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**California Department of Managed Health Care
980 Ninth Street, Suite 500, Sacramento, CA 95814**

ADOPTION OF REGULATIONS

CALIFORNIA CODE OF REGULATIONS

Section 1300.67.205. Standard Prescription Drug Formulary Template

The following standards are minimum standards, and unless otherwise noted, apply to all health plan formularies subject to section 1367.205 of the Health and Safety Code. A health plan may implement additional provisions exceeding these requirements.

(a) Definitions.

- (1) “Coverage document” is a health plan contract, evidence of coverage, certificate of coverage, schedule of benefits, or any other contract for health coverage between an enrollee or subscriber and health plan.
- (2) “Dosage form” is the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or an injectable.
- (3) “Established name” is the official nonproprietary name for a prescription drug that appears on the label, as defined in section 111225 of the Health and Safety Code, which must appear on the label pursuant to section 111355 of the Health and Safety Code. ~~Cosmetic Act.~~
- (4) “Exception request” is the process by which an enrollee requests and gains access to clinically appropriate nonformulary drugs as set forth in sections 1367.24, 1367.241, and 1367.244 of the Health and Safety Code.
- (5) “Exigent circumstances” is when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.
- (6) “Formulary” is the complete list of prescription drugs preferred for use and eligible for coverage under a health plan product, and includes all drugs covered under the outpatient prescription drug benefit of the health plan product.

(7) "Nonformulary drug" is any prescription drug where an enrollee's copayment or out-of-pocket costs are different than the copayment or out-of-pocket costs for a formulary prescription drug, except as otherwise provided by law or regulation, and when a prescription drug that is not listed on the formulary is covered pursuant to an exception request.

(8) "Prescription drug" or "drug" is a self-administered outpatient drug approved by the federal Food and Drug Administration (FDA) for sale to consumers that requires a prescription and is not provided for use on an inpatient basis. Self-administered means those drugs that are not administered in a clinical setting or by a licensed health care provider. The term "drug" or "prescription drug" includes: (i) disposable devices that are medically necessary for the administration of a covered prescription drug, such as spacers and inhalers for the administration of aerosol outpatient prescription drugs; (ii) syringes for self-injectable prescription drugs that are not dispensed in pre-filled syringes; (iii) drugs, devices, and FDA-approved products covered under the prescription drug benefit of the product pursuant to sections 1367.002, 1367.25, and 1367.51 of the Health and Safety Code, including any such over-the-counter drugs, devices, and FDA-approved products; and (iv) at the option of the health plan, any vaccines or other health care benefits covered under the prescription drug benefit of the health plan product.

(9) "Product" is a discrete package of health care coverage benefits that a health plan offers for a particular policy with a specific network service area.

(10) "Quantity Limit" is a restriction on the number of doses or any other limitations on the quantity of a prescription drug a health plan will cover that will be covered by a health plan during a specific time period.

(11) "Strength" is the amount of active ingredient or ingredients that is present in each dose of a prescription drug.

(b) Format of the formulary. The formulary shall be in a searchable format that is searchable and shall include the following sections in the order listed:

(1) Cover page;

(2) Table of contents;

(3) Informational section;

(4) Categorical list of prescription drugs; and

(5) Index of prescription drugs.

(c) Cover page. The cover page of the formulary shall include all of the following:

(1) The title of the document.

(2) The name of the health plan offering the formulary.

(3) The name of each health plan product applicable to which the formulary applies. ~~Product names shall be consistent with the naming standards required pursuant to the Uniform Provider Directory Standards under section 1367.27 of the Health and Safety Code. These standards include the names used on coverage documents, summary of benefits and coverage documents, network provider directories, and other communications with the enrollees including identification cards.~~

(4) The date the formulary was last updated.

(5) A ~~N~~ notice that the formulary is subject to change and all previous versions of the formulary are no longer in effect.

(6) A direct website link/URL for the location of the electronic version of the formulary posted on the health plan's public website. The formulary shall be accessible to potential enrollees, enrollees, providers and the general public. The formulary is accessible if it can be viewed on the website through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number, and if the health plan offers more than one health plan product, when an individual can easily discern which formulary applies to which health plan product.

