



Edmund G. Brown Jr., Governor
State of California
Health and Human Services Agency
Department of Managed Health Care
Office of Legal Services
980 Ninth Street, Suite 500
Sacramento, CA 95814-2725
916-322-6727 – Phone
916-322-3968 – Fax
www.dmhcca.gov

DATE: September 28, 2018

ACTION: **Notice of Proposed Regulatory Action**

SUBJECT: Standard Prescription Drug Formulary Template, Adding Section 1300.67.205 to Title 28, California Code of Regulations, Control No. 2017-5229.

Public Proceedings

Notice is hereby given that the Director of the Department of Managed Health Care (Department) proposes to add a regulation under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act) and corresponding regulations contained in Title 28, California Code of Regulations (CCR). The proposed regulation implements Senate Bill (SB) 1052¹ by specifying a standardized prescription drug formulary template health care service plans (health plans) must utilize for their prescription drug coverage. The proposed regulation provides the formulary template, clarifying terms and educational information relevant to the provision of prescription drug benefits.

This rulemaking action proposes to add section 1300.67.205, Standard Prescription Drug Formulary Template, to title 28 of the CCR. Before undertaking this action, the Director of the Department (Director) will conduct written public proceedings, during which time any interested person, or such person's duly authorized representative, may present statements, arguments, or contentions relevant to the action described in this notice.

PUBLIC HEARING

The Department will hold a public hearing regarding this regulation on **November 13, 2018**. The public hearing will begin at **10:00 a.m.** and end when all public comment have been received or 12 p.m., whichever is earlier. The location of the public hearing is:

**980 Ninth Street, 6th Floor
Room of Inspiration
Sacramento, CA 95814**

¹ Sen. Bill No. 1052 (2013-2014 Reg. Sess.) Ch. 575.

The facility is accessible to persons with mobility impairments. Persons with sight or hearing impairments are requested to notify the contact person for these hearings in order to make special arrangements. At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The Department requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written statements, arguments, or contentions (hereafter referred to as comments) relating to the proposed regulatory action by the Department. Comments must be received by the Department, Office of Legal Services, **by 5 p.m. on November 13, 2018.** which is hereby designated as the close of the written comment period.

Please address all comments to the Department of Managed Health Care, Office of Legal Services, Attention: Jennifer Willis, Attorney IV. Comments may be transmitted by regular mail, fax, or email:

Website: <http://www.dmhc.ca.gov/LawsRegulations.aspx#open>
Email: regulations@dmhc.ca.gov
Mail: Department of Managed Health Care
Office of Legal Services
980 Ninth Street, Suite 500
Attn: Jennifer Willis, Attorney IV
Sacramento, CA 95814
Fax: (916) 322-3968

Please note: If comments are sent via email or fax, there is no need to send the same comments by mail delivery. All comments, including via email, fax, or mail, should include the author's name and a U.S. Postal Service mailing address so the Department may provide commenters with notice of any additional proposed changes to the regulation text.

Please identify the action by using the Department's rulemaking title and control number, **Standard Prescription Drug Formulary Template, Control No. 2017-5229**, in any of the above inquiries.

CONTACTS: Inquiries concerning the proposed adoption of this regulation may be directed to:

Jennifer Willis
Attorney IV

OR **Emilie Alvarez**
Regulations Coordinator

Department of Managed Health Care
Office of Legal Services
980 9th Street, Suite 500
Sacramento, CA 95814
(916) 324-9014
(916) 322-3968 fax
jennifer.willis@dmhc.ca.gov

Department of Managed Health Care
Office of Legal Services
980 9th Street, Suite 500
Sacramento, CA 95814
(916) 445-9960
(916) 322-3968 fax
emilie.alvarez@dmhc.ca.gov

AVAILABILITY OF DOCUMENTS

The Department prepared and has available for public review the Initial Statement of Reasons, text of the proposed regulation and all information upon which the proposed regulation is based (rulemaking file). This information is available by request to the Department of Managed Health Care, Office of Legal Services, 980 9th Street, Sacramento, CA 95814, Attention: Regulations Coordinator.

The Notice of Proposed Rulemaking Action, the proposed text of the regulation, and the Initial Statement of Reasons are also available on the Department's website at <http://www.dmhc.ca.gov/LawsRegulations.aspx#open>.

You may obtain a copy of the final statement of reasons once it is completed by making a written request to the Regulation Coordinator named above.

AVAILABILITY OF MODIFIED TEXT

The full text of any modified regulation, unless the modification is only non-substantial or solely grammatical in nature, will be made available to the public at least 15 days before the date the Department adopts the regulation. A request for a copy of any modified regulation(s) should be addressed to the Regulations Coordinator. The Director will accept comments via mail, fax, or email on the modified regulation(s) for 15 days after the date on which the modified text is made available. The Director may thereafter adopt, amend, or repeal the foregoing proposal substantially as set forth without further notice.

AUTHORITY AND REFERENCE

Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate health plans.

Health and Safety Code section 1341.9, vests the Director of the Department with all duties, powers, purposes, responsibilities, and jurisdiction as they pertain to health plans and the health plan business.

Health and Safety Code section 1344 grants the Director the authority to adopt, amend, and rescind such rules, forms and orders as necessary to carry out the

provisions of the Knox-Keene Act.

Health and Safety Code section 1363.01 requires health plans offering prescription benefits to provide notice of such benefits in their Evidence of Coverage form. Health plans must also provide specific information regarding how a health plan determines which prescription drug are included or excluded in their benefits. If requested by a member of the public, health plans must provide notification that existence of a drug on a formulary does not guarantee that an enrollee will be prescribed that drug for a particular medical condition.

Health and Safety Code section 1367.20 requires health plans that provide coverage for prescription drug benefits and maintain a formulary to provide to a requesting party the most current list of prescription drugs available on the formulary. The prescription drugs must be listed by major therapeutic category showing preferred drugs.

Health and Safety Code section 1367.24 requires health plans maintain an expeditious process for prescribing providers to obtain authorization for a medically necessary nonformulary prescription drug.

Health and Safety Code section 1367.241 sets forth the use and requirement of prior authorization and step-therapy exception request forms and the timeline for responses to non-urgent and exigent prior authorization and step-therapy exception requests.

