

DEPARTMENT OF MANAGED HEALTH CARE

INITIAL STATEMENT OF REASONS

Standard Formulary Template Title 28, Section 1300.67.205

(Control No. 2017-5229)

Pursuant to Government Code section 11346.2, the Director of the Department of Managed Health Care (Department) submits this Initial Statement of Reasons in support of the proposed adoption of section 1300.67.205, in title 28 of the California Code of Regulations (CCR).

I. AUTHORITY

California Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate health care service plans (health plans). Under section 1341.9, the Director of the Department (Director) is vested with all duties, powers, purposes, responsibilities, and jurisdiction as they pertain to health plans (health plans) and health plan business.

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 are necessary to carry out the provisions of the Knox-Keene Health Care Service Plan Act of 1975 (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, enacted by Senate Bill (SB) 1052 (Torres, 2014)¹ requires the Department and the Department of Insurance (CDI), along with input from interested parties from at least one public meeting, to develop a standard formulary template for each product offered by a health plan.

Brief Procedural History

The Department and the CDI collaborated closely during the drafting of the formulary template required by SB 1052. The Department and CDI conducted public meetings where drafts of the text were disseminated to various stakeholders and public comments on the proposed draft formulary were solicited. The Department's public hearing occurred on August 25, 2017. The CDI held its public hearing with their stakeholders on August 23, 2017. Both the Department and the CDI attended the hearing of the other department.

II. Specific Problems Addressed, and Necessity of Regulations

In 2014, the Legislature enacted SB 1052 to promote accessibility and transparency in prescription drug coverage by requiring the Department to create a formulary template for easy access to clear and comparable prescription drug information for health plan enrollees. In drafting the formulary template, the Department worked with the CDI and stakeholders and reviewed a study done by California HealthCare Foundation (CHCF) on insights in the consumer experience in accessing prescription drug coverage. The CHCF found that a formulary with specific information and format would be greatly beneficial to health plan enrollees. The study found the single most important factor for enrollees in selecting a health plan is affordability. This includes monthly premiums and out-of-pocket costs.² At the same time two of the biggest challenges for enrollees is simply attempting to check whether their medications would be covered under their plan choices and understanding terms within different health plan formularies.³ By implementing a formulary template, the Department hopes to address some of the primary problems facing enrollees and further implement the legislative goals of SB 1052.

Pursuant to SB 1052, the standard formulary template shall include: (1) information on cost sharing tiers; (2) utilization controls for each drug covered; (3) the method to indicate any drugs on a formulary that are preferred over other drugs; (4) information to educate the enrollees about the differences between drugs administered under a health plan's medical benefit and drugs that are prescribed under a health plan's prescription benefit;

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

² Amy Adams, California HealthCare Foundation, "Hidden From View: How Enrollees Find Information About Prescription Coverage," October 19, 2015, page 4.

³ Adams, page 5.

(5) information to educate the enrollees on how an enrollee may obtain prescription drugs not listed on the formulary; include information on which medications are covered (including both generic and brand name); and (6) information on what tier of the plan's drug formulary each medication is located.

This 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 health plans and enrollees. This ensures uniform implementation of the formulary template by health plans and greater accessibility of prescription drug coverage for enrollees.

The specific problems addressed and the necessity of the proposed regulations are described in greater detail in the following paragraphs.

Subdivision (a) of proposed title 28, CCR section 1300.67.205 (hereinafter "Rule 1300.67.205"), addresses the problem of ambiguity in key terms and phrases used in drafting requirements for a health plan formulary. Without this subdivision, health plans could use varying definitions that would take away from one of the key goals of section 1367.205, which is alleviating enrollee confusion. These required terms ensure all formularies are substantially similar and assist health plans in drafting their formularies in compliance with the statute. Moreover, uniformity in key terms has the benefit of clarity regarding prescription drug benefits for health plans and enrollees.

Subdivision (a)(1) defines "coverage document" to include all documents health plans provide enrollees for coverage. This definition provides clarity regarding what a coverage document is and how it affects an enrollee and provides a clear term for use by health plans. This will ensure a consistent and uniform application of this term and the documents contained within this term.

Subdivision (a)(2) defines "dosage form." This provision provides for a consistent and uniform definition based on the federal U.S. Food and Drug Administration (FDA) definition. It is essential that this term is used in a consistent manner by health plans to give enrollees a clear understanding of the form in which a prescription drug is prescribed. By providing a defined term, all health plans will provide the same information relating to dosage form, thereby allowing enrollees a greater understanding of how this term impacts their drug coverage.

Subdivision (a)(3) defines "established name." This provision is needed to ensure all health plans are correctly listing and uniformly labeling a drug as generic and/or brand name drug. This provision removes any ambiguity as to what generic drug means and assists in the implementation and understanding of a formulary. Further, this subdivision assists in implementing section 1367.205, subdivision (2)(E), requiring a formulary to include information on brand and generic names.

Subdivision (a)(4) defines "exception request." This definition clarifies health plans must use this term in a consistent and uniform manner and ensures compliance with sections 1367.24, 1367.241, and 1367.244 of the Health and Safety Code. These sections set

forth essential rights of enrollees relating to obtaining nonformulary drugs, prior authorizations, and step therapy. Additionally, this subdivision of the regulation ensures consistent use and understanding of this term by both health plans and enrollees.

Subdivision (a)(5) defines “exigent circumstances.” This definition ensures health plans and enrollees have a consistent and uniform understanding of this term. This subdivision implements this term in accordance with Health and Safety Code section 1367.241, subdivision (a)(1). Subdivision (a)(1) of Health and Safety Code section 1367.241 defines exigent circumstances. By providing the same definition as used previously in the Knox-Keene Act, this subdivision of a formulary also eliminates any ambiguity and inconsistent application of this term by the industry.

