

From: [DMHC Licensing eFiling](#)
Subject: APL 19-023 (OPL) - Standard Prescription Drug Formulary Template
Date: Wednesday, December 4, 2019 8:05:32 AM
Attachments: [APL 19-023 \(OPL\) - Standard Prescription Drug Formulary Template \(12.4.19\).pdf](#)

Dear Health Plan Representative,

Please see attached All Plan Letter regarding recently adopted regulations outlining minimum standards and requirements for health care service plan prescription drug formularies subject to Health and Safety Code section 1367.205.

Thank you.



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ALL PLAN LETTER

DATE: December 4, 2019
TO: All Health Care Service Plans
FROM: Phuc Nguyen, Acting Deputy Director
Office of Plan Licensing
SUBJECT: APL 19-023 (OPL) Standard Prescription Drug Formulary Template

The Department of Managed Health Care (the DMHC or Department) issues this All Plan Letter (APL) to provide guidance regarding recently adopted regulations outlining minimum standards and requirements for health care service plan prescription drug formularies subject to Health and Safety Code section 1367.205. The regulation is codified in California Code of Regulations, title 28, § 1300.67.205¹ (Formulary Regulation) and became effective October 1, 2019. This APL instructs health care service plans (plans) to make a filing due no later than January 24, 2020.

I. Background

In 2014, the Legislature enacted Senate Bill 1052 (Torres, Ch. 575, Stats. 2014) to promote accessibility and transparency in prescription drug coverage by requiring the Department to create a prescription drug formulary template for easy enrollee access to clear and comparable prescription drug information. In drafting the prescription drug formulary template, the Department reviewed a California HealthCare Foundation (CHCF) study regarding the consumer experience in accessing prescription drug coverage, and worked with the California Department of Insurance (CDI) and stakeholders. The CHCF found a prescription drug formulary with specific information and format would be greatly beneficial to plan enrollees. By implementing a standard prescription drug formulary template, the Department hopes to address some of the primary problems facing enrollees when accessing prescription drug information, and to further the goals of Senate Bill 1052 (Torres, Ch. 575, Stats. 2014).

¹ References to sections of the California Health and Safety Code will be designated as "Section," e.g., Section 1367.205, and references to sections of the California Code of Regulations, title 28, will be designated as "Rule," e.g., Rule 1300.67.205.

II. Key Requirements for Formulary's Informational Section

Rule 1300.67.205, subdivision (b) requires a plan's prescription drug formulary (formulary) to contain a cover page, table of contents, informational section, categorical list of prescription drugs, and an index of prescription drugs. In addition, Rule 1300.67.205, subdivision (d) requires a plan's formulary to include certain information. The following is a non-exhaustive listing of key components required to be in a formulary's informational section.²

- A description of drug tiers in the formulary, if the drugs are grouped into tiers. Rule 1300.67.205(d)(6).
- Information about the differences between drugs covered under the medical benefit and drugs covered under the outpatient prescription drug benefit of the health plan product, and instructions on how to obtain coverage information concerning drugs under the medical benefit. Rule 1300.67.205(d)(8).
- Notice describing the types of changes a plan may make to its formulary and when changes will be effective. Rule 1300.67.205(d)(9).
- Notice that the plan covers nonformulary drugs when medically necessary, and a detailed description of the process for requesting coverage of a nonformulary drug. Rule 1300.67.205(d)(11).
- Detailed description of the process for requesting prior authorization or a step therapy exception. Rule 1300.67.205(d)(13).
- Description of the coverage provided under the outpatient prescription drug benefit for drugs, devices, and FDA-approved products. Rule 1300.67.205(d)(16).
- If applicable, a detailed description of the process for requesting coverage and obtaining drugs that are subject to specialty pharmacy restrictions or other network limitations on coverage. Rule 1300.67.205(d)(18).

