

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

#	FROM	COMMENT	DEPARTMENT RESPONSE
1-1	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>The California Association of Health Plans (CAHP) and America's Health Insurance Plans (AHIP) write to provide comments on the Department's proposed adoption of regulations entitled "Standard Prescription Drug Formulary Template, Control No. 2017-5229." CAHP represents 47 public and private health care service plans (plans) that collectively provide coverage to over 28 million Californians. AHIP is the national association whose members provide insurance coverage for health care and related services.</p> <p>We appreciate the Department's efforts to implement Senate Bill No. 1052 (SB 1052) from 2014. The purpose of that law was to help plan members determine whether a particular drug is covered by a particular health plan.<sup>1</sup> We fear that the proposed regulations will result in an extremely long and complicated document that will be difficult for members to understand – a result that directly conflicts with the purpose of SB 1052. More specific edits in that regard are suggested below and we generally recommend that the proposed regulations be reviewed for readability and revised to reflect no more than a sixth grade reading level.<sup>2</sup></p> <p><sup>1</sup> See Unfinished Business analysis of SB 1052 (as amended Aug. 18, 2014), p. 5 ("currently, obtaining information to confirm whether a person's drugs are covered by a qualified health plan is impossible or incredibly time consuming").</p> <p><sup>2</sup> In that regard, some of the definitions in the parallel regulations adopted by the California Department of Insurance (CDI) are written in the third person, which may be more reader-friendly.</p>	<p>No specific change requested. Thank you for your comment.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-2	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>Another purpose of SB 1052 was to standardize the presentation of formulary information. In fact, SB 1052 expressly requires the Department and the CDI to jointly develop "a" standard formulary template.<sup>3</sup> However, the proposed regulations we consider here differ in many respects from the regulations adopted by CDI. At a minimum, we request that the regulations be amended to allow entities regulated by both CDI and the Department to use the CDI template in accordance with the enacted CDI regulations.</p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>3</sup> Hlth &amp; S. Code, §1367.205(b)(1).</p>	<p>DECLINED. The Department worked with the California Department of Insurance (CDI) to draft one uniform template but the Department's and the CDI's templates were later amended based on individual department needs and the different laws and regulations governing both departments. It should be noted the variations between the templates promulgated by both departments are minor, such as the requirement that generic drugs be listed in bold and italicized lowercase letters, as opposed to CDI's requirement of only lowercase letters. The Department decided for policy reasons that it was necessary to add the requirement of "bold" to ensure the consumer protection purposes of SB 1052 were fully met in the regulation.</p>
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**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-3	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>SB 1052 also expressly requires the Department and CDI to take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services.<sup>4</sup> However, these proposed regulations impose requirements that are inconsistent with Medicare drug formularies. Currently, there are large numbers of consumers aging into Medicare; those consumers will greatly appreciate having the formulary templates look the same when they move from the commercial market to the Medicare market. Thus, we recommend that the regulations support as much consistency as possible with the more consumer-friendly Medicare formulary.</p> <hr/> <p><sup>4</sup> Hlth. &amp; S. Code, §1367.205(b)(1).</p>	<p>DECLINED. SB 1052 specifically states, "In developing the template, the department and Department of Insurance shall take into consideration existing requirement for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services." (Health and Safety Code section 1367.205.) The Department has taken into consideration the existing Medicare formulary. In fact, the Department utilized the Centers of Medicare and Medicaid Services' "2017 Part D Model Formulary (Abridged and Comprehensive)" as the foundation for the proposed formulary template as requested under the statute. Moreover, the Department has also considered and revised the existing formulary based on the comments received during the first comment period as well as the stakeholder meetings held prior to the finalization of the proposed template formulary.</p>
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-4	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>Lastly, the proposed regulations lack needed clarity and accuracy in some areas and impose additional burdens on plans that are inconsistent with industry standards and system limitations and would be infeasible from an implementation perspective. Below we analyze each subdivision of the proposed regulations and provide more detailed feedback on those issues and the other issues described above.</p>	<p>No specific change requested. Thank you for your comment.</p>
1-5	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>I. Definitions (Subdivision (a))</b></p> <p>a. The definition of the term “established name” is unclear. We request that the Department clarify whether this term refers to the generic name of a drug, the chemical name of a drug, or some other name.</p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p> <p>The Department has revised the existing definition of “established name” to reflect the definition in Health and Safety Code section 111225 as well as to take into account Health and Safety Code section 111355. This amended definition clarifies the meaning of the term “established name.”</p>