(7) A direct website link/URL for the location of, or specific instructions for locating, plan-specific coverage documents that include cost sharing applicable to prescription drugs for each health ~~benefit~~ plan product to which the formulary applies, ~~and which are posted on the health plan's website.~~

(d) Informational section. The informational section of the formulary shall include all of the following:

(1) Instructions for contacting the health plan's customer service department. A health plan shall have the customer service representatives readily available on staff during normal business hours who are prepared and knowledgeable to provide accurate, specific information concerning prescription drug benefits, including but not limited to: ~~actual dollar amount of cost sharing for drugs under an enrollee's benefit, including for drugs subject to copayment or coinsurance.~~

A. information concerning drugs covered under the medical benefit of an enrollee's benefit contract;

B. the actual dollar amount of cost sharing under the enrollee's contract for drugs subject to a copayment or coinsurance; and

C. the process for submitting an exception request and request for prior authorization and step therapy exceptions.

(2) Definitions. The following terms shall be defined in informational section of the formulary shall have a definition section as prescribed below. A health plan may request an omission, deviation or substitutions of the stated definitions to the Director ~~an exception from the stated definitions from the Department~~ for review and approval.

A. "Brand name drug" is a drug that is marketed under a proprietary, trademark protected name. The brand name drug shall be listed in all CAPITAL letters.

B. "Coinsurance" is a percentage of the cost of a covered health care benefit that an enrollee pays after the enrollee has paid the deductible, if a deductible applies to the health care benefit, such as the prescription drug benefit.

C. "Copayment" is a fixed dollar amount that an enrollee pays for a covered health care benefit after the enrollee has paid the deductible, if a deductible applies to the health care benefit, such as the prescription drug benefit.

D. "Deductible" is the amount an enrollee pays for covered health care benefits before the enrollee's health plan begins payment for all or part of the cost of the health care benefit under the terms of the policy.

E. "Drug Tier" is a group of prescription drugs that corresponds to a specified cost sharing tier in the health plan's prescription drug

coverage. The tier in which a prescription drug is placed determines the enrollee's portion of the cost for the drug.

F. "Enrollee" is a person enrolled in a health plan ~~and who is a recipient of~~ entitled to receive services from the plan. All references to enrollees in this this formulary template shall also include subscriber as defined in this section below.

G. "Exception request" is a request for coverage of a ~~prescription nonformulary~~ drug. If an enrollee, ~~or his or her designee or~~ prescribing health care provider submits an exception request for coverage of a ~~prescription nonformulary~~ drug, ~~a the~~ health plan must cover the ~~prescription nonformulary~~ drug when the drug is determined to be medically necessary to treat the enrollee's condition.

H. "Exigent circumstances" ~~is~~ are when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

I. "Formulary" is the complete list of drugs preferred for use and eligible for coverage under a health plan ~~policyproduct~~, and includes all drugs covered under the outpatient prescription drug benefit of the health plan ~~policyproduct~~. Formulary is also known as a prescription drug list,

J. "Generic drug" is the same drug as its brand name equivalent in dosage, safety, strength, how it is taken, quality, performance, and intended use. A generic drug is listed in ***bold and italicized lowercase*** letters.

K. "Nonformulary drug" is a prescription drug that is not listed on the health plan's formulary.

L. "Out-of-pocket cost" ~~is a~~ are copayments, ~~or~~ coinsurance, and the applicable deductible, plus all costs for health care services ~~benefits~~ that are not covered by the health plan.

M. "Prescribing provider" is a health care provider authorized to write a prescription to treat a medical condition for a health plan enrollee.

N. “Prescription” is an oral, written, or electronic order by a prescribing provider for a specific individual enrollee that contains the name of the prescription drug, the quantity of the prescribed drug, the date of issue, the name and contact information of the prescribing provider, the signature of the prescribing provider if the prescription is in writing, and if requested by the enrollee/patient, the medical condition or purpose for which the drug is being prescribed.

O. “Prescription drug” is a drug that is prescribed by the enrollee’s prescribing provider and requires a prescription under applicable law.

P. “Prior Authorization” is a health plan’s requirement that the enrollee or the enrollee’s prescribing provider obtain the health plan’s authorization for a prescription drug before the health plan will cover the the drug. ~~when an enrollee’s provider must obtain authorization from the health plan prior to prescribing a medically necessary nonformulary prescription drug.~~ The health plan ~~must~~ shall grant a prior authorization when it is medically necessary for the enrollee to obtain the drug.

Q. “Step therapy” is a process specifying the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are prescribed. The health plan may require the enrollee to ~~first~~ try one or more drugs to treat the enrollee’s medical condition before the health plan will cover a particular drug for the condition pursuant to a step therapy request. If the enrollee’s prescribing provider submits a request for step therapy exception, the health plans shall make exceptions to step therapy when the criteria is met ~~under Rule 1300.67.241(f)(2).~~

R. “Subscriber” means the person who is responsible for payment to a plan or whose employment or other status, except for family dependency, is the basis for eligibility for membership in the plan.

(3) Definitions ~~for~~ of any additional or different terms used in the formulary that are necessary to understand the outpatient prescription drug benefit. The health plan must request review and approval from the Department for all additional or different terms used in the formulary, pursuant to section 1352 of the Health and Safety Code.