Health and Safety Code section 1367.205 requires the Department, along with the California Department of Insurance (CDI), to create a formulary template for use by health plans. This section also requires health plans to publicly post on their websites complete prescription drug formularies for each of the health plans' products including information such as cost sharing, tiers and utilization controls.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Senate Bill 1052 directs the Department, in conjunction with CDI and with input from at least one stakeholder meeting, to develop a standard formulary template. Health and Safety Code section 1367.205, requires the Department to take into consideration existing requirements for the reporting of formulary information established by the Centers for Medicaid and Medicare Services (CMS) and, to the extent feasible, take into consideration cost sharing information for drugs, including for drugs subject to coinsurance, when drafting the proposed regulation.

This proposed regulation sets forth the requirements of Health and Safety Code section 1367.205 and implements the goals of SB 1052 by providing a standard prescription drug formulary template for use by all health plans. The formulary template will ensure enrollees are provided with uniform drug benefit information. This regulation also creates easier access for enrollees to their prescription drug coverage as required under the Knox-Keene Act. The regulation serves an important purpose in increasing

transparency in the area of prescription drug formularies. The regulation implements the requirements of Health and Safety Code section 1367.205, by mandating the health plans to publicly post on their websites complete prescription drug formularies for each of the health plans' products, including cost sharing tiers and utilization controls, such as prior authorization and step therapy requests. Currently, health plans do not use a common organizational structure for formularies, causing prescription drug formulary comparisons between health plans to be difficult. Many health plans post only their most commonly prescribed drugs, not the entire list of pharmaceutical drugs covered under the prescription drug benefit. The requirements of this regulation will assist enrollees, especially those with chronic conditions who rely on prescription drugs to manage their illness, to make an easier comparison of prescription drug coverage among different health plans and health plan products.

This rulemaking action implements the requirement of SB 1052 for the Department to develop a standardized prescription drug formulary template for use by the health plans and enrollees.

BROAD OBJECTIVES AND SPECIFIC BENEFITS OF THE REGULATION

Pursuant to Government Code section 11346.5, subdivision (a)(3)(C), the broad objective of this regulation is to specify the standard prescription drug formulary template health plans must utilize for their prescription drug benefits pursuant to the requirements of Health and Safety Code section 1367.205.

The objective of proposed subdivision (a) addresses the problem of ambiguity in key terms and phrases used to draft a formulary as required under section 1367.205 of the Health and Safety Code. Without this subdivision, health plans employ varying definitions that take away from the goal of section 1367.205 of the Health and Safety Code to create consistency amongst pharmacy benefits. Senate Bill 1052 is intended to ensure all health plan formularies are substantially similar and to assist health plan enrollees in understanding prescription drug benefits. Uniformity in key terms has the benefit of clarity for regulated entities, as well as efficient compliance and enforcement review by the Department.

Subdivision (a)(1) defines "coverage document" to include all documents that encompass the enrollee's health care coverage under a health plan contract. The broad objective is to ensure health plans provide consistent information regarding drug benefits in the health plan documents by defining the scope of a coverage document. The specific benefit is that this definition allows for a reference for health plans to use and creates a term easily understandable for an enrollee.

Subdivision (a)(2) defines "dosage form." The broad objective of this definition is to provide a consistent and uniform understanding of this term that is based on the federal United States Food and Drug Administration (FDA) definition. The specific benefit is this term is vital for both health plans and enrollees in providing clarity and

understanding of the form in which a prescription drug is prescribed (e.g.: liquid vs. tablet) and ensures all health plans utilize the same terminology for types and forms of prescription drugs.

Subdivision (a)(3) defines “established name.” The broad objective of this definition is to ensure that all health plans are appropriately listing and uniformly labeling a prescription drug as generic and/or the brand name drug. The specific benefit is to prevent any ambiguity as to the name brand or generic of the prescription drug and assist health plans and enrollees in implementing and understanding the types of drugs available on their formularies.

Subdivision (a)(4) defines “exception request.” The broad objective of this definition is to assist health plans and enrollees in the understanding of this term by noting the relevant Health and Safety Code provisions that impact this term. The specific benefit is ensuring a consistent use and understanding of this term under the Knox-Keene Act as well as consistent application of this term by health plans.

Subdivision (a)(5) defines “exigent circumstances.” The broad objective of this definition is to ensure health plans and enrollees have a uniform understanding of this term and how it applies to specific circumstances that may exist for an enrollee and impact the enrollee’s access to prescription drugs. The specific benefit is ensuring consistent use and application of this term as defined in Health and Safety Code section 1367.241, subdivision (h)(2).

Subdivision (a)(6) defines “formulary.” The broad objective of this definition is requiring health plans provide a uniform application of this term to better assist enrollees in understanding their available drug benefits. The specific benefit of this definition is ensuring all health plans are utilizing the definition of a formulary as set forth in section 1367.205 of the Health and Safety Code. The definition of this term ensures consistency amongst various Knox-Keene Act provisions involving pharmacy benefits. This term eliminates confusion for both health plans and enrollees that might be caused by inconsistent definition and application of this term.

Subdivision (a)(7) defines “nonformulary.” The broad objective of this definition is ensuring uniform understanding of this term by health plans and enrollees for prescription drug benefits. The specific benefit of this definition is implementing subdivision (i) of Health and Safety Code section 1367.24 and ensuring consistency of terms within the Knox-Keene Act. This definition is necessary for uniform compliance with the law and enabling enrollees to better understand their prescription drug rights when reviewing health plan formulary documents.

Subdivision (a)(8) defines “prescription drug.” The broad objective of this definition is ensuring consistent application and understanding of this term by health plans and enrollees. The specific benefit is defining this term in a consistent manner with Health and Safety Code sections 1367.002 and 1367.25, and rule 1300.67.24. This definition

ensures consistency of this term under the provisions of the Knox-Keene Act and will enable health plans to better understand their obligations regarding enrollee access to prescription drug benefits.

Subdivision (a)(9) defines “product.” The broad objective of this definition is to ensure uniform understanding and application of this term by all health plans. The specific benefit is to ensure compliance with section 1367.27 of the Health and Safety Code. Section 1367.27 contains the uniform provider directory standards requirements and requires health plans to provide information in their directories for each product the health plan markets. This further ensures uniform use of the term “product.” Defining this term also ensures consistent understanding of the standards throughout all health plan documents and alleviates potential confusion for both the health plans and the enrollees.