1-6	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. In the definition of “formulary” in subdivision (a)(6), the phrase “preferred for use” may be confusing given that the definitions of tiers under section 1342.71 of Health and Safety Code includes “non-preferred” drugs. We recommend replacing the proposed definition of the term “formulary” with the following:</p> <p>“Formulary” is the complete list of drugs preferred and non-preferred for use and covered under a health plan policy. Formulary is also known as a drug list.</p>	<p>DECLINED. The Department defined the term “formulary” consistently with SB 1052. (See Health and Safety Code section 1367.205(c)). The revised definition suggested by the commenter is inconsistent with the definition in the statute and would cause more confusion in its interpretation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-7	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>c. Subdivision (a)(7) defines a “nonformulary drug” as “any prescription drug where <i>an enrollee’s copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug</i>, except as otherwise provided by law or regulation and when a prescription drug that is not listed on the formulary is covered pursuant to an exception request.”</p> <p>In reality, however, a nonformulary drug is a drug that is not listed on the formulary and may require an exception request for coverage. The benefit drives whether or not the copayment is the same or different from a formulary drug. Thus, the italicized part of the proposed definition above is not always a true statement. The formulary is meant to convey the formulary status and not benefit information. We recommend replacing the proposed definition with the following:</p> <p>“Nonformulary drug” is a drug that is not listed on the formulary.</p>	ACCEPTED. The Department has made the proposed amendment to the regulation.
1-8	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>		

**DEPARTMENT OF MANAGED HEALTH CARE**  
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**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-9	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>Second, the term "self-administered" is problematic. In Medi-Cal, some medications are covered that can be used in an outpatient setting and are not necessarily self-administered.</p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p>
1-10	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>Third, the phrase "not provided for use on an inpatient basis" is confusing and may conflict with medical-only language that appears later in the proposed regulation.</p>	<p>DECLINED. The Department has defined "prescription drug" or "drug" per existing law and has revised the definition per comments received. Moreover, the Department does not find the phrase "not provided for use on an inpatient basis" confusing or in conflict with medical-only language in the proposed regulation as suggested by the commenter. This provision is consistent with Health and Safety Code sections 1367.24, 1367.002, and 1367.25 and title 28, California Code of Regulations, section 1300.67.24.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-11	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>Finally, it is not clear whether this definition includes OTC drugs. We request that the Department provide clarity on that point and make necessary revisions to address the other issues identified above; one such revision might include providing separate definitions for the terms "prescription drug" and "drug."</p>	<p>ACCEPTED. The Department has revised the definition to clearly state whether OTC drugs are part of the prescription drug benefit.</p>
1-12	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>e. We recommend the following edit to the definition of "strength" in subdivision (a)(11): "Strength" is the amount of active ingredient or ingredients that is present in each <del>dose</del> <u>dosage form</u> of a prescription drug.</p>	<p>DECLINED. The Department is using the definition of the term "strength" as set forth in the "Glossary" for the U.S. Food and Drug Administration. The use of this definition is done for clarity and to prevent confusion regarding the meaning of the term.</p>
1-13	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>II. Format of the Formulary (Subdivision (b))</b></p> <p>a. The proposed regulations require that the formulary include a table of contents ("TOC") followed by an informational section. We request that the TOC section be made optional. Many plans do not currently include a TOC in their formularies.</p>	<p>DECLINED. One of the goals of SB 1052 is to make formularies more accessible and easier to compare between different health plans. By requiring a table of contents, consumers will be easily able to review the table of contents to determine where specific sections of the formularies are located to find answers to their questions regarding prescription drug benefits.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-14	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. We also request switching the order of the TOC and informational sections. It is the current industry standard to make the TOC come after the informational pages so that page numbers can be programmatically assigned when they are directly before the categorical list of prescription drugs. Also, the informational section should come first in order to orient the reader as to the content before telling the reader the page on which a specific drug can be found. This would ease the coding and programming burden for all plans as well as make more sense for the reader.</p>	<p>DECLINED. The Department requires the table of contents to follow the cover page to help consumer "orient" themselves to the formulary. The table of contents must include the page numbers for all sections of the formulary, including the information section. This allows the consumers to easily access the information they are looking for within the formulary. The purpose of having the TOC come after the title page and to include numbers for all sections of the formulary, including the informational section and the index, and not just the categorical list of prescription drugs.</p>