- (4) Instructions on for locating a prescription drug in the categorical list of prescription drugs. The instructions shall explain: (i) if a prescription drug may be located by looking up the therapeutic category and class of the drug or the brand or generic name of the drug in the alphabetical index; and (ii) if a generic equivalent for a brand name drug is not available or is not covered, the drug will not be separately listed by its generic name.
- (5) A description of how drugs are listed in the categorical list of prescription drugs. At minimum, the description shall explain: (i) a drug is listed alphabetically by its brand and generic names in the therapeutic category and class to which it belongs; (ii) the generic name of a brand name drug is included after the brand name in parenthesis and all **bold and italicized lowercase** letters; (iii) if a generic equivalent for a brand name drug is available, and both the brand name and generic equivalents are covered, the generic drug will be listed separately from the brand name drug in all **bold and italicized lowercase** letters; and (iv) in the event a generic drug is marketed under a proprietary, trademark protected brand name, the brand name will be listed in all CAPITAL letters after the generic name in parentheses and regular typeface with first letter of each word capitalized. The description shall include an example of a drug available both as a brand name drug and a generic equivalent to illustrate how such a drug is listed.
- (6) A description of the drug tiers in the formulary, if the drugs are grouped into tiers. The description shall include tier numbers designating the tiers and shall accurately describe the types of prescription drugs that are placed in each tier. The same description shall be used in the corresponding coverage documents. The description shall explain how to determine the following: (i) which prescription drugs on the formulary are preferred drugs; and (ii) the cost sharing for each drug tier, including any applicable dollar maximum amounts for products subject to ~~sections section~~ 1342.71 and 1342.73 of the Health and Safety Code. If the formulary has four tiers and is subject to ~~sections section~~ 1342.71 and 1342.73 of the Health and Safety Code, drugs shall be placed in tiers consistent with the drug tier definitions in ~~that subdivision~~ those sections of the Knox-Keene Act.
- (7) A description of all utilization management restrictions the health plan imposes on prescription drug coverage, including but not limited to, prior authorization requirements, step therapy requirements, quantity limits, and network limitations on access including specialty pharmacy restrictions.
- (8) 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 covered under the medical benefit.

- (9) Notice that the health plan will update the formulary with any changes on a monthly basis. The notice shall include a description of the types of changes a health plan may make to the formulary during the policy year, the dates on which such changes shall be effective, and may include a description of any prior notification a health plan will provide an affected enrollee of a formulary change. At minimum, the notice shall include, but not be limited to, the following information: (i) change in drug or dosage form; (ii) changes in tier placement of a drug that results in an increase in cost sharing; and (iii) any changes of utilization management restrictions, including any additions of these restrictions.
- (10) An explanation that the presence of a prescription drug on the formulary does not guarantee ~~that~~ an enrollee will be prescribed that prescription drug by his or her prescribing provider for a particular medical condition.
- (11) Notice that the health plan shall cover nonformulary drugs when medically necessary and a detailed description of the process for requesting coverage of a nonformulary drug. Subject to the exception in subdivision (k) of section 1367.24 of the Health and Safety Code, the description shall state that: (i) the health plan shall notify the enrollee or his or her designee and the enrollee's prescribing provider of its coverage determination within 24 hours of receipt of a request based on exigent circumstances and within 72 hours of receipt of all other requests ~~no later than 72 hours following receipt of a non-urgent request and 24 hours following based on exigent circumstances~~; (ii) the health plan shall provide coverage pursuant to a non-urgent request for the duration of the prescription, including refills; and (iii) the health plan shall provide coverage, including refills, pursuant to a request based on exigent circumstances for the duration of the exigency. The description shall also state ~~that~~ an enrollee may file a grievance or complaint, pursuant to section 1368 of the Health and Safety Code, relating to denial of a coverage request and that the coverage documents provide ~~more~~ information on appeal rights and procedures.
- (12) Instructions on how to locate and fill a prescription through a network retail pharmacy, mail order pharmacy, and specialty pharmacy, as applicable.
- (13) A detailed description of the process for requesting prior authorization or a step therapy exception. Subject to the exceptions in subdivision (b) of section 1367.241 of the Health and Safety Code, the description shall state that if a health plan fails to respond to a completed prior authorization or step therapy request within 72 hours of receiving a non-urgent request and 24 hours of receiving a request based on exigent circumstances, the request is deemed granted.