Subdivision (a)(6) defines “formulary.” This definition provides for a consistent and uniform understanding and application of this term. The Department is ensuring all health plans utilize the definition of a formulary as set forth in Health and Safety Code section 1367.205. The definition of the term eliminates confusion by providing a consistent and uniform definition that is easily understandable for health plans and enrollees. Additionally, using the definition in Health and Safety Code section 1367.205 guarantees health plans are providing a complete list of drugs available to enrollees.

Subdivision (a)(7) implements subdivision (i) of Health and Safety Code section 1367.24 by defining “nonformulary.” The Department clarifies the meaning of “nonformulary” and eliminates any inconsistent definition of this term by incorporating the existing definition. This definition will also assist enrollees in understanding the differences between formulary and nonformulary drugs under their prescription benefits. Uniform compliance with the law ensures that enrollees have a clear understanding of their rights when reviewing health plan formulary documents and provides transparency in prescription drug coverage.

Subdivision (a)(8) defines “prescription drug” by consistently implementing the Knox-Keene Act terminology contained in Health and Safety Code sections 1367.002 and 1367.25, and Rule 1300.67.24 under Title 28 of the California Code of Regulations. This ensures uniform application of this term by health plans. The consistent terminology is also beneficial to enrollees by helping them understand their prescription drugs benefit in a clear and concise manner.

Subdivision (a)(9) defines “product” to comply with Health and Safety Code section 1367.27. Health and Safety Code section 1367.27 details provider directory requirements and requires health plans to provide information in their directories for each product the health plan markets. The definition in subdivision (a)(9) ensures consistent understanding of the Knox-Keene Act standards in all health plan documents and alleviates potential confusion that would occur by health plans and enrollees.

Subdivision (a)(10) defines “quantity limit” to be consistent with the definition provided by the National Association of Insurance Commissioner’s (NAIC) “Health Carrier Prescription Drug Benefit Management Model Act.” The Department is utilizing the definition proposed by the NAIC because it is known within the healthcare community and was reviewed by

the NAIC for use with prescription drug coverage on a federal scale. This subdivision also implements Health and Safety Code section 1367.205, subdivision (2)(A), requiring a formulary to include utilization limitations for prescription drugs. Accordingly, this definition ensures there is a consistent use and understanding of the term “quantity limit” and uniform application of this definition by health plans. Defining quantity limit is also vital to an enrollee’s understanding of prescription drug benefits and whether a health plan may limit the quantity of a prescription drug that an enrollee utilizes and how and why that limitation occurs.

Subdivision (a)(11) defines “strength.” The definition of this term implements Health and Safety Code section 1367.205, subdivision (2)(A), requiring a formulary to note any utilization limits. Accordingly, this provision ensures there is a consistent use and understanding of what qualifies as the “strength” of a prescription drug by health plans and enrollees. The strength of a prescription drug is vital to an enrollee’s understanding of his or her prescription drug benefit and ensures an enrollee is clearly informed about how this term is used within a health plan formulary document.

Subdivision (b) contains the comprehensive format of a formulary and requires a formulary to be searchable by health plan enrollees. Health plans must include the specific sections noted under subdivision (b) of the regulation to ensure enrollees are provided with uniform and consistent formulary information. This provision requires all formularies to have the following elements within their formularies: (1) Coverage Page; (2) Table of Contents; (3) Informational Section; (4) Categorical List of Prescription Drugs; and (5) Index. All of the components are discussed in detail below except for the table of contents. The table of contents is necessary to ensure the enrollee has an easy method to locate necessary information in a formulary.

Subdivision (c) further clarifies the goals of subdivision (b)(1) of the formulary by setting forth the specific provisions that shall be contained in the cover page of the formulary. This requirement is necessary to ensure that all formularies contain similar prescription drug information, thereby making a formulary more accessible to enrollees regardless of the health plan or health plan product. This subdivision is supported by research conducted by the CHCF. A survey taken by the CHCF found that the cover page of a formulary is considered essential information by consumer and three-quarters of individuals surveyed want the cover page to specify the type of formulary coverage and product information contained in the formulary.⁴

Subdivision (c)(1) requires all formularies to include the title of the document. This information will ensure that enrollees clearly understand which health plan document they are reviewing or referencing. This will also alleviate confusion on the part of the enrollees when they are trying to locate a formulary or determine their prescription drug benefit because the enrollee will be able to more quickly identify which document to access.

Subdivision (c)(2) requires all formularies to contain the name of the health plan. This clarifies the specific health plan offering the particular formulary making it easier for

⁴ Amy Adams, California HealthCare Foundation, “Hidden From View: How Enrollees Find Information About Prescription Coverage, October 19, 2015, page 9.

enrollees to contact the health plan if the enrollee has a question regarding a formulary. This subdivision also ensures enrollees are provided with the names of health plans in a consistent manner and understand what benefits each health plan is offering under their prescription drug coverage.

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 contained in Health and Safety Code section 1367.27. This subdivision also requires the health plan product names to correspond with other identifiable coverage documents. This consistency will help enrollees identify the specific coverage documents applicable to a particular product and eliminates confusion between multiple coverage documents and products. This subdivision also implements Health and Safety Code section 1367.205, subdivision (1)(a), requiring health plans to post formularies for each product offered on the health plan's website. This subdivision also advances the goal of SB 1052 by allowing enrollees the ability to compare formularies of different health plans in a manner that is easily accessible.

Subdivision (c)(4) requires a formulary to contain an updated reference date. This clarifies the date a formulary was last updated and guarantees enrollees are reviewing the most recent formulary applicable to their coverage. This provision also ensures health plans are consistently updating their formularies and providing the most recent information to enrollees.