Subdivision (a)(10) defines “quantity limit.” The broad objective of this definition is to ensure uniform understanding of this term by health plans and enrollees. The specific benefit is that this term furthers the implementation of Health and Safety Code section 1367.205, which requires the formulary template to include utilization control information for drug benefits. This term is defined consistently with the National Association of Insurance Commissioners’ (NAIC) “Health Carrier Prescription Drug Benefit Management Model Act.” The Department is utilizing the definition proposed by the NAIC as it has been vetted and reviewed by the NAIC for use with prescription drug coverage and is understood within the healthcare industry. Defining quantity limit is essential to an enrollee’s understanding of their prescription drug benefits and any limits on the quantity of a prescription drug that are allowed under their coverage.

Subdivision (a)(11) defines “strength”. The broad objective of this definition is to ensure uniform understanding and application of this term and to allow for an easier understanding of this term by both the health plans and the enrollees. The specific benefit is that the definition ensures enrollees are provided a plain English definition of the term’s meaning. The strength of a prescription drug is vital to an enrollee’s understanding of their prescription drug benefit and its application to their medical condition and ensuring the enrollee is clearly informed about how the term is used within a health plan formulary.

Subdivision (b) provides the overall format of a formulary and requires a formulary to be searchable by enrollees. By setting forth the specific format and information required of health plans under subdivision (b), the formulary template provides enrollees with uniform and consistent information. This provision also requires all formularies to contain the following sections: (1) Coverage Page; (2) Table of Contents; (3) Informational Section; (4) Categorical List of Prescription Drugs; and (5) Index. The broad objectives and specific benefits for including these sections are discussed further below except for the table of contents requirement. The broad objective of the table of contents is to provide another easily understood method for enrollees to locate their prescription drugs and other information within the formulary.

Subdivision (c) sets forth the cover page requirements of a formulary. The broad objective of this subdivision is to make available a cover page that provides uniform and consistent information to all enrollees. This also ensures all enrollees are viewing substantially similar formulary templates regardless of their health plan. The specific benefit implementing subdivision (b)(1) of the formulary template by setting out the specific information that must be included in the cover page to meet the regulatory requirement. This requirement benefits both health plans and enrollees by setting forth specific criteria to be included in a drug formulary and easy understanding of the location of health plan information contained in the formulary document. This subdivision is also supported by the California Health Care Foundation's (CHCF) research. A survey taken by the CHCF found that a cover page of a formulary is vital as three-quarters of individuals surveyed wanted the cover page of a formulary to specify the type of coverage and product information.²

Subdivision (c)(1) requires all formularies to contain the name of the document. The broad objective is to ensure that all formularies are consistently and clearly identified by the name referenced in all health plan documents. The specific benefit is that enrollees will be able to identify the formulary for each product of a health plan quickly and efficiently.

Subdivision (c)(2) requires all formularies to contain the name of the health plan. The broad objective is to make clear who is offering the particular formulary. The specific benefit is that this will ensure from the beginning that enrollees are aware of each health plan formulary. This will assist enrollees in determining whether a particular benefit is included in a health plan's formulary, which may impact whether the enrollees choose a particular health plan.

Subdivision (c)(3) requires all health plans to name each health plan product applicable to a formulary and requires the product names to comply with the uniform provider directory standards set forth in Health and Safety Code section 1367.27. Health and Safety Code section 1367.26, subdivision (b), requires that health plans provide the directory or directories for the specific network offered for each health plan product using a consistent product naming, numbering or other classification method. The broad objectives of this subdivision are to ensure all enrollees are able to determine the formularies that apply to specific health plan products and ensure conformity of the product names across all health plan coverage documents. The specific benefit is that this subdivision implements section 1367.205, subdivision (a)(1). This subdivision of the statute requires health plans to post a formulary or formularies for each product offered by a health plan on the health plan's website. This subdivision will also allow enrollees to compare formularies of different health plans in a manner that is easy and accessible.

² California HealthCare Foundation, "Hidden From View: How Enrollees Find Information About Prescription Coverage," August 2015, page 9.

Subdivision (c)(4) requires a formulary to set forth the date the formulary was last updated. The broad objective is to ensure all health plans notify enrollees and prospective enrollees of the effective date to ensure enrollees are reviewing the most accurate up-to-date information. The specific benefits are ensuring enrollees are aware of the date when a formulary was last updated and enabling enrollees to understand they are reviewing the most recent formulary applicable to their health plan product. This provision also assists enrollees with comparing the most recent versions of various health plan formularies when making coverage decisions.

Subdivision (c)(5) furthers the implementation of subdivision (c)(4) of the formulary template by requiring notification to enrollees that a formulary is subject to change and outdated copies of a formulary should be discarded by enrollees. The broad objective of this subdivision is to eliminate any misunderstanding or confusion for enrollees when accessing drug benefits for their plan product. The specific objectives are to ensure enrollees understand they are reviewing the most recent copy of a formulary and that only the most recent formulary is applicable to their prescription drug coverage. This provision will also assist enrollees with comparing formularies of different health plans in a manner made accessible by ensuring the review of the most current health plan documents.

Subdivision (c)(6) requires health plans to provide a direct website link/URL for the location of the electronic version of the formularies posted on their website. If there is more than one health plan product, the enrollee must be able to identify each health plan product. The broad objective of this subdivision is requiring health plans provide the enrollees an option to obtain an electronic version of a formulary. The specific benefit is that this subdivision implements Health and Safety Code section 1367.205, subdivision (a)(1) by requiring a health plan to post the formularies for each product offered by the health plan on its website in a manner that is accessible and searchable by enrollees, potential enrollees, providers, the general public and the Department.

Subdivision (c)(7) requires a formulary to contain a direct health plan website link for enrollees to locate specific coverage documents containing cost sharing information. The broad objective of this provision is providing enrollees access to information on cost sharing so they understand the financial implications of accessing types of drugs in the health plan formulary. The specific benefit is implementing subdivisions (a)(1) and (b)(1) of Health and Safety Code section 1367.205. These subdivisions of the Health and Safety Code require a formulary be posted on the health plan's website in an accessible manner for enrollees and, if possible, contain cost sharing information.