1-15	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>c. The proposed regulations require that the formulary include an index of prescription drugs. We request that the index be made optional. Many plans do not currently include an index in their formularies and question whether this can be added based on system limitations with how the document is developed.</p>	<p>DECLINED. One of the goals of SB 1052 is to make the formulary more accessible and understandable for consumers. The Department determined an alphabetical index allows a consumer to locate a particular drug or section of the formulary if helpful and necessary and meets the requirements of Health and Safety Code section 1367.205.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-16	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>III. Cover Page (Subdivision (c))</b></p> <p>a. In subdivision (c)(3), we request deleting the reference to the Uniform Provider Directory Standards. Listing out all of the plan's products, as defined by the Uniform Provider Directory Standards, on the Formulary Booklet will result in pages of plan products that will not provide any valuable information to the member. In order to meet this requirement, plans will need to list all the product plan names that have different variations of network (PPO vs. HMO vs. EPO), metal levels, deductible levels – this easily amounts to 100 product variations/plan names for the large group alone.</p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p>
1-17	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. We request deletion of subdivision (c)(4) "The date the formulary was last updated." That language requires plans to update the cover page every month, which is impractical, unnecessary, and inconsistent with the current practice of most plans.</p>	<p>DECLINED. Health and Safety Code section 1367.205(a)(2) requires the posted formularies be updated with any changes to the formulary on a monthly basis. Additionally, the consumer needs to have the ability to determine he or she is reviewing the most current version of their formulary template and understanding what is a covered benefit.</p>

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**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-18	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>IV. Informational Section (Subdivision (d))</b></p> <p>a. With respect to subdivision (d)(2), many of the proposed defined terms will already be part of the Rx supplement and/or member EOC. We request that the Department confirm whether it is requiring plans to include all of the defined terms in a plan's formulary.</p>	<p>No specific change requested. Thank you for your comment.</p> <p>The proposed regulation clearly states in subdivision (d) that the formulary shall include the definitions listed. The purpose of having the definitions in one document, in one location, is to allow consumers easier access to information that is necessary for a clear understanding of the consumer's prescription drug benefits while the formulary is reviewed. Allowing health plans to have these definitions located in various plan documents defeats the purpose of SB 1052 which was to create an all-inclusive consumer friendly formulary template.</p>
1-19	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. In subdivision (d)(2)(E), because there is no share of cost for members in Medi-Cal managed care plans, we request the following revision:</p> <p>E. "Drug Tier" is a group of prescription drugs that corresponds to a specified cost sharing <u>tier or basis of coverage</u> in the health plans' prescription drug coverage. The tier in which a prescription drug is placed determines the enrollee's <del>portion of the cost</del> <u>coverage and contribution</u> for the drug.</p>	<p>DECLINED. The Department believes the phrases "basis of coverage" and "coverage and contribution" may lead to potential consumer confusion regarding the meanings of the terms. A large goal of SB 1052 is to create a user-friendly health plan formulary for enrollees. Under subdivision (d)(6) of the template formulary, it is noted that health plans must provide a description of the drug tiers in the formulary but only <u>if the drugs are grouped into tiers.</u> (Emphasis added.) If the formulary is not grouped into tiers, then this information is not required under the terms of the regulation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
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1-20	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	c. In subdivision (d)(2)(G), we request removal of the term "nonformulary."	ACCEPTED. The Department has made the proposed amendment to the regulation.
1-21	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>d. We reiterate our comment above regarding the use of the phrase "preferred for use" (see section I.b., <i>supra.</i>) and recommend replacing the proposed definition of the term "formulary" in (d)(2)(I) with the following:</p> <p>"Formulary" is the complete list of drugs preferred and non-preferred for use and covered under a health plan policy. Formulary is also known as a drug list.</p>	DECLINED. The Department defined the term "formulary" consistently with SB 1052. (See Health and Safety Code section 1367.205(c)). The revised definition suggested by the commenter is inconsistent with the definition in the statute and would cause more confusion in its interpretation.