Subdivision (c)(5) requires health plans to provide notice to enrollees that a formulary is subject to change and that outdated copies of a formulary should be discarded. This will prevent enrollee confusion. This subdivision ensures enrollees are reviewing the most recent health plan formulary and understand only the most recent formulary is applicable to their coverage.

Subdivision (c)(6) requires health plans to provide a direct website link/URL for the location of the electronic version of a formulary posted on their website. If there is more than one health plan product, the enrollee must be able to determine which formulary applies to a specific health plan product. This subdivision implements subdivision (a)(1) of Health and Safety Code section 1367.205, which requires a health plan to post a formulary or 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, the Department, and federal agencies. This eliminates potential confusion for the public and regulatory agencies when reviewing or researching health plan formularies.

Subdivision (c)(7) requires a formulary to contain a direct health plan website link to specific coverage documents that contain cost sharing information. This provision implements subdivisions (a)(1) and (b)(1) of Health and Safety Code section 1367.205. These statutory subdivisions require a formulary be posted on the health plan's website in an accessible manner and, if possible, contain cost sharing information. As noted above, one of the most, if not the foremost, factor for enrollees in purchasing coverage is

affordability.⁵ This regulatory provision requiring a website link to documents containing specific cost sharing information balances the needs of the enrollees to access this information to understand their cost sharing versus the health plans' argument that doing so within the formulary itself is difficult and inefficient.

Subdivision (d) describes the information a health plan formulary must contain. This provision is necessary for an enrollee's understanding of the meaning and purpose of a drug formulary, how to use a drug formulary and enrollee's prescription drug benefits. This "informational" section of a formulary is required under 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 1) cost sharing; 2) utilization controls; 3) drugs that are preferred over other drugs; 4) drugs covered under the medical benefit versus drugs covered under the prescription drug benefit; 5) how to obtain drugs not listed on a formulary; 6) information on generic and brand name drugs; and 7) the tiering of prescription drugs. This subdivision of the formulary template also addresses one of the goals of the CHCF's research – educating enrollees about their prescription drug benefits. The CHCF determined increasing enrollee education was one of the most important steps in addressing the gap in knowledge for enrollees concerning access to prescription drug benefits.⁶

Subdivision (d)(1) specifies the requirements for a health plan to ensure enrollees contacting member services receive accurate information. The subdivision requires a health plan to ensure its customer service staff are knowledgeable and able to provide specific information regarding the enrollee's prescription drug benefits applicable to their health plan product. This provision ensures an enrollee can obtain information on a specific health plan product in a consistent and accurate manner and is not transferred from one health plan representative to another in order to obtain formulary information. This provision will streamline member access to drug information and create greater transparency of formulary benefits.

Subdivision (d)(2) requires health plans to define noted terms in the subdivision, or, if a related term is used, to define the term in a similar manner. A health plan may request an exception to the listed definition from the Department under this subdivision. This subdivision is crucial for an enrollee's correct understanding of the terms in a formulary and transparency in a health plan prescription drug coverage. The requirement to define terms in a uniform and understandable manner will assist enrollees in understanding their prescription drug benefits. This subdivision implements the goals of SB 1052 to provide enrollees with a document they can easily understand.

Subdivision (d)(2)(A) sets forth the definition of "Brand name drug" and requires brand name drugs to be listed in all capital letters. This subdivision clarifies the requirement that all health plans define brand name drugs in a consistent and uniform manner. This subdivision further clarifies the required format of brand name drugs, which will allow enrollees to easily identify the brand name drugs regardless of the health plan formulary reviewed. The requirements in this provision are supported by the CHCF's

⁵ Adams, "Hidden From View," page 4.

⁶ Adams, "Hidden From View," page 9.

recommendation that formularies be easily accessible by clearly indicating the drugs with brand names versus drugs with generic names.⁷ If brand and generic drugs are identified in a consistent and uniform manner, an enrollee looking at the format of the name of a particular drug can easily identify whether it is a brand or generic. This subdivision of the formulary implements a key purpose of SB 1052 by giving enrollees the ability to compare formularies of different health plans in an easy and accessible manner.

Subdivision (d)(2)(B) defines “coinsurance” to ensure this term is used in a consistent and uniform manner by the health plans. This subdivision clarifies the meaning of the term for enrollees and gives enrollees a better understanding of their prescription drug benefit and its financial impact on their policy. In its research, the CHCF found that specific out-of-pocket, copayments, and coinsurance amounts were important considerations for enrollees with chronic conditions because of the potential long term cost associated with chronic conditions.⁸ A clear definition of this term will clarify its meaning for enrollees and assist in their understanding of how their coinsurance is calculated so they can understand the cost of their prescription drug benefits.

Subdivision (d)(2)(C) defines “copayment” to ensure this term is used by the health plans in a consistent and uniform manner. This definition clarifies the meaning of copayment and its potential impact on the cost of an enrollee’s prescription drug coverage. In its research, the CHCF found that specific out-of-pocket costs such as copayments and coinsurance amounts were important interests for enrollees when determining the scope of their prescription drug coverage. The specific out-of-pocket costs were listed by nearly half of the people surveyed as one of the most important factors in drug coverage.⁹ The definition of this term will give enrollees clarity to its meaning and how the cost may affect enrollee access to prescription drug coverage.

Subdivision (d)(2)(D) defines “deductible” to ensure that this term is used by the health plans in a consistent and uniform manner. The definition of this term will assist enrollees in a clear understanding of the meaning of deductible and how it may impact their access to prescription drugs. This definition ensures health plans use this term in a consistent and uniform manner and helps enrollees understand this term. The CHCF determined one of the most important factors for choosing between products offering prescription drug coverage are out-of-pocket costs such as deductibles and copayments. Defining the term “deductible” will provide a clear and concise understanding of how an enrollee’s deductible may impact the affordability of the policy the enrollee chooses.¹⁰

Subdivision (d)(2)(E) defines “drug tier.” This subdivision requires health plans to define this term in a consistent and uniform manner to give enrollees a better understanding of the term and its impact on drug pricing and accessibility. This provision creates an enrollee-friendly definition and clarifies the term and how it is used in a health plan formulary. As noted by the CHCF, enrollees at times confuse drug tiers with metal tiers

⁷ Adams, “Hidden From View,” page 9.