Subdivision (d) describes overall the information a formulary must contain to assist enrollees in understanding the meaning of a formulary, including utilization information and its application to an enrollee's prescription drug coverage. The broad objective of this subdivision is providing enrollees with educational information in a consistent and uniform manner. This is done by setting forth the information health plans must include

in their product formularies. The specific benefit is implementing Health and Safety Code section 1367.205, subdivisions (b)(2)(C) and (D). These subdivisions of the Health and Safety Code require a formulary to contain information regarding cost sharing, utilization controls, and indicate which drugs are preferred drugs. These subdivisions also require the health plans to educate enrollees on drugs covered under the health plan's medical benefit and drugs covered under the health plan's prescription drug benefit. This is important as it can affect the cost of an enrollee access to prescription drugs. This regulatory provision educates enrollees about obtaining drugs that are nonformulary, information on generic and brand name drugs, and the tier information of prescription drugs, all of which impact costs. In a study, the CHCF determined that increasing enrollee education was one of the most important steps in addressing the gap in knowledge about prescription drug benefits.³ The Department is implementing subdivision (d) to assist enrollees in understanding the purpose of a health plan formulary and how to utilize the formulary to understand their prescription drugs coverage and costs.

Subdivision (d)(1) requires a health plan to provide a way for an enrollee to contact a health plan's member services department and obtain information that is specific to an enrollee's prescription drug coverage. The broad objective is ensuring all health plans provide access to a health plan contact in a consistent and timely manner. The specific benefit is enrollees will have a knowledgeable plan contact information based on the enrollees' specific prescription drug coverage. This allows enrollees to receive assistance in a timely manner when contacting their health plan for information or assistance. The enrollee information available from the health plan contact must include specific cost sharing and prior authorization assistance as detailed in Health and Safety Code section 1367.205, subdivision (b)(1).

Subdivision (d)(2) requires health plans to define terms used in this subdivision or, if a similar term is used, to define the substituted term. This subdivision allows a health plan to request an exception from the Department to replace the stated definition with another reasonable definition. The broad objective is requiring health plans to define key terms used in the formulary in a uniform and consistent manner. The specific benefit is assisting enrollees in their understanding of important terms used in a health plan formulary. According to the CHCF's study, most enrollees are not familiar with key terms routinely used in a health plan's formulary.⁴ By requiring health plans to define terms in a consistent and uniform manner, as well as in plain English, the Department is ensuring enrollees clearly understand the terms and their application to the enrollee's prescription drug benefits.

Subdivision (d)(2)(A) defines "Brand name drug" and requires brand name drugs to be listed in all capital letters. The broad objective of this subdivision is ensuring health plans define brand name drugs in a consistent and uniform manner. The specific

³ Adams, "Hidden From View", page 9.

⁴ Adams, "Hidden From View," page 6.

benefit is ensuring enrollees may easily identify the brand name drugs and creating transparency between brand name and generic drugs, both of which impact enrollee costs. This provision is supported by the CHCF's recommendation that health plan formularies are more accessible to an enrollee if the formulary indicates whether the drugs available are generic or brand name. The CHCF surveyed participants, who provided comments on how to make formularies easier to access and interpret.⁵ If brand and generic drugs are identified in a consistent manner, an enrollee looking at the name of a particular drug will have a better understanding of the pharmaceutical benefit and associated cost of the drug.

Subdivision (d)(2)(B) defines "coinsurance" to ensure health plans use this term in a consistent manner. The broad objective of defining this term is to ensure enrollees understand their formulary and how coinsurance may impact access to their prescription drug benefits. The specific objective of this provision is to ensure an enrollee has a clear understanding of the financial impact of choosing certain prescription drugs. The CHCF study found enrollees with a chronic condition identified knowing specific out-of-pocket drug costs, copayments, and coinsurance amounts as an important component in understanding their prescription drug benefits.⁶

Subdivision (d)(2)(C) defines "copayment" to ensure health plans use this term in a consistent and uniform manner. The broad objective is ensuring enrollees have a clear understanding of this term and how it impacts their prescription drug benefits. The specific objective is ensuring enrollees' understanding of how a health plan copayment works with the enrollee's prescription drug benefits. The CHCF noted in its research the importance of this information for enrollees with chronic conditions. Knowing the specific out-of-pocket drug costs for their conditions was listed as an important component for understanding a health plan formulary by nearly half of the people surveyed.⁷

Subdivision (d)(2)(D) defines "deductible" to ensure health plans use this term in a consistent and uniform manner. The broad objective of defining this term is ensuring enrollees have a clear understanding of how the term is used in a health plan formulary. The specific objective of this definition is ensuring enrollees understand how their deductibles impact their prescription drug benefits. The CHCF determined one of the most important factors for consumers shopping for prescription drug coverage is out-of-pocket costs, including deductibles and copays.⁸

Subdivision (d)(2)(E) defines "drug tier." The broad objective is ensuring this term is defined by health plans in a consistent and uniform manner. The specific benefits are ensuring enrollees understand the meaning of the term and how it is used in a health

⁵ Adams, "Hidden From View," page 9.

⁶ Adams, "Hidden From View," page 6.

⁷ *Id.*

⁸ Adams, "Hidden From View," page 4.

plan formulary. The CHCF study found enrollees confusing drug tiers with metal tiers as used in the Patient Protection and Affordable Care Act.⁹ The definition of the term will assist enrollees in understanding how a drug tier is used by a health plan in a formulary, and how higher tiers affect the pricing of prescription drug benefits.

Subdivision (d)(2)(F) defines “enrollee.” The broad objective is ensuring health plans define the term in a consistent and uniform manner. The specific benefit is ensuring an enrollee understands the meaning of this term when used in a health plan formulary. This definition is the same as the definition in Health and Safety Code section 1345 thereby maintaining consistency within the Knox-Keene Act.

Subdivision (d)(2)(G) defines “exception request” to assist enrollees in understanding an exception for a nonformulary drug under certain circumstances. The broad objective of this provision is to clarify how an enrollee requests an exception to prescription drug benefits under the health plan formulary. The specific benefit is assisting enrollees who may need prescription drugs that are not available except through the exception request process. Many enrollees are unfamiliar with the exception request process and do not have an understanding of the term. Defining this term within a health plan formulary will educate enrollees on the scope of their prescription drug benefits.