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1-22	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>e. In subdivision (d)(2)(J), we recommend eliminating the requirement that a generic drug be listed in bold letters. Current industry practice is to use italicized lowercase letters – that practice is also reflected in the SB 1052 regulations adopted by the CDI.<sup>5</sup></p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>5</sup> See 10 Cal. Code Regs. § 2218.82 (c)(1)(I), (c)(4)(A), (d)(4).</p>	<p>DECLINED. The Department believes the requirement that the generic name of the drug be bolded allows the generic names to be clearly distinguished from the brand names. One of the formulary improvements recommended for consumers by the California HealthCare Foundation (CHCF) was clearly differentiating between branded drugs and generic drugs. This recommendation meets the consumer friendly purpose of SB 1052 and the standard formulary prescription drug benefit template.</p>
1-23	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>f. We recommend replacing that definition of “nonformulary drug” in (d)(2)(K) with the following:</p> <p>“Nonformulary drug” is a drug that is not listed on the formulary.</p>	<p>DECLINED. The Department's definition of “nonformulary” is similar to the recommended change. As written, the definition is clear in its meaning. The Department's definition is consistent with existing law in the Knox-Keene Act, including sections 1367.205, 1367.24 and title 28, California Code of Regulations, section 1300.67.24.</p>

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**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-24	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>g. The definition of "prior authorization" in subdivision (d)(2)(P) may be misleading because some plans require prior authorization even if a drug is on the formulary. The definition for "prior authorization" adopted by the CDI under SB 1052 is more accurate and reader-friendly, so we request use of that definition here.</p> <p>Alternatively, we request the following edit:</p> <p>"Prior Authorization" is when an enrollee's provider must obtain authorization from the health plan prior to prescribing a medically necessary <del>nonformulary prescription</del> drug. The health plan must grant a prior authorization when it is medically necessary for the enrollee to obtain the drug.</p>	ACCEPTED. The Department has made the proposed amendment to the regulation.
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-25	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>h. We recommend shortening the definition of "step therapy" in subdivision (d)(2)(Q) and referring to "treatments" in place of "prescription drugs." In addition, we recommend eliminating the reference to Rule 1300.67.241(f)(2) – this reference does not provide meaningful information to consumers.</p> <p>In sum, we recommend the following edits to this definition:</p> <p><u>"Step therapy" is a process specifying the sequence in which different <del>prescription drugs</del> treatments for a given medical condition <del>and must be tried and failed prior to the requested treatment being deemed</del> medically appropriate for a particular patient <del>are prescribed. The health plan may require the enrollee to first try one or more drugs to treat the enrollee's medical condition before the health plan will cover a particular drug for the condition pursuant to a step therapy request.</del> If the enrollee's prescribing provider submits a request for step therapy exception, the health plans shall make exceptions to step therapy when <u>the certain criteria is are met under Rule 1300.67.241(f)(2).</u></u></p>	<p>PARTIALLY ACCEPTED. The Department has struck out "nonformulary" from the definition as suggested.</p> <p>PARTIALLY DECLINED. The Department obtained the definition of "step therapy" from the Centers of Medicare and Medicaid Services and revised the definition following several informal stakeholder meetings. The use of the term "treatment" is not necessarily and is not consistent with the statute and its meaning could be unclear. Moreover, the use of the term "failed" is also unclear in the recommended language and could be a violation of the Knox-Keene Act if it is erroneously construed to meet requirements under Health and Safety Code section 1367.241 or title 28, section 1300.67.241.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-26	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>i. Proposed subdivision (d)(3) requires plans to request review and approval from the Department for all additional or different terms used in the formulary. The process and timeline for requesting that review and approval is needed but not stated. We also question whether this review and approval is truly necessary or helpful. In that regard, there are likely terms that plans use and should have the ability to define, such as "medically necessary" or "biologics." Thus, we request that the Department reconsider requiring review and approval for all additional or different terms.</p>	<p>ACCEPTED. The Department will review and approve the formulary pursuant to Health and Safety Code section 1352 and title 28, section 1300.52 and has amended this subdivision to indicate this change. This amended provision requires a health plan to file any change in the information contained in the health plan application within 30 days after the change in information occurs. This type of filing is a normal and routine action done by health plans pursuant to their license under the Knox-Keene Act.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