⁸ Adams, “Hidden From View,” page 6.

⁹ *Id.*

¹⁰ Adams, “Hidden From View,” pgs. 4-5.

used under the Affordable Care Act.¹¹ A clear definition of this term will assist enrollees in understanding its use in a drug plan formulary and its potential impact on an enrollee's access to drug coverage.

Subdivision (d)(2)(F) defines “enrollee” to ensure all health plans are defining the term in a consistent and uniform manner consistent with the requirements of Knox-Keene Act. This definition eliminates any confusion a different definition may cause enrollees and health plans. This subdivision is consistent with the definition of enrollee contained in Health and Safety Code section 1345. This definition is also necessary to ensure health plans and enrollees understand how the terminology is used in the formulary as well as in other coverage documents.

Subdivision (d)(2)(G) defines “exception request” to assist the enrollee in requesting an exception for a nonformulary drug. This provision clarifies the meaning of an exception to the prescription drug formulary when a nonformulary drug may be available. As noted by the CHCF, many enrollees are unfamiliar with the prescription drug exception process and increasing enrollee education in this area would be beneficial to enrollees' access to nonformulary prescriptions. The exception request is an essential enrollee protection under the Knox-Keene Act and this definition is consistent with the definition already contained in Health and Safety Code section 1367.241 and Rule 1300.67.241.

Subdivision (d)(2)(H) defines “exigent circumstances” to assist enrollees' understanding of this term when it is utilized in a formulary. Exigent circumstances require prescription drug decisions to be made in a timely manner depending on the circumstances of the enrollee and as determined by the enrollee's provider. This subdivision is consistent with Health and Safety Code section 1367.241, which defines exigent circumstances, and ensures the term is utilized by health plans in a consistent manner.

Subdivision (d)(2)(I) defines “formulary.” This subdivision implements, and is consistent with, Health and Safety Code section 1367.205, subdivision (c), which defines this term. This definition contained in this subdivision is necessary to assist enrollees in understanding the meaning of the term “formulary” and its application to the scope of their drug benefits within their health plan coverage documents.

Subdivision (d)(2)(J) defines “generic drug” and requires generic drugs to be listed in all bold and italicized in lowercase letters. This requirement ensures health plans are defining and referencing generic name drugs in a consistent and uniform manner. The definition of this term provides clarity to enrollees and ensures enrollees may easily identify generic versus brand name drugs in their health plan formulary documents. The requirements in this provision are supported by the CHCF's recommendation that one way for formularies to be easily accessible is to indicate the brand and generic named drugs in

¹¹ Covered California health insurance plans — and all health plans in the individual and small-group markets — are sold in four primary levels of coverage: Bronze, Silver, Gold and Platinum. As the metal category increases in value, so does the percentage of medical expenses that a health insurance plan covers, compared with what you are expected to pay in copays and deductibles. For more information, see <https://www.coveredca.com/individuals-and-families/getting-covered/coverage-basics/coverage-levels/>.

a uniform and clear manner.¹² This subdivision also implements SB 1052 and its goal of providing enrollees with formulary documents they can review and understand, increasing health plan transparency of prescription drug coverage.

Subdivision (d)(2)(K) defines “nonformulary drug” in a consumer friendly manner to assist enrollees in understanding how this term is used in a health plan formulary. The definition in this subdivision clarifies the meaning of the term for enrollees and assists them in understanding how they may be able to obtain prescription drugs not otherwise covered under the health plan product. This provision increases accessibility and transparency of prescription drug coverage.

Subdivision (d)(2)(L) defines “out-of-pocket cost.” This subdivision ensures the term is defined in a consistent and uniform manner by health plans. The definition of out-of-pocket cost is necessary to help enrollees understand how this term is used in their health plan formulary. The cost of prescription drugs was one of the factors identified by the CHCF as a key concern for enrollees. The CHCF reported affordability of monthly premiums and other out-of-pocket costs, such as copayment and coinsurance, as the foremost consideration when an enrollee purchases health care coverage.¹³ By defining this term in the template formulary, the Department is providing clarity to the meaning of this term and ensuring enrollees have a clear understanding of the impact of out-of-pocket costs for drug benefits.

Subdivision (d)(2)(M) defines “prescribing provider” to ensure health plans are using this term consistently. This definition is necessary to assist enrollees in understanding who is allowed to prescribe a prescription drug under the term of their health plan formulary.

Subdivision (d)(2)(N) defines “prescription” to ensure health plans are using this term consistently in their drug formularies. The definition of this term is necessary to clarify its meaning in plain English for better enrollee understanding of their rights to prescription drugs. This definition assists enrollees in their understanding of which drugs require a prescription and how that prescription may be obtained under the terms of a health plan formulary.

Subdivision (d)(2)(O) defines “prescription drug” in plain English and ensures health plans are using this term in a consistent manner within the drug formularies. This definition clarifies how this term is used within a health plan formulary. The definition of this term will assist enrollees in understanding which drugs require a prescription and the process for obtaining a prescription drug under the terms of the health plan formulary. An enrollee’s understanding of the prescription drug process is a key element to ensure enrollees are aware of their full rights under the health plan formulary.

Subdivision (d)(2)(P) defines “prior authorization” to help enrollees understand the use of this term in a formulary and their rights to obtain drugs that require prior approval by the health plan. This provision implements Health and Safety Code section 1367.205,

¹² Adams, “Hidden From View,” page 9.