Subdivision (d)(2)(H) defines “exigent circumstances” to assist enrollees in understanding when an exigent circumstance exists and requires different timeframes for obtaining prescription drugs. The broad objective of this subdivision is to clarify the meaning of exigent circumstance. The specific benefit is assisting enrollees in requesting a review of their timely access to a prescription drug based on exigent circumstances.

Subdivision (d)(2)(I) defines “formulary.” The broad objective of this subdivision is to clarify the meaning of the term “formulary” for enrollees and to ensure health plans define the term in an easily understood and consistent manner. The specific benefit is that this subdivision implements Health and Safety Code section 1367.205, subdivision (c), and further assists enrollees in a comprehensive understanding of their ability to obtain prescription drug benefits under the terms of a health plan formulary.

Subdivision (d)(2)(J) defines “generic drug” and requires health plans to list generic named drugs in bold and italicized lowercase letters. The broad objective of this subdivision is ensuring health plans define generic drugs in a consistent, noticeable and uniform manner in the formulary. The specific benefits are ensuring enrollees easily identify generic named drugs versus drugs that are name brand within the health plan formulary. If brand and generic drugs are identified in a consistent manner, an enrollee will be able to identify a drug as generic or name brand by reviewing the font and format of the drug. This provision creates a uniform, accessible and transparent standardized formulary.

⁹ Adams, *supra*, page 6.

Subdivision (d)(2)(K) defines “nonformulary drug.” The broad objective is requiring health plans to define this term in a consistent and uniform manner. This definition will assist enrollees in understanding their drug benefits under the terms of a health plan formulary. The specific benefit is helping enrollees understand their rights under their prescription drug benefit, including the right to access nonformulary drugs in certain situations that would not otherwise be covered.

Subdivision (d)(2)(L) defines “out-of-pocket cost.” The broad objective is ensuring the term is defined by health plans in a consistent and uniform manner. The specific benefit is helping enrollees to better understand their cost in accessing prescription drug benefits. The CHCF identified that one of the biggest concerns for enrollees when purchasing prescription drugs was the cost. The CHCF further reported affordability of monthly premiums and other out-of-pocket costs as the foremost consideration in purchasing coverage.¹⁰ This provision helps to address this concern by adding an easily understood definition to the term “out-of-pocket cost” to assist enrollees in understanding the impact of accessing prescription drugs under the terms of their formulary.

Subdivision (d)(2)(M) defines “prescribing provider.” The broad objective is ensuring health plans are using this term in a consistent and uniform manner within their prescription drug formulary. The specific benefit is assisting enrollees in understanding how to obtain a prescription and who must provide the prescription for a drug under the terms of the health plan formulary.

Subdivision (d)(2)(N) defines “prescription.” The broad objective is ensuring health plans define this term in a consistent and uniform manner. The specific benefit is helping enrollees understand the meaning of this term and how it is used by health plans within a formulary. This provision clarifies what is considered a prescription and must be obtained by a prescribing provider by an enrollee to access drugs under the terms of their prescription drug benefit.

Subdivision (d)(2)(O) defines “prescription drug.” The broad objective is to ensure health plans are using this term in a consistent and uniform manner by complying with the term as noted in subdivision (d)(2)(O) of the formulary template. The specific benefits are to assist enrollees who are reviewing formularies, ensure enrollees have a clear understanding of the term and how it applies to them when obtaining or requesting prescription drugs.

Subdivision (d)(2)(P) defines “prior authorization.” The broad objective is to ensure health plans are using this term in a consistent and uniform manner in their formularies by requiring the term to comply with subdivision (d)(2)(P) of the formulary template. The specific benefits are to help enrollees understand the use of this term in a formulary and

¹⁰Adams, “Hidden From View,” page 4.

their rights to obtaining drugs that require a prior approval by a health plan. This provision also implements subdivision (b)(2)(A) of section 1367.205 requiring a formulary to include information on health plan utilization controls such as prior authorization.

Subdivision (d)(2)(Q) defines “step therapy.” The broad objective is to ensure that this term is defined in a consistent and uniform manner by requiring health plans comply with subdivision (d)(2)(Q) of the formulary template. The specific benefit is to assist enrollees in their understanding of the step therapy process for prescription drugs and other important rights of the enrollees such as the requirement that an enrollee use one drug before the enrollee can be prescribed another drug. This provision also implements subdivision (b)(2)(A) of section 1367.205, requiring health plans include information on utilization controls such as step therapy in the formularies.

Subdivision (d)(2)(R) defines “subscriber.” The broad objective is ensuring health plans define the term in a consistent and uniform manner. The specific benefit is ensuring an enrollee understands the meaning of this term when used in a health plan formulary. This definition is the same as the definition in Health and Safety Code section 1345 thereby maintaining consistency within the Knox-Keene Act.

Subdivision (d)(3) requires health plans to set forth any additional key terms health plans use in a formulary. The broad objective is to ensure that health plans define any additional key terms in a consistent and uniform manner by requiring compliance with subdivision (d)(3) of the formulary template. The specific benefit is assisting enrollees in understanding the health plan formularies and their rights and obligations under their prescription drug benefit.

Subdivision (d)(4) lists instructions on how enrollees locate their prescription drugs in the categorical list of prescription drugs contained in a health plan formulary. The broad objective is to ensure health plans explain to enrollees how to use a formulary by requiring compliance with subdivision (d)(4) of the formulary template. The specific benefit is to help the enrollees understand how the prescription drugs are organized in a formulary. The other specific benefit is to clarify and alleviate confusion that enrollees may have when trying to locate drugs on a formulary.

Subdivision (d)(5) lists how drugs should be listed in a formulary including an explanation of what drugs are generic or name brand, and the availability of obtaining these drugs. The broad objective is to ensure that all health plans list the drugs in a consistent and uniform manner by requiring compliance with subdivision (d)(5) of the formulary template. The specific benefit is making it easier for enrollees to compare formularies, including generic or name brand availability, of different drugs in a health formulary. This subdivision assists in creating accessibility and transparency in prescription drug coverage.

Subdivision (d)(6) requires health plans to provide a description of the drug tiers utilized

on a formulary. The broad objective is ensuring health plans describe the drug tiers in a consistent and uniform manner by requiring compliance with subdivision (d)(6) of the formulary template. The specific benefit is implementing subdivision (b)(2)(F) of Health and Safety Code section 1367.205, which requires this tiering information be included in the regulation.