There are numerous descriptions required to be included in the formulary's informational section. These descriptions may contain explanations or details regarding the various processes relating to a health plan's formulary. Plans should review relevant definitions to ensure compliance with any referenced statutes. In addition, plans should review coverage documents to ensure any changes to a plan's formulary (to comply with Formulary Regulation requirements) are applied and/or reflected in applicable coverage document(s).

Plans that have products licensed under the jurisdiction of both DMHC and the California Department of Insurance may create a "joint standard formulary template" so long as the combined template meets all the DMHC's formulary requirements specified in Rule 1300.67.205.

² This APL and the noted key provisions do not purport to describe the Formulary Regulation in its entirety, and should not be considered a substitute for a review of the entire Formulary Regulation.

Health and Safety Code section 1367.205(a)(3) requires that no later than six months after the date a standard formulary is developed, plans must use the template to display the formulary or formularies for each product offered by the plan.

III. Formulary Regulation Acknowledgement Filing

By January 24, 2020, plans are required to submit via eFiling an Exhibit E-1 as a **Report/Other** acknowledging and affirming the plan's intent to comply with the Formulary Regulation requirements. **Title the filing** "APL 19-023: Standard Prescription Drug Formulary Template Acknowledgement Filing."^{3, 4}

A. Exhibit E-1 Summary of eFiling Information

The Exhibit E-1 must include a summary description of the plan's efforts to implement Formulary Regulation requirements. Specifically, the plan should acknowledge and affirm it will amend its formularies to comply with the Formulary Regulation standard template and other requirements effective April 1, 2020, including acknowledgment the plan will complete the following:

- The plan's formularies are in a searchable format and include the sections enumerated in Rule 1300.67.205, subdivisions (b)(1) through (5).
- Cover pages for the plan's formularies include all information in Rule 1300.67.205, subdivisions (c)(1) through (7).
- The plan's formularies contain a table of contents as required in Rule 1300.67.205, subdivision (b)(2).
- The plan's formularies contain all information set forth in Rule 1300.67.205, subdivisions (d)(1) to (19).
- The plan's formularies contain a categorical list of prescription drugs as set forth in Rule 1300.67.205, subdivisions (e)(1) to (8).
- The plan's formularies contain an index as set forth in Rule 1300.67.205, subdivision (f).

The plan must also review its disclosure and coverage documents, including but not limited to its Evidence of Coverage, Disclosure Forms, and Schedule of Benefits and other documents, to ensure no inconsistencies exist between these documents and the requirements of the Formulary Regulation. If no inconsistencies exist, the plan should make an affirmation indicating it reviewed its disclosure and coverage documents and verified there are no inconsistencies with the Formulary Regulation's requirements. However, if inconsistencies do exist, the plan must summarize the inconsistencies in a narrative, and explain the plan's process to amend the inconsistent document(s).

³ Plans with plan formularies not subject to Section 1367.205 are not subject to the requirements of Rule 1300.67.205 and therefore are not required to submit a compliance filing.

⁴ Plans are not required as a part of this APL's acknowledgement filing to submit copies of its formulary or formularies.

If applicable, the plan must include in its Exhibit E-1 a request for the Director's review and approval for any omission, deviation or substitutions of stated definitions. The request must include the basis for an approval, and should highlight the requested variations in the plan's formularies. See Rule 1300.67.205, subdivision (d)(2).

If applicable, the plan must include in its Exhibit E-1 a request for the Director's review and approval for all additional or different terms used in a formulary that are necessary to understand the outpatient prescription drug benefit. The request must include the basis for an approval, and should highlight the requested variations in the plan's formularies. See Rule 1300.67.205, subdivision (d)(3).

IV. Effective Date and Deadline

The Formulary Regulation became effective on October 1, 2019. To acknowledge and affirm compliance with the Formulary Regulation, plans are required to submit an Exhibit E-1 as a **Report/Other** via eFiling. The APL 19-023: Standard Prescription Drug Formulary Template Acknowledgement Filing is due **no later than January 24, 2020**.

Please direct questions regarding this APL to your plan's assigned Licensing reviewer.