California Department of Managed Health Care
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ADOPTION OF REGULATIONS

CALIFORNIA CODE OF REGULATIONS
Title 28, Article 7, Section 1300.67.205

Standard Prescription Drug Formulary Template

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

(a) Definitions for compliance purposes.

(1) "Coverage document" means a health care service plan contract, evidence of coverage, certificate of coverage, schedule of benefits, or any other contract for health coverage.

(2) "Dosage form" means the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

(3) "Established name" means the nonproprietary or generic name for a prescription drug that appears on the label, as defined in the Federal Food, Drug, and Cosmetic Act.

(4) Exception request means the process by which an enrollee requests and gains access to clinically appropriate drugs as set forth in sections 1367.24, 1367.241, and 1367.244 of the Health and Safety Code.

(5) "Exigent circumstances" means 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” means the complete list of prescription drugs preferred for use and eligible for coverage under a health care service plan product, and includes all drugs covered under the prescription drug benefit of the product.

(7) “Nonformulary drug” includes any prescription drug for which an enrollee’s copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation and when a drug is covered pursuant to an exception request.

(8) “Prescription drug” or “drug” means a self-administered drug approved by the federal Food and Drug Administration for sale to the public through retail or mail order pharmacies that requires a prescription and is not provided for use on an inpatient basis or administered in a clinical setting or by a licensed health care provider. The term 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 and 1367.25 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 care service plan, any vaccines or other health benefits covered under the prescription drug benefit of the product.

(9) “Product” means a discrete package of health coverage benefits that a health care service plan offers using a particular product network type within a service area.

(10) “Strength” means the amount of active ingredient that is present in each dose of a prescription drug.

(b) Format of the formulary. The formulary shall include the following sections:

(1) Cover page;

(2) Table of Contents;

(3) Informational section;

(4) Categorical list of prescription drugs; and

(5) Index.

(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 care service plan offering the formulary.

(3) The name of each product to which the formulary is applicable. Product names shall conform to the naming standards required pursuant to the uniform provider directory standards under Senate Bill 137 (Stats. 2015, Ch. 649). Product names shall correspond with names used on coverage documents, summary of benefits and coverage documents (SBCs), provider directories, and other communications as required under the uniform provider directory standards.

(4) The date the formulary was last updated.

(5) Notice that the formulary is subject to change and all previous copies of the formulary should be discarded.

(6) A direct website link/URL for the location of the electronic version of the formulary posted on the health care service plan's public website. The formulary must 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 care service plan offers more than one health benefit plan, an individual can easily discern which formulary applies to which plan.

(7) Contact information for the health care service plan including the customer service phone number, email address, physical address, and hours of operation for the phone number. Customer service representatives must be prepared to provide specific information concerning prescription drug benefits, including but not limited to, actual dollar amounts of consumer cost sharing, information concerning drugs covered under the medical benefit, and the processes for requesting prior authorization for nonformulary drugs or drugs requiring prior authorization and step therapy exceptions.

(8) 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 to which the formulary is applicable, and which are posted on the health care service plan's website.

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

(1) Definitions. The following terms shall be defined in the formulary as prescribed if that particular term is used in the formulary. If a similar term is used, the formulary shall define that term as closely as possible to the prescribed definition. An exception to the stated definitions may be requested by a health care service plan. The health care service plan shall submit the exception request to the Department for review and approval.

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

ii. Coinsurance means the percentage of costs of a covered health benefit that an enrollee pays after the enrollee has paid his/her deductible, if a deductible applies.

iii. Copayment means a fixed dollar amount that an enrollee pays for a covered health benefit after the enrollee has paid the deductible, if a deductible applies.

iv. Deductible means the amount an enrollee pays for covered health benefits before the enrollee's health care service plan begins to pay for part of the cost of the health benefit.

v. "Drug Tier" means a group of prescription drugs that fall within a particular description and category of drugs, and/or utilization management requirement, tied to a specified copayment, coinsurance, or deductible. The tier in which a prescription drug is placed determines the enrollee's portion of the prescription drug cost.

vi. "Enrollee" means a person who is enrolled in a plan and who is a recipient of services from the plan.

vii. "Exigent circumstances" means 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.

viii. "Formulary," also called a prescription drug list, means the complete list of drugs preferred for use and eligible for coverage under a health care service plan product, and includes all drugs covered under the prescription drug benefit of the product.