Subdivision (d)(7) requires health plans to describe all utilization management requirements imposed on prescription drug benefits. The broad objective is ensuring health plans disclose the utilization controls of the prescription drugs in a consistent and open manner by complying with the requirements of subdivision (d)(7) of the formulary template. An additional benefit is giving the enrollees a method to compare one formulary against another. The specific benefit is to implement section 1367.205, subdivision (b)(2)(A), requiring a formulary to include information regarding health plan utilization controls.

Subdivision (d)(8) requires health plans to give information in the formulary on the difference between prescription drugs covered under the medical benefit and prescription drugs covered under the prescription drug benefit of an enrollee's coverage. The broad objective is to provide information on whether the prescription drug benefit is covered under the medical benefit or the prescription benefit, including related cost and authorization differences, per subdivision (d)(8) of the formulary template in a clear and concise manner. The specific benefit is to implement Health and Safety Code section 1367.205, subdivision (b)(2)(C). Another benefit is assisting enrollees in differentiating whether it is the health plan or another entity that is responsible for the approval or disapproval of a prescription drug authorization request, since the responsibility depends on the financial benefit responsibility contracted between the health plans and other entities.

Subdivision (d)(9) requires health plans to provide notice to enrollees that a formulary is updated monthly to show the most current benefits available. The broad objective is ensuring enrollees understand the type of changes that are being made to a formulary and whether those changes impact the enrollee's access to his or her prescription drug access. The specific benefit is implementing section Health and Safety Code section 1367.205, subdivision (a)(2), requiring health plans provide notice to enrollees that the formulary is updated monthly. This provision ensures enrollees will understand that changes are being made to their formularies and how these changes impact their coverage options.

Subdivision (d)(10) requires health plans to provide an explanation that presence of a prescription drug on the prescription drug formulary does not guarantee enrollee will be prescribed the prescription drug. The broad objective is ensuring all health plans are notifying enrollees of this requirement in a consistent and uniform manner for enrollee awareness. The specific benefit is assisting the enrollees in understanding their rights and obligations for obtaining prescription drug benefits under a health plan's formulary and knowing the presence of a drug does guarantee that the enrollee will receive an

authorization for the drug from a provider or health plan.

Subdivision (d)(11) requires health plans to provide a notice of coverage of nonformulary drug when the drug is medically necessary as well as the process for obtaining the coverage. The broad objective is ensuring all health plans provide this notice in a clear and consistent manner by requiring mandatory compliance with subdivision (d)(11) of the formulary template. The specific benefit is implementing Health and Safety Code section 1367.205, subdivision (b)(2)(D), requiring health plans provide notice of nonformulary drug coverage when medically necessary and the process for obtaining coverage. This provision also ensures consistent application of Health and Safety Code section 1367.24, which requires health plans maintain an expeditious process by which prescribing providers may obtain authorization for medically necessary nonformulary prescription drug.

Subdivision (d)(12) requires health plans to provide information to enrollees on how to locate and fill a prescription drug through a network retail pharmacy, mail order, and specialty pharmacy. The broad objective is to ensure that all health plans are providing the information on various types of physical access to prescription drugs in a consistent and uniform manner by requiring compliance with subdivision (d)(12) of the formulary template. The specific benefits are ensuring enrollees have access to prescription drugs and helping them compare different formularies and determine the level of accessibility of prescription drugs available through different types of pharmacy options.

Subdivision (d)(13) requires a detailed description of the process for an enrollee to request a prescription drug prior authorization or step therapy exception. The broad objective is to ensure that all health plans provide prior authorization and step therapy information in a consistent and uniform manner by requiring compliance with subdivision (d)(13) of the formulary template. The specific benefit is providing enrollees with information regarding access to prescription drugs that may not be as easily available as other types of prescription drugs through their health plan formulary. This subdivision also implements Health and Safety Code section 1367.205, subdivisions (b)(2)(A) and (D). These subdivisions of the Health and Safety Code require health plans to provide information regarding prior authorization and step therapy processes. Also, in its study on enrollees and prescription drug, the CHCF identified enrollees' lack of familiarity with the prescription drug exception and appeals processes and enrollees' ability to easily locate this information in existing formularies as obstacles to obtaining prescription drugs.¹¹ This subdivision helps by requiring health plans to provide such information in a consistent, clear, and uniform manner.

Subdivision (d)(14) requires health plans to provide information on the meaning of step therapy. The broad objective is to ensure that all health plans are providing information on step therapy in a consistent and uniform manner by requiring compliance with subdivision (d)(14) of the formulary template. The specific benefit is implementing

¹¹ Adams, "Hidden From View," pages 7 and 9.

Health and Safety Code section 1367.205, subdivision (b)(2)(A), by requiring notification of an enrollee's rights regarding step therapy and the method for obtaining prescription drugs through the step therapy process. Another specific benefit is ensuring that enrollees are educated on an important right of obtaining their prescription drug coverage, even when it is not as easily accessible. Step therapy can be a confusing process and enrollees need to better understand their rights to obtain certain types of prescription drugs under the step therapy process.

Subdivision (d)(15) requires notification of coverage of prescription drugs previously approved for the enrollee's medical condition if certain criteria are met. The broad objective is to ensure that all health plans are providing this notification in a consistent and uniform manner by requiring compliance with subdivision (d)(15) of the formulary template. The specific benefit is ensuring this vital enrollee right to their previous prescription drug benefits as enrollees may not be aware of this important means of access.

Subdivision (d)(16) provides information on the specific prescription drugs that are covered under a health plan's formulary. The broad objective is to ensure that all health plans are providing information on the covered prescription drug in a consistent and uniform manner by setting forth the specific information on coverage of prescription drugs and FDA-approved devices. The specific benefits are providing information that is essential to assist enrollees in a proper understanding of each health plan's available formularies and giving enrollees the ability to compare access to prescription drugs between health plans.

Subdivision (d)(17) requires health plans to set forth any limit on cost sharing for orally administered anti-cancer drugs. The broad objective is ensuring all health plans are setting forth the cost sharing limits in a consistent manner by requiring specific information on cost sharing be included in the formulary. The specific benefits are implementing Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring health plans set forth any limit on cost sharing for orally administered anti-cancer drugs and assisting enrollees in determining their cost sharing for specific types of prescription drugs by noting the information in the formulary. The CHCF reported affordability of monthly premiums and other out-of-pocket costs as the foremost consideration in purchasing healthcare coverage.¹² This subdivision will specifically assist enrollees in understanding their cost amounts for certain types of prescription drugs.