¹³ Adams, “Hidden From View,” page 4.

subdivision (b)(2)(A), requiring a formulary to include information on utilization controls, including prior authorization. The definition of prior authorization is necessary for clarity of an enrollee's understanding of prescription drug coverage. Defining this term aids in consistency and understanding of its use by health plans and enrollees.

Subdivision (d)(2)(Q) defines "step therapy" to assist enrollees in their understanding of the step therapy process for obtaining certain prescription drugs. This definition clarifies how the requirement for the step therapy process works and the requirement that some health plans may impose on an enrollee to use one drug before the enrollee may be prescribed another drug under the terms of the health plan formulary. This subdivision also implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring a formulary include information on utilization control, which includes step therapy.

Subdivision (d)(2)(R) defines "subscriber" to ensure all health plans are defining the term in a consistent and uniform manner consistent with the requirements of Knox-Keene Act. This definition eliminates any confusion a different definition may cause enrollees and health plans. This subdivision is consistent with the definition of subscriber contained in Health and Safety Code section 1345. This definition is also necessary to ensure health plans and enrollees understand how the terminology is used in the formulary as well as in other coverage documents.

Subdivision (d)(3) requires health plans list and define any additional terms used in the formulary. This provision clarifies the rights and obligations of enrollees under the terms of the health plan formulary. Defining terms within the formulary assists enrollees in their understanding the full scope of their rights to access prescription drugs under the terms of the health plan formulary.

Subdivision (d)(4) requires instructions to assist enrollees in locating their prescription drugs in the categorical list of prescription drugs contained in a health plan formulary. The instructions clarify for enrollees how to use a formulary and how the categorical list of prescription drugs is organized. The provision is necessary to alleviate confusion on the part of the enrollee as well as greater transparency in the prescription drug process.

Subdivision (d)(5) describes how drugs must be listed in a formulary including an explanation of which drugs are generic or brand, and the availability of both types of drugs to enrollees. This provision is necessary to ensure health plans list the prescription drugs in a consistent manner for all drug formularies. One of the primary purposes of SB 1052 is to allow enrollees to compare formularies of different health plans. The availability of consistently organized information about generic or brand name drugs implements the purpose of the statute.

Subdivision (d)(6) requires the description of the drug tiers contained in a formulary. This subdivision implements Health and Safety Code section 1367.205, subdivision (b)(2)(F) by requiring a formulary to include information about tiering of drugs in a health plan formulary. The information in this subdivision assists enrollees in understanding how drug tiering impacts the financial costs involved in choosing a formulary and accessing

necessary prescription drugs.

Subdivision (d)(7) requires health plans to describe all utilization controls imposed on prescription drug benefits in the health plan formulary. This provision implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring a formulary include information about utilization controls. This provision makes it easier for enrollees to compare different health plan formularies and clarifies the limits or requirements a health plan may impose on enrollee access to a particular drug in the formulary.

Subdivision (d)(8) implements Health and Safety Code section 1367.205, subdivision (b)(2)(C), by requiring a health plan to set forth information on the difference between prescription drugs covered under the medical benefit of the health plan contract and prescription drugs covered under the prescription drug benefit of the health plan contract. This definition assists enrollees in understanding which benefit the prescription drug falls under and how that benefit type may impact their prescription drug coverage and cost.

Subdivision (d)(9) implements Health and Safety Code section 1367.205, subdivision (a)(2), requiring health plans to provide notice to enrollees that a formulary is updated on a monthly basis. This information clarifies the type of changes made to a formulary and whether those changes impact the enrollee's access to his or her prescription drug benefits. This definition also ensures health plans are updating formularies in a consistent and timely manner and enrollees have access to the updated formulary information.

Subdivision (d)(10) requires health plans to explain the presence of a prescription drug on the health plan prescription drug formulary does not guarantee the enrollee will be prescribed the prescription drug. This provision clarifies enrollee rights, limits and obligations for obtaining prescription drug benefits under the health plan prescription drug coverage. This information is important for an enrollee's accurate understanding of their prescription drug benefits as well as limits of coverage.

Subdivision (d)(11) implements Health and Safety Code section 1367.205, subdivision (b)(2)(D), requiring health plans to provide notice of nonformulary drug coverage when medically necessary and the enrollee process for obtaining such coverage. This provision is also consistent with Health and Safety Code section 1367.24, which requires health plans to maintain an expeditious process by which prescribing providers may obtain authorization for medically necessary nonformulary prescription drugs. This subdivision implements an important enrollee right regarding coverage of medically necessary drugs and helps with increasing transparency and accessibility in the drug formulary process.

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. This is an important provision in a drug formulary to educate enrollees on how to access prescription drugs. This subdivision also assists enrollees in comparing different formularies and drug prices and helps enrollees determine the level of accessibility to prescription drugs within a health plan formulary. The level of accessibility may impact whether an enrollee chooses a particular health plan's prescription drug coverage based upon availability of the drug and the drug cost.

Subdivision (d)(13) implements Health and Safety Code section 1367.205, subdivisions (b)(2)(A) and (D), requiring a detailed description of the enrollee prior authorization or step therapy exception process. This information is essential for enrollees in understanding their rights to access prescription drugs that may require prior approval before being covered by the health plan. The CHCF identified enrollees' lack of familiarity with the prescription drug exception or appeals process as a notable problem impeding enrollee rights as well as the enrollees' inability to locate this information in existing health plan formularies.¹⁴ This subdivision addresses these issues by requiring health plans to provide this important information in a consistent and uniform manner.