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

x. "Nonformulary drug" means a prescription drug that is not listed on the formulary but which must be covered when medical necessity is demonstrated unless the drug is excluded from coverage.

xi. "Out-of-pocket cost" means a copayment or coinsurance, and applicable deductible, plus all costs for benefits that are not covered.

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

xiii. "Prescription drug" means a drug that is prescribed by the enrollee's prescribing provider, bought at a pharmacy (including specialty pharmacy and mail order), prescribed for and intended to be used by one person, and regulated by the federal Food and Drug Administration ("FDA").

xiv. "Prescribing provider" means a provider authorized to write a prescription to treat a medical condition.

xv. "Prior Authorization" means when an enrollee or an enrollee's provider must get approval from a health care service plan before the enrollee fills his/her prescription. A health care service plan will only

accept the prior authorization form required by state law (Form No. 61-211 as incorporated by reference in section 1300.67.241) or an electronic prior authorization process as specified in the law unless an exception is noted. Nonformulary prescription drugs that are not excluded from coverage require prior authorization to be covered.

xvi. "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed. For a drug subject to step therapy, the health care service plan may require the enrollee to first try certain drugs to treat the enrollee's medical condition before it will cover another drug for that condition. Plans must make exceptions to step therapy when medical necessity is demonstrated.

(2) Definitions for any additional or different terms used in the formulary that are necessary for comprehension of the prescription drug benefit.

(3) Instructions on how to locate a prescription drug in the categorical list of prescription drugs. The instructions must explain that: (i) a prescription drug may be located by looking up the therapeutic category and class to which the drug belongs 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 on the market, the drug will not be separately listed by its generic name.

(4) A description of how drugs are listed in the categorical list of prescription drugs. The description must explain that: (i) the generic name for a brand name drug is included after the brand name in parentheses and all *lowercase italicized* letters; (ii) 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 *lowercase italicized* letters; and (iii) in the event a generic drug is marketed under a proprietary, trademark protected brand name, the brand name will be listed after the generic name in parentheses and in all CAPITAL letters. The description must include an example of a drug that is available both as a brand name drug and a generic equivalent to illustrate how such a drug is listed.

(5) A description of the drug tiers in the formulary. The description may include tier numbers designating the tiers and/or standard drug tier definitions accurately indicating the types of prescription drugs that are placed in each tier and which are 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. If a health care service plan for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan must use the definitions for each tier as set forth in section 1342.71 of the Health and Safety Code.

(6) A description of all utilization management restrictions that the health care service plan imposes on prescription drug coverage, including but not limited to, prior authorization requirements, step therapy requirements, quantity limits, and network limitations including restricted specialty pharmacy access.

(7) Information about the differences between drugs covered under the medical benefit and drugs covered under the prescription drug benefit of the product and instructions on how to obtain coverage information concerning drugs covered under the medical benefit.

(8) Notice that the health care service plan must update the formulary with changes on a monthly basis.

(9) 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.

(10) Notice that the health care service plan must 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 care service plan must notify the enrollee or his or her designee and the enrollee's prescribing provider of its coverage determination no later than 72 hours following receipt of a non-urgent request and 24 hours following receipt of a request based on exigent circumstances; and (ii) the health care service plan must provide coverage pursuant to a non-urgent request for the duration of the prescription, including refills, and pursuant to a request based on exigent circumstances, for the duration of the exigency. The description shall also state that denial of a coverage request for a nonformulary drug may be appealed and that the coverage documents provide more information on appeal rights and procedures.

(11) Instructions on how to locate a network retail pharmacy and fill a prescription through a network retail pharmacy, mail order pharmacy, and specialty pharmacy, as applicable.

(12) A detailed description of the process for requesting prior authorization or an exception to a step therapy requirement. 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 care service plan fails to respond to a completed prior authorization 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 approved.

(13) Notice of an enrollee's rights concerning step therapy as provided in subdivision (d)(2) of section 1300.67.24 of title 28 of the California Code of Regulations.

(14) Notice pursuant to section 1367.22 of the Health and Safety Code that a health care service plan may not limit or exclude coverage for a drug if the health care service plan previously approved coverage of the drug for an 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.