Subdivision (d)(18) requires health plans to list any prescription drugs limited to specialty pharmacy or other network access limitations. The broad objective is ensuring all health plans provide enrollees with information on any limitations to accessibility and network coverage in a consistent and uniform manner. The specific benefit is providing important information to enrollees in understanding their access to prescription drug benefits. This provision of the regulation ensures that enrollees can compare

¹² Adams, "Hidden From View," page 4.

formularies of different health plans and determine the necessary level of accessibility to their prescription drugs. This information may factor into which health product the enrollee chooses.

Subdivision (d)(19) requires an annotated legend or key to all abbreviations, symbols and notations used in a health plan formulary. The broad objective ensuring all abbreviations, symbols and notations are used in a consistent and uniform manner by health plans when used in a formulary. The specific benefit is ensuring that enrollees understand all the abbreviations, symbols, and notations that health plans are using and the definitions of those abbreviations symbols and notations. Also, this information is a way to increase enrollee accessibility and understanding of formularies.

Subdivision (e) provides directions on how prescription drugs should be listed in a health plan formulary in the “categorical list of prescription drugs” section. The broad objective is to ensure that all health plans are listing the prescription drugs in a consistent and uniform manner by providing specific directions on how the prescription drugs should be classified. The specific benefits are that this information is important in creating a formulary that is comparable for all health plans and provides enrollee with better access and understanding of their prescription drug coverage as the prescription drugs will be listed in a specific manner.

Subdivision (e)(1) states how health plans must organize the categorical list of prescription drugs available in a formulary. The broad objective is requiring all health plan formularies are comparable by requiring their organization of the prescription drug benefits available to enrollees in a consistent manner. The specific benefits are a more accessible and understandable formulary for enrollees.

Subdivision (e)(2) requires a formulary to contain brand and generic names as well as, where possible, a plain language description of the prescription drugs. The broad objective is requiring a consistent and uniform listing of generic and brand name drugs by setting forth the requirement in subdivision (e)(2) of the regulation. The broad objective is also creating a formulary that is comparable by requiring specific information be included by all health plans. The specific benefits are an easily understandable formulary, uniform explanation on how a formulary works, and informing enrollees of the types of prescription and non-prescription drugs available for certain conditions. This subdivision also implements Health and Safety Code section 1367.205, subdivisions (b)(2)(E), which requires a formulary include information on which medications are covered, including both generic and brand name.

Subdivision (e)(3) requires specific headings for each column of a formulary. The broad objective is that this type of consistent format is important in creating a formulary that is comparable by enrollees. The specific benefit is that it provides better accessibility and understanding to enrollees regarding what prescription drugs are covered through a consistent organizational structuring of the formulary.

Subdivision (e)(4) lists how health plans must provide the prescription drug names in the first column, which is labeled “Prescription Drug Name.” The broad objective is to ensure that all health plans display consistent formatting of their formulary. The specific benefits are better accessibility and understanding for enrollees regarding what prescription drugs are covered as well as creating a formulary that is easily comparable between health plans.

Subdivision (e)(5) requires health plans to place information regarding utilization controls and limits to prescription drugs in a particular column of a formulary. The broad objective is ensuring health plan formularies are organized uniformly as all health plans are required to list formulary information in a consistent format. The specific benefit is the formulary will contain information helpful to an enrollee’s understanding of prescription drug coverage under the health plan formulary. This subdivision of the regulation implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring the formulary contain information on health plan access and utilization controls.

Subdivision (e)(6) requires health plans to provide specific information in the “Drug Tier” column. The broad objective is creating a formulary that is comparable for all health plans by requiring the formulary contain similar information. The specific benefits are that it provides accessibility and transparency of an enrollee’s prescription drug coverage by requiring consistent formulary information organized in an understandable manner. This subdivision of the regulation clarifies and implements Health and Safety Code section 1367.205, subdivision (b)(2)(F), requiring a formulary contain tier information for prescription drugs.

Subdivision (e)(7) requires health plans to provide specific information in the “Coverage Requirements and Limits” column. The broad objective is creating a comparable formulary format to ensure similar information is organization in a consistent manner under the regulation. The specific benefit is creating a standard formulary format for enrollees that is accessible and easily understood. This subdivision of the regulation also clarifies and implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), which requires a formulary contain information on cost sharing and utilization control.

Subdivision (e)(8) requires an annotated legend or key to all abbreviations, symbols and notations used in a formulary. The broad objective is creating a formulary that is comparable as all abbreviations, symbols and notations are defined. The specific benefit is ensuring enrollees have a clear understanding of the complete formulary. Providing explanation of abbreviations, symbols, and notations is a simple way to increase accessibility and understanding of health plan formularies.¹³

Subdivision (f) requires an index to the formulary. The broad objective is to require all

¹³ Adams, “Hidden From View,” page 9.

health plans provide an index in a consistent and uniform manner by have an index for a formulary. The specific benefit is to help enrollees locate their prescription drugs in an accessible and understandable manner.

COMPARISON WITH EXISTING REGULATIONS

The regulation proposed in this rulemaking action is neither inconsistent nor incompatible with existing state regulations. The Department compared the following related existing regulations, CCR, title 28, sections 1300.67.24 and 1300.67.241, and found no inconsistencies or incompatibilities with the proposed regulation.

ALTERNATIVES CONSIDERED

1. Centers for Medicare and Medicaid Services, Prescription Drug Plan Formulary, Pharmacy Network and Information Files

Pursuant to Health and Safety Code section 1367.205, subdivision (a)(3), the Department considered information published by the Centers for Medicare and Medicaid Services (CMS). The Department utilized this information during the drafting the proposed regulation and during the discussions with consumers and stakeholders regarding the proposed regulation. The CMS approach to a formulary template as a whole is not a reasonable alternative to the template proposed by this regulation. The biggest drawback of the CMS approach is that it is specifically adapted for Medicare Part D determinations. Health and Safety Code section 1367.205 requires that the formulary template be used by every health plan that provides prescription drug benefits. The CMS template does not offer sufficient flexibility in its format or information requested to be used as a standard drug formulary by all health plans.