Subdivision (d)(14) implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring notification of an enrollee's rights regarding step therapy and the method for obtaining prescription drugs through the step therapy process. This information is crucial for an enrollee's complete understanding of their rights to access certain types of prescription drugs that might not otherwise be available. This subdivision ensures there is uniform and consistent notification of the right for enrollees to access drugs through the step therapy process. This information assists enrollees with understanding the step therapy process specifically relating to prescription drug coverage under their health plan product.

Subdivision (d)(15) requires notification of coverage for prescription drugs previously approved for an enrollee's medical condition if certain criteria are met. This notification requirement is a vital enrollees' right for access to prescription drug benefits. The clarification of an enrollee's right to continue to access certain medically necessary drugs under specific circumstances is crucial to the health of enrollees. This subdivision clarifies the notification requirements and ensures enrollees are aware of their rights and the procedures for obtaining drugs previously approved by the health plan.

Subdivision (d)(16) requires information on specific prescription drugs that are covered under a health plan's formulary. This information is essential to clarify which drugs on a health plan formulary are available to the enrollee. This provision clarifies the statute by providing enrollees with details on all covered prescription drugs instead of a limited list of certain drugs.

Subdivision (d)(17) implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), requiring health plans to set forth limitations on cost sharing for orally administered anti-cancer drugs. This provision helps enrollees estimate their cost for obtaining specific prescription drugs. Additionally, the CHCF reported affordability of monthly premiums and other out-of-pocket costs as the foremost consideration of enrollees when purchasing health care coverage.¹⁵ Clearly identifying the cost sharing limits assists enrollees in understanding their health care costs.

Subdivision (d)(18) implements Health and Safety Code section 1367.205, subdivision

¹⁴ Adams, "Hidden From View," pgs. 7 and 9.

¹⁵ Adams, "Hidden From View," page 4.

(b)(2)(A), by requiring health plans to list any prescription drugs that are limited to specialty pharmacy or other network access limitation restrictions. This information is crucial for enrollees in obtaining access to their prescription drug benefits. This provision requires a drug formulary to contain essential information that assists enrollees in comparing and choosing a health plan's prescription drug benefit.

Subdivision (d)(19) requires an annotated legend or key for all abbreviations, symbols and notations used in a health plan formulary to ensure enrollees have a complete understanding of benefits within a formulary. This provision was recommended by the CHCF as a simple way to increase enrollee accessibility and understanding of health plan formularies.¹⁶ This provision will enable enrollees to better understand their formularies and ensure they do not have to search throughout their health plan coverage document for the individual meaning of each abbreviation or symbol.

Subdivision (e) requires health plans to list prescription drugs in the health plan formulary in the required section titled "categorical list of prescription drugs." This provision clarifies the requirements for health plan organization of information within their formularies. This information is important in creating a formulary that is comparable for all health plans and provides enrollees with better access and understanding of their prescription drug coverage.

Subdivision (e)(1) states how health plans must categorically list prescription drugs as required by Health and Safety Code section 1367.205. This requirement will create a formulary that is comparable for all health plans, and provide enrollees with better access and understanding of their prescription drug coverage through a consistent formulary organization.

Subdivision (e)(2) implements Health and Safety Code section 1367.205, subdivisions (b)(2)(C) and (E), by requiring a formulary to contain brand and generic names and, when possible, a plain language description of a prescription drug. This information will assist enrollees in gaining a comprehensive understanding of their health plan formulary. This subdivision also creates a drug formulary that is comparable across health plans for enrollees and provides better enrollee access and understanding of their prescription drug coverage. The plain language recommendation will assist enrollees in understanding which prescriptions drugs they can access for their specific condition. All these factors help increase accessibility and transparency in health plan prescription drug coverage.

Subdivision (e)(3) requires specific headings for each column of a health plan formulary to ensure that all formularies are arranged in the same manner. This consistent organization is important for creating a comparable formulary for health plans and provides enrollees with better access and understanding of their prescription drug coverage.

Subdivision (e)(4) sets forth how health plans must list prescription drugs in column one of the formulary, which is titled "Prescription Drug Name." This requirements ensures health plans display all formularies for prescription drugs in a consistent and uniform manner.

¹⁶ Adams, "Hidden From View," page 9.

This subdivision implements SB 1052 by creating a uniform format for health plan formularies that is comparable across health plans for enrollees and provides enrollees with better access and understanding of their prescription drug coverage.

Subdivision (e)(5) implements Health and Safety Code section 1367.205, subdivisions (b)(2)(A) and (B), by requiring restrictions for quantity limits and prior authorizations to be noted in a column of a formulary. This provision ensures health plan formularies are organized in a consistent and uniform manner and contain information that assists an enrollee's understanding and accessibility to prescription drugs within their formulary.

Subdivision (e)(6) sets forth required information health plans must place in the "Drug Tier" column of their formulary. This provision creates a formulary that is comparable among all health plans by requiring health plans to have specific information within their formulary template. This information assists enrollees with accessibility and understanding of their health plan formularies by requiring formularies to contain similar information. This subdivision of a formulary further clarifies and implements Health and Safety Code section 1367.205, subdivision (b)(2)(F), requiring a formulary to contain information on which tier of the health plan's formulary each medication is located.

Subdivision (e)(7) sets forth the information health plans must place in the "Coverage Requirements and Limits" column of their drug formulary. This information clarifies health plans are required to create a formulary that will be comparable to other health plans and must contain specific information in a consistent organization to assist enrollees in understanding the scope of their drug coverage. This subdivision creates uniformity for all health plan drug formularies. This subdivision further clarifies and implements Health and Safety Code section 1367.205, subdivision (b)(2)(A), which requires health plan formularies to 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. This creates a formulary that is comparable for all health plans as all abbreviations, symbols and notations are explained in a formulary. This provision provides clarity to enrollees in their understanding of a formulary and the abbreviations, symbols and annotations used by the health plans. An annotated legend or key was also recommended by the CHCF as a simple way to increase accessibility and understanding of health plan formularies by enrollees.¹⁷ Further, this requirement increases accessibility and transparency as all symbols, abbreviations, and annotations are explained on each page of the list of available prescription drugs. Accordingly, this makes it easier for enrollees to understand their coverage. Enrollees will not have to refer to other sections of a formulary or other coverage documents to understand the terms used by their health plan.

