therapy, it does not contain a definition of the term and is more related to the process a health plan must have in place to handle these types of requests, which also include non-drug requests. Therefore, the Department determined the reference to the Rule could be confusing for enrollees who might not understand its correct application. Other non-substantive, grammatical changes were made to this subdivision.
- The Department added a reference to Health and Safety Code section 1352 in subdivision (d)(3) to further clarify the process a health plan will follow when requesting additional or different terms in the formulary. The health plan will follow the process explained in Health and Safety Code section 1352, which is a

long-standing established process easily understood by health plan staff, with clear deadlines for the Department responding to the health plan request.

- After receiving feedback from stakeholders, the Department added the terms “if applicable” to section 1300.67.205, subdivision (e)(6) to account for government products and other potential products that do not contain drug tiers in their formularies. Certain programs, such as the state Medi-Cal program, do not have drug tiers, and therefore, adding this clarifying language will assist health plans in understanding that this information must be added to the health plan formulary only if it is applicable to the product.
- The Department added two references to Health and Safety Code section 1342.73 in subdivision (d)(6) to reference newly effective, applicable law that has been enacted. Health and Safety Code section 1342.73 became effective on January 1, 2019, and provides that consumer co-pays are capped at \$250 for a 30-day supply of a prescription drug. Since this new law is directly related to the proposed subdivision in the formulary template, the Department added the reference to the provision to align with the standard and clearly indicate that it applies to a drug in the health plan’s formulary.
- The Department added a reference to Health and Safety Code section 1368 in subdivision (d)(11) to clarify that the reference to “grievance or complaint” refers to the processes and requirements outlined in section 1368. The Department determined this information was necessary to notify enrollees that a health plan decision regarding a non-formulary prescription drug is subject to the health plan’s grievance process and can be appealed by the enrollee. This information will assist enrollees in understanding their rights related to their health plan formulary drug coverage.

Non-Substantive Changes

- The Department has made non-substantive changes to correct grammar and spacing in the regulations.

Update of Material Relied Upon

No material other than the public comments, the Notice of Proposed Rulemaking Action, the 45-day and 15-day comment period documents, the transcript of the public hearing, the informal stakeholder meeting and comments 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 including the Center for Medicaid and Medicare Services documents and determined that there is no comparable federal law that adequately accomplishes the purpose of these regulations.

Alternatives to the Proposed Regulation

As discussed in the Initial Statement of Reasons, the Department considered various alternatives to the proposed regulation during the informal rulemaking process. Further, the Department determined during the rulemaking process 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 regulated entities, and would not be more cost-effective in implementing the requirements of Health and Safety Code section 1367.205 and the entirety of the Knox-Keene Act.

Summary of and Responses to Comments

The Department's summary and responses to comments from the first and second comment periods are contained in tabs I and M of the rulemaking record.