2. Information Obtained from Informal Public Hearing

The Department and the CDI drafted the proposed formulary template with input from stakeholder groups and jointly conducted pre-notice discussions pursuant to Government Code section 11346.45 and Health and Safety Code section 1367.205, subdivision (a)(3). Through written and verbal comments submitted during stakeholder workshops and the required public hearing presented by the stakeholders. Based on written and verbal comments from stakeholders, the Department and the CDI developed a formulary template that took into account the consumer and stakeholder input. The formulary template developed with substantial consumer and stakeholder input meets the demands of the individuals and businesses that will utilize the form on a daily basis.

Pursuant to Government Code section 11346.5, subdivision (a)(13), a rulemaking agency must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency (1) would be more effective in carrying out the purpose for which the action is proposed, (2) would be as effective and less burdensome to affected private persons than the

proposed action, or (3) would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. As described in the Initial Statement of Reasons for this rulemaking action, the Department has not determined that any known alternatives meet the standards contained in Government Code section 11346.5, subdivision (a)(13), described above.

The Department invites interested persons to present statements or arguments with respect to alternatives to the requirements of the proposed regulations during the written comment period.

PURPOSE OF THE REGULATION

The regulation implements section 1367.205, requiring the creation of a standard prescription drug formulary template by the Department and CDI. Specifically, section 1367.205 requires: (1) health plans to post a formulary or formularies for each product offered by the health plans on their websites in a manner that is accessible and searchable by an enrollee; (2) health plans to update all formularies with any changes on a monthly basis; and (3) the Department to develop a standard formulary template containing specific provisions related to the formulary.

The regulation serves an important purpose in increasing transparency in the area of health plan prescription drugs through a consumer friendly standardized formulary. This regulation requires health plans to publicly post on their websites complete prescription drug formularies for each of the health plans' products, including cost sharing tiers and utilization controls such as prior authorization and step therapy. Currently, health plans do not use a common organizational structure for formularies, making comparisons difficult. Many health plans post only their most "commonly prescribed drugs," not the entire list of pharmaceutical drugs covered under the prescription drug benefit. The requirements of this regulation will assist enrollees, especially those with chronic conditions who rely on prescription drugs to manage their illness, make an easier comparison of prescription drug coverage among health plans.

Most enrollees base their choice of coverage on affordability of monthly premiums, access to covered drugs, and out-of-pocket costs. However, when attempting to read formularies, enrollees find it difficult to locate specific drugs, understand the terms that impact their prescription drug coverage, or compare different formularies. The Department seeks to alleviate some of the challenges enrollees face today by requiring a standardized formulary, which will allow enrollees to compare formularies from different health plans as well as more easily find information. In addition, including information regarding step therapy and the exception request process in a formulary will eliminate the number of documents enrollees must review in order to understand their full rights under their health plan's prescription drug coverage.

SUMMARY OF FISCAL IMPACT

- Mandate on local agencies and school districts: None
- Cost or Savings to any State Agency: None
- Direct or Indirect Costs or Savings in Federal Funding to the State: None
- Cost to Local Agencies and School Districts Required to be Reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None
- Costs to private persons or businesses directly affected: The Department has determined that this regulation will have cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. As described in the Economic Impact Assessment in the Initial Statement of Reasons for this rulemaking action, there is an impact on 49 health plans. The impact on businesses (health plans) is estimated to be \$608,689, or approximately \$12,422 (rounded down) per health plan.
- Effect on Housing Costs: None
- Other non-discretionary cost or savings imposed upon local agencies: None

DETERMINATIONS

The Department has made the following initial determinations:

- The Department has determined the regulation will not impose a mandate on local agencies or school districts, nor are there any costs requiring reimbursement by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.
- The Department has determined the regulation will have no significant effect on housing costs.
- The Department has determined the regulation does not affect small businesses. Health care service plans are not considered a small business under Government Code section 11342.610, subdivisions (b) and (c).
- The Department has determined the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. Please see the Economic Impact Assessment in the Initial Statement of Reasons for this rulemaking action for additional information about this initial determination.
- The Department has determined that this regulation will have no cost or savings in federal funding to the state.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS (Government Code sections 11346.3(b), 11346.5(a)(10))

The Initial Statement of Reasons for this rulemaking action describes the basis for the following Economic Impact Analysis results:

- **Creation or Elimination of Jobs Within the State of California**

This regulation is designed to assist health plans and enrollees in understanding their prescription drug coverage and help enrollees review different formularies. Accordingly, the Department has determined that no new jobs will be created or eliminated in the state of California as a result of the regulation. This regulation pertains to a narrow subset of health care benefits – prescription drugs and is required pursuant to Health and Safety Code section 1367.205.

- **Creation of New Businesses or Elimination of Existing Businesses Within the State of California**

This regulation is designed to assist health plans and enrollees in determining their prescription drug coverage as well as to help the enrollees easily review and compare the different formularies of health plans. This regulation impacts the health care industry and enrollees. Accordingly, the Department determined the proposed regulation will neither create new businesses nor eliminate existing businesses.

- **Expansion of Businesses Currently Doing Business Within the State of California**

This regulation is designed to assist health plans and enrollees in determining their prescription drug coverage as well as to help the enrollees easily review and compare the different formularies of health plans. This regulation impacts the health care industry and enrollees. Accordingly, the Department determined the proposed regulation will not significantly affect the expansion of businesses currently doing business within the State of California.

- **Benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment**

This regulation is designed to assist health plans and enrollees in determining their prescription drug coverage as well as to help the enrollees easily review and compare the different formularies of health plans. This regulation impacts the health care industry and enrollees. This regulation will not adversely affect the health and welfare of California residents, worker safety, or California's environment.

Accordingly, as described above, the proposed regulation benefits the health and

welfare of California residents by providing health plan enrollees with uniform prescription drug formularies and an easier and more clear process for enrollees to review and understand their prescription drug coverage.

BUSINESS REPORT:

This rulemaking package implements the provisions of SB 1052 and gives direction to health plans for their prescription drug formulary template to better assist enrollees in understanding their prescription drug coverage. The need for this regulation to apply to businesses is necessary for the health, safety or welfare of the people of the State of California.