Subdivision (f) requires an index to a formulary to help enrollees locate their prescription drugs in an accessible and understandable manner. This provides consumers another method for quickly identifying the prescription drugs.

¹⁷ Adams, "Hidden From View," page 9.

DOCUMENTS RELIED UPON

- Health and Safety Code section 1367.205.
- Title 28, California Code of Regulations sections 1300.67.24 and 1300.67.241.
- Centers of Medicare and Medicaid, 2017 Part D Model Formulary (Abridged and Comprehensive).
- California Health Care Foundation, “Hidden from View: How Enrollees Find Information About Rx Coverage,” August, 2015.

REASONABLE ALTERNATIVES TO THE REGULATION

The Department conducted pre-notice discussions with interested parties pursuant to Government Code section 11346.45. Through written and verbal comments submitted during stakeholder workshops and meetings, the Department considered different alternative approaches presented by the stakeholders. Based on written and verbal comments from stakeholders, the Department developed the proposed regulation. The Department finalized the proposed regulation after considering written comments from stakeholders. The current proposed regulation meets the demands of enrollees and health plans that will utilize the regulation on a daily basis.

Pursuant to Government Code section 11346.2, the following alternatives were considered:

Prescriptive Standard

The Department considered whether a prescriptive standard rather than the current regulation, would be a reasonable alternative. For example, instead of utilizing the current formulary template, an alternative template was drafted that set forth word-by-word each provision and definition that health plans had to use in creating their formularies. Ultimately, the Department determined this type of formulary was an unreasonable requirement for health plans that would not result in a greater understanding of available drug benefits by enrollees. The Department determined the current version of the proposed regulation requiring standardized definitions and an extensive informational section had greater consumer protections and necessary information about prescription drug benefits. These provisions are intended to increase enrollee understanding of cost sharing under the provisions of their health plan formulary and a greater understanding of how their prescription drug benefits work.

Medicare Part D Standard

The Department considered a regulation similar to the Medicare Part D Formulary. However, under the Medicare Part D Formulary, health plans are not required to provide standardized definitions or an extensive information section explaining the various elements of the formulary and how the formulary operates. Under the Medicare Part D Formulary, health plans are able to decide whether to include tier

placement or actual cost sharing values for a drug in a formulary, although dollar amounts for of cost sharing for prescription drugs subject to coinsurance are not required. The Department determined this was not a feasible alternative for health plans because requiring specific cost sharing would necessitate health plans maintain a separate formulary for each benefit plan, rather than at the benefit level, as is current practice. This level of detail and requirements for health plan formularies would cause more confusion because it would not be clear what formulary applied to the enrollee's product. It would also be difficult, time consuming, and more costly for health plans to post on their website all the different formularies if the Medicare Part D standard were adopted. The Department's proposed formulary template regulation does not impose a requirement on the health plans that would be more costly or overly prescriptive. Instead, the proposed regulation balances the needs and costs of stakeholders while still ensuring enrollees have access to necessary prescription drug information as envisioned by SB 1052.

Other Standards Considered

The Department also considered providing a template that listed only the format for the listing of prescription drugs without any informational section or definitions. However, the Department determined that these alternatives would be unduly burdensome and would not provide information needed to comply with SB 1052. The Department also determined that it did not provide sufficient flexibility to the stakeholders as well the Department and did not provide enrollees the information needed to assist them in using and understanding a health plan formulary as required under SB 1052. The Department's proposed regulation makes it easier for consumers to compare health plan formularies and determine which formulary is more beneficial to them.

Government Code section 11346.2

Pursuant to Government Code section 11346.2, subdivision (b)(4)(A), the Department shall describe reasonable alternatives that were considered by the Department or that have otherwise been identified or brought to the attention of the Department and that are proposed as more effective in carrying out the purpose for which the above action is proposed, or are proposed as equally effective and less burdensome to affected private persons than the proposed action, or are proposed as more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department will consider all reasonable alternatives submitted by members of the public during the comment period.

SUMMARY OF BENEFITS OF THE REGULATION

One of the benefits of the regulation is increasing transparency in the area of health plan prescription drug formularies. This regulation requires health plans to publicly post on their websites a complete prescription drug formulary 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 comparison across formularies difficult. Additionally, 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 health plans.

Another benefit is eliminating enrollee confusion and frustration about their prescription drug benefits. Most enrollees base their choice of coverage on affordability of monthly premiums, access, and out-of-pocket costs. However, when reviewing their current health plan formularies, enrollees find it difficult to locate information they need about coverage of their prescription drugs. Enrollees also face issues in understanding the terms that are being used in the formularies. By requiring a template formulary, some of the access and lack of information will be mitigated. A template formulary will allow enrollees to easily find information they need to make an informed decision as all formularies are formatted in a similar fashion. Including information regarding step therapy and exception request process in the template formulary will eliminate the number of documents enrollees shall review before understanding their full rights. Further, defining certain terms will also help enrollees understand their formularies as well as their prescription drug benefits.

ECONOMIC IMPACT

The Department has determined the proposed Rule will not have a significant statewide economic impact. As required by SB 1052, the proposed regulation establishes a standard template formulary for prescription benefits that all health care service plans must utilize.