<p>1-27</p>	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>j. We have several concerns with respect to the requirements in subdivision (d)(5). First, these requirements will produce a 600-700 page document that will be unusable by consumers. Second, the requirements in clauses (ii), (iii) and (iv) will impose costly burdens on plans, requiring expensive IT changes to ensure information is added to existing systems that is not currently standard practice. This will be very complicated from a coding standpoint and it is unclear if or how this can be automated. Furthermore, there are thousands of names of drugs and preferred products can change over time. For example, a generic birth control medication can have 10 proprietary changes in a relatively short period of time. Third, the bolding requirement in clauses (ii) and (iv) is inconsistent with industry practice. Fourth, these requirements are inconsistent with the Medicare formulary format, which is an approved and accepted standard format for the formulary.</p> <p>We think that subdivision (d)(5) should be revised to address those concerns and recommend the following edits in particular:</p> <p>i. With respect to clause (ii), we recommend elimination of the requirement to add in the generic name next to a brand only drug. Most readers will not know a generic drug name unless the generic drug is available on the market as standalone, which would then be listed in its own row if on the formulary.</p> <p>ii. Elimination of clause (iv).</p> <p>iii. Elimination of all bolding requirements.</p> <p>iv. Revision of these provisions to mirror that required for the Medicare formulary.</p>	<p>DECLINED. One of the goals of SB 1052 is to make the prescription drug formulary accessible to consumers. The requirement that the generic name be listed next to the brand name is to assist consumers in identifying generic drugs, when available, and the difference in cost sharing between generic and brand name drugs. See Health and Safety Code section 1367.205, subdivisions (b)(1)(A) and (b)(1)(E). This is also true for clause (iv) which requires the brand name to be listed in all CAPITAL letters after the generic name if the generic is marketed under a proprietary and trademark protected brand name.</p> <p>Please also see the response to comment #1-22.</p>
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**Standard Prescription Drug Formulary Template (2017-5229)**  
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**Comment Period #1, September 28, 2018 – November 13, 2018**

1-28	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>k. Subdivision (d)(6)(ii) requires the informational section to include a description of how to determine the cost sharing for each drug tier. Because the purpose of SB 1052 is the creation of a standard formulary document, not a cost sharing document, we recommend eliminating clause (ii) or making that information optional. In that regard, we also point out that Medicare formularies do not list cost sharing information; instead, the member is referred back to their EOC or summary of benefits. Furthermore, while cost sharing is dictated in Covered California plans, it is discretionary for large group plans.</p>	<p>DECLINED. If feasible, Health and Safety Code section 1367.205 requires the Department to include cost sharing information for drugs in the formulary template. The statute also requires the formulary to include information on cost sharing tiers for each drug covered. (See Health and Safety Code section 1367.205(b)(2)(A).) Additionally, subdivision (d)(6) of the formulary notes that drug tier information is only needed if the drugs are grouped into tiers. Therefore, types of products, such as the Covered California large group product, that do not utilize cost tiers, do not have to list this information.</p>
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**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-29	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>I. We request that the Department clarify its expectation regarding the requirement in subdivision (d)(8). Is the intent to explain to the consumer that some medications will be provided under their medical benefit and would be rendered in a facility setting? Or is the intent to identify if any of the medications on the drug template could also be provided in a facility setting when appropriate or medically necessary?</p>	<p>DECLINED. Health and Safety Code section 1367.205 requires the formulary template include information educating consumers about the differences between drugs administered or provided under a health plan's medical benefit and drugs prescribed under a health plan's prescription drug benefit. The statute also requires enrollee information on obtaining drugs not covered under the health plan's drug benefit. Based upon these statutory requirements, whether a drug must be included in a health plan formulary per the template requirements, is established by the benefit under which a drug is covered, i.e., medical benefit, prescription drug benefit, or both benefits, rather than the location in which the drug is administered.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-30	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>m. We also request that the Department clarify its expectations regarding subdivision (d)(9). Specifically, the regulations do not indicate how plans need to identify or capture changes on a month-to-month basis. For example, is this indicating that plans have to flag all changes besides adding the changes on a monthly basis? If so, what would that flag consist of – having the changes on a separate page of the template? A new denotation in the key?</p> <p>In addition, we note that subdivision (d)(9) suggests that plans need to provide monthly updates on changes in drug or dosage forms. This requirement is extremely burdensome on plans and is in excess of the requirements imposed by the SB 1052. Thus, we specifically request elimination of clause (i) of subdivision (a)(9).</p>	<p>DECLINED. Subdivision (d)(9) of the formulary requires health plans to provide a notice that the health plans will update the formulary on a monthly basis as required under Health and Safety Code section 1367.205. Subdivision (d)(9) of the formulary also notes that the notice shall include a description of the types of formulary changes. However, in providing flexibility, the Department did not specify how the health plans need to identify or capture these changes. The Department believes this will give the consumers necessary benefit information while providing health plans some flexibility in making the monthly updates.</p>