- (14) Notice of an enrollee's rights to step therapy as provided in subdivision (d)(2) of Rule 1300.67.24.
- (15) Notice pursuant to section 1367.22 of the Health and Safety Code that a health plan may not limit or exclude coverage for a drug if the health plan previously approved coverage of the drug for ~~an~~ the enrollee's medical condition and the prescribing provider continues to prescribe the drug for the medical condition, provided ~~that~~ the drug is appropriately prescribed and safe and effective for treating the enrollee's medical condition.
- (16) A description of the coverage provided under the outpatient prescription drug benefit for drugs, devices, and FDA-approved products pursuant to sections 1367.002, 1367.25, and 1367.51 of the Health and Safety Code. The description shall include a detailed explanation of the requirements and process to acquire those drugs, devices, and FDA-approved products through the outpatient prescription drug benefit.
- (17) A description of the limit on cost sharing for orally administered anti-cancer drugs required by section 1367.656 of the Health and Safety Code.
- (18) If applicable to any drugs listed on the formulary, 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.
- (19) An annotated legend or key to all abbreviations, symbols and notations used in the formulary.

(e) Categorical list of prescription drugs.

- (1) The categorical list of prescription drugs shall be organized by drug category and class based on a commonly used and widely accepted drug classification system such as the most current version of the U.S. Pharmacopeial Convention (USP) Medicare Model Guidelines or the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification. The formulary shall identify the drug classification system ~~that~~ is used. Prescription drugs shall be listed in drug classes consistent with the drug classification system. Prescription drugs belonging to multiple drug classes shall be listed in each applicable class. Category names shall appear alphabetically, and class names shall appear alphabetically within those categories. Brand name and generic prescription drugs shall be alphabetically listed by respective brand or established name within classes.

In addition to a category and class name provided by the drug classification system, the categorical list shall include, where possible, a plain language description of the category and class.

- (2) The categorical list shall include a complete list of all covered prescription drugs, including both generic and brand name drugs, and shall include, where possible, a plain language description of a prescription drug. A health plan may include prescription drugs covered only under the medical benefit of the product, provided that each such drug is clearly identified as a drug covered only under the medical benefit. A health plan may include nonformulary prescription drugs provided that each such drug is clearly identified as a nonformulary drug.
- (3) The categorical list shall include columns in the following order from left to right: (1) **Prescription Drug Name**; (2) **Drug Tier**; and (3) **Coverage Requirements and Limits**. The column headings shall appear on the top of each page of the categorical list.
- (4) In the “Prescription Drug Name” column, the proprietary name for a brand name drug shall appear in all CAPITAL letters. The established name for the brand name drug shall be placed in parentheses after the brand name in all ***bold and italicized lowercase*** letters. The established name for a generic drug shall appear in all ***bold and italicized lowercase*** letters. If a generic drug is sold under a brand name, the brand name shall be placed in parentheses after the established name in regular typeface with the first letter of each word capitalized.
- (5) The “Prescription Drug Name” column shall include all covered dosage forms and strengths for each prescription drug. If there are differences in tier placement, quantity limit, prior authorization, step therapy, or other utilization restrictions or plan benefit offerings for a prescription drug based on its differing dosage forms or strengths, the categorical list of prescription drugs shall include separate rows for the dosage forms and/or strengths of the prescription drug to clearly identify the differences.
- (6) The “Drug Tier” column shall identify the cost sharing tier where the prescription drug is placed, if applicable. A health plan shall use a unique tier number, abbreviation or symbol for the following: (i) prescription drugs, devices, and FDA-approved products covered under the outpatient prescription drug benefit of the product pursuant to sections 1367.002, 1367.25 and 1367.51 of the Health and Safety Code; (ii) orally administered

anti-cancer drugs that are subject to the cost sharing limit in section 1367.656 of the Health and Safety Code; (iii) nonformulary drugs; and (iv) drugs covered only under the medical benefit. The tier abbreviations, notations or symbols shall be explained in the annotated legend or key of the formulary.

(7) The “Coverage Requirements and Limits” column shall include abbreviations, notations or symbols for all utilization management restrictions that the health plan imposes on prescription drug coverage, including but not limited to prior authorization, step therapy, quantity limits, and network limitations on access including specialty pharmacy restrictions, in addition to any other requirements, limits, or other relevant information applicable to the coverage provided for a prescription drug. For each prescription drug subject to quantity limits, the applicable quantity limits shall be described with specificity. Each abbreviation, symbol, or notation used in the “Coverage Requirements and Limits” column shall be explained in the annotated legend or key of the formulary.

(8) The annotated legend or key to all abbreviations, symbols and notations used in the formulary shall appear on each page of the categorical list.

(f) Index. The index shall list each covered brand name and generic drug by respective brand name or established name in alphabetical order and include the page number for the location of the drug in the categorical list of prescription drugs.

AUTHORITY: Health and Safety Code sections 1342.71, 1367.002, 1367.205, 1367.24, 1367.241, 1367.25 and 1367.656. REFERENCE: Health and Safety Code section 1367.205.