(15) A description of the coverage provided under the prescription drug benefit for drugs, devices, and FDA-approved products pursuant to sections 1367.002 and 1367.25 of the Health and Safety Code, including any such over-the-counter drugs, devices, and FDA-approved products. The description must include a detailed explanation of the requirements and process to acquire those drugs, devices, and FDA-approved products.

(16) 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.

(17) If applicable to any drugs listed on the formulary, a detailed description of the process for requesting coverage and obtaining drugs that are limited to restricted specialty pharmacy access or subject to other network limitations on coverage.

(18) 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 covered prescription drugs shall be organized by drug category and class on the basis of 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 that belong to multiple drug classes shall be listed in each applicable class. Category names shall appear alphabetically. Class names shall appear alphabetically within categories. Brand name and generic prescription drugs shall be alphabetically listed by brand or established name, respectively, within classes. In addition to a category and class name provided by the drug classification system, the categorical list may include 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 may include a plain language description of a prescription drug, as applicable. A health care service plan may include prescription drugs covered under the medical benefit of the product, provided that each such drug is clearly identified as a medical benefit drug. A health care service plan may include nonformulary prescription drugs, provided that each such drug is clearly identified as a nonformulary drug and is not excluded from coverage.

(3) The categorical list shall include the following columns in the following order from left to right: (i) **Prescription Drug Name**; (ii) **Drug Tier**; and (iii) **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 *lowercase italicized* letters. The established name for a generic drug shall appear in all *lowercase italicized* 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 restrictions or benefit offerings for a prescription drug based on its differing dosage forms or strengths, the formulary 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 in which the prescription drug is placed. A health care service plan shall use a unique tier abbreviation or symbol for the following: (i) prescription drugs, devices, and FDA-approved products covered under the prescription drug benefit of the product without cost share pursuant to sections 1367.002 and 1367.25 of the Health and Safety Code, if required; (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 if included; and (iv) drugs covered under the medical benefit if included. The tier abbreviations or symbols shall be explained in the key.

(7) The "Coverage Requirements and Limits" column shall include abbreviations or symbols for all utilization management restrictions that the health care service plan imposes on prescription drug coverage, including but not limited to prior authorization, step therapy, quantity limits, and network limitations including restricted specialty pharmacy access, 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 amount of prescription drug that will be dispensed per time period must be specified. Each abbreviation, symbol, or notation used in the "Coverage Requirements and Limits" column shall be explained in the annotated legend or key.

(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) Example categorical list based on USP Medicare Model Guidelines Version 6.0, for illustration purposes only.

Drug Name	**Drug Tier**	**Coverage Requirements and Limits**
Analgesics – Drugs for Relief of Pain		
Nonsteroidal Anti-inflammatory Drugs – [Optional: <Plain Language Description>]		
<Drug Name 1>	<Tier 1>	<Util. Mgmt.>
<Drug Name 2, Dosage Form A, Strength A>	<Tier 1>	<Util. Mgmt.>
<Drug Name 2, Dosage Form B, Strength A>	<Tier 2>	<Util. Mgmt.>
<Drug Name 2, Dosage Form B, Strength B>	<Tier 3>	<Util. Mgmt.>

Drug Name	Drug Tier	Coverage Requirements and Limits
Opioid Analgesics, Long-acting – [Optional: <Plain Language Description>]		
<Drug Name 3>	<Tier 2>	<Util. Mgmt.>
<Drug Name 4, Dosage Form A, Strength A>	<Tier 1>	<Util. Mgmt.>
<Drug Name 4, Dosage Form A, Strength B>	<Tier 2>	<Util. Mgmt.>
Opioid Analgesics, Short-acting – [Optional: <Plain Language Description>]		
<Drug Name 4, Dosage Form B>	<Tier 3>	<Util. Mgmt.>
<Drug Name 5>	<Tier>	<Util. Mgmt.>
Anesthetics – Drugs for Blocking Pain		
Local Anesthetics – [Optional: <Plain Language Description>]		
<Drug Name 6>	<Tier>	<Util. Mgmt.>
<Drug Name 7>	<Tier>	<Util. Mgmt.>

(g) Index. The index shall list each covered brand name and generic drug by brand name or established name, respectively, 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.