The specific economic impact on various categories is as follows:

GENERAL ANALYSIS

As previously stated, the Department is required to promulgate this regulation pursuant to SB 1052. This bill added section Health and Safety Code section 1367.205 to the Knox-Keene Act and requires a standardized formulary template is developed for use by the health plans regulated by the Department. The Knox-Keene Act requires all health plans providing prescription drug benefits to maintain one or more drug formularies to provide members of the public, and, upon request, a copy of the most current list of prescription drugs on the health plan formulary. If a health plan maintains more than one formulary, the health plan must notify the requesting party that a choice of formulary lists is available pursuant to Health and Safety Code section 1367.20.

The Affordable Care Act (ACA), under 45 Code of Federal Regulations (CFR) section 156.122, requires a health plan providing essential health benefits (EHB) cover at least the greater of: (1) one drug in every United States Pharmacopeial Convention (USP) category and class; or (2) the same number of prescription drugs in each USP category and class as the state’s EHB-benchmark plan. All health plans seeking a Qualified Health

Plan (QHP) certification to operate in the federal healthcare marketplace under the ACA must cover EHB and comply with CFR section 156.122.

One of the goals of the ACA is to increase insurance market competition by enabling consumers to more completely and accurately compare health plans. The ACA seeks to improve transparency and comparability in health benefits through the health insurance marketplace and consumer-friendly tools such as the standardized summary of benefits and coverage. Currently, health plans do not maintain their drug formularies in a manner that is comparable, consistent and searchable. The standardized formulary required under SB 1052 helps consumers make such comparisons between health plans regulated by the Department.

The majority of the provisions within the proposed regulation are required pursuant to Health and Safety Code section 1367.205, subdivision (b); however, there are some provisions implemented by the Department not specifically required pursuant to the statute. The Department analyzed these additional provisions to assess their economic impact on impacted stakeholders. In its analysis, the Department carefully considered whether the impacted health plans already possessed the information being required, and the only impact was to place the information in their formulary, or whether obtaining the information itself was a new requirement. The Department determined that all of the information being imposed under the proposed regulation was already in the possession of the health plans, but health plans would need a one-time computer system upgrade to update the information contained in their formularies to comply with the regulation.

The Department currently licenses seventy-five (75) full-service plans. Of those 75 full-service plans, forty-nine (49) offer prescription drug benefits. This number includes full-service plans who operate a qualified health plan (QHP) under Covered California. The Department considered the costs of computer system upgrades for these impacted health plans that will be needed to process formularies complying with the additional regulation requirements, but did not factor in the costs of information specifically required to be included under the provisions of Health and Safety Code section 1367.205(b). These costs can be attributed to the statute itself and not the proposed regulation.

TABLE 1. Cost of Formulary System Upgrades

Health Plan System Upgrades	Health Plan Number	Computer Programmer Hours	Computer Programmer Hourly Wage	Total Cost
Minor Upgrades	15	150	\$43.54	\$97,965
Average Upgrades	25	300	\$43.54	\$326,550
Multiple System Upgrades	9	470	\$43.54	\$184,174
TOTAL	49			\$608,689

The Department anticipates that the computer upgrades associated with the proposed

regulation may be broken down into three distinct categories: 1) minor upgrades; 2) average upgrades; and 3) multiple system upgrades. The Department expects the three categories to be divided amongst the impacted health plans, with the majority of the health plans having an average impact, and with the minority having either minor impacts or multiple system impacts.

The computer system upgrades may be done by a skilled computer programmer. Based upon the amount of time it is estimated the computer programmer will need to upgrade the health plan systems with the new regulatory requirements, the Department anticipates the following hours of work broken down by the type of system upgrades: 1) minor – 150 hours; 2) average – 300 hours; and 3) multiple – 470 hours. According to the Employment Development Department's Labor Market Information Division, in the first quarter of 2017, the median hourly wage of a computer programmer was \$43.54.¹⁸ Based on this information, the total anticipated costs for upgrading the health plan computer systems to comply with the regulation is \$608,689, or approximately \$12,422 (rounded down) per health plan.

Creation or Elimination of Jobs Within the State of California

This regulation is designed to assist health plans with meeting the requirements of SB 1052 and to enable enrollees in understanding their prescription drug coverage benefits. As stated above, the per health plan economic impact is nominal. Senate Bill 1052 already required health plans to upgrade their systems to meet the statutory requirements. 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 applies to a narrow subset of health care benefits, prescription drugs, and must be promulgated pursuant to the requirements of Health and Safety Code section 1367.205.

Creation of New Businesses or the 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. The health plan marketplace is competitive within California. When choosing a health plan, consumers weigh many options, including premium costs and benefits available under a particular health plan product. Any impact this regulation has on business is anticipated to be minor and widespread across the health plan industry. Accordingly, the Department has determined the proposed regulation will neither create new businesses nor eliminate existing businesses in the State of California.

¹⁸ California Employment Development Department Labor Market Information Division, Employment and Wages Data Table for the State of California in the First Quarter of 2017, Median Hourly Wage for Computer Programmer (SOC Code 15-1131), available at <http://www.labormarketinfo.edd.ca.gov/data/oes-employment-and-wages.html>.

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. The health plan marketplace is competitive within California. When choosing a health plan, consumers weigh many options, including premium costs and benefits available under a particular health plan product. Any impact this regulation has on business is anticipated to be minor and widespread across the health plan industry. Accordingly, the Department has determined the proposed regulation will not significantly affect the expansion of businesses currently doing business within the State of California.

The Benefits to the Health and Welfare of California Residents

This regulation is designed to assist health plans in complying with the law and to assist enrollees in determining their prescription drug coverage 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 ultimate benefits to health and welfare of residents of California from the proposed regulation is increased protection of the public health and safety through a more uniform prescription drug coverage requirement and an easier and more clear process for enrollees to review and understand their prescription drug coverage under each health plan formulary.