1-31	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>V. Categorical List of Prescription Drugs (Subdivision (e))</b></p> <p>a. With respect to listing brand names, we request that the Department allow each health plan to list brand names in a format that their systems can support due to system limitations as long as they have a key. Not making that allowance will cost the plans capital and add unnecessary burdens solely for the purpose of conforming to a template style.</p>	<p>DECLINED. One of the goals of SB 1052 is to make formularies more accessible and easier to compare. A study by the CHCF determined that differentiating generic and brand name drugs by font is an easy way to make the formularies more accessible to consumers, which is the goal of SB 1052. Furthermore, Health and Safety Code section 1367.205 also requires the formulary to include information on which medications are covered including both generic and brand name as well as include information on what tier of the health plan's drug formulary each medication is located.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-32	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. The requirements of subdivision (e)(1) are very burdensome for plans and would produce a document that is complicated for consumers. There are some drugs that would need to be listed in numerous classes. We recommend revision of this requirement to mirror Medicare requirements and require identification only of the class that is most commonly used.</p>	<p>DECLINED. Following multiple stakeholder meetings, the Department drafted subdivision (e)(1) of the formulary to allow health plans to organize the drug category and class on a <b>commonly used and widely accepted drug classification system</b> such as the most current version of the U.S. Pharmacopeial Convention (USP) Medicare Model Guidelines or the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification. The Department determined this takes into account the requirement of providing consumers with a formulary that is helpful and clear as well as providing health plans with necessary flexibility.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-33	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>c. In subdivision (e)(1) and (2), the meaning of the phrase "plain language description" is not clear. Plans are not sure what such a description would need to look like. Furthermore, in our view, mandating this language is in excess of the statutory requirements.</p>	<p>DECLINED. The term "plain language" description is a term of art and merely means that the health plans should try to use the simplest language possible when describing prescription drug benefits. The Department is not mandating that health plans provide a "plain language" description in all circumstances. The comment is confusing because as stated above, the term "plain language" is a word of art and used elsewhere in the Knox-Keene Act with no confusion regarding the meaning of the term previously noted from health plans. See Health and Safety Code sections 1385.07 and 1399.829.</p>
1-34	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>b. We request the following edits to subdivision (e)(4):</p> <p>In the "Prescription Drug Name" column, the proprietary name for a brand name drug shall appear in all CAPITAL letters. The established <u>generic</u> name for the brand name drug shall be placed in parentheses after the brand name in all <b><i>bold and italicized lowercase</i></b> letters. The established name for a generic drug shall appear in all <b><i>bold and italicized lowercase</i></b> letters. <del>If a generic drug is sold under a brand name, the brand name shall be placed in parentheses after the established name in regular typeface with the first letter of each word capitalized.</del></p>	<p>DECLINED. The Department determined that having both generic and brand name will be beneficial to the consumers and makes the formulary more accessible and understandable to enrollees. This is consistent with the findings of the CHCF that providing a distinct font to differentiate between generic and brand name drugs are greatly beneficial to the consumers in understanding their pharmacy benefits.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-35	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>c. The first sentence of subdivision (e)(5) requires that the "Prescription Drug Name" column include all covered dosage forms and strengths for each prescription drug. Listing all covered dosage forms and strengths with no limits as proposed will add many pages and thereby produce an unwieldy document for consumers. As stated previously, this document should be consumer friendly and look similar to the Medicare formulary. The Medicare formulary includes additional dosage forms and strengths if there are differences in the items listed in the second sentence of proposed subdivision (e)(5). Accordingly, we request the following revisions to subdivision (e)(5):</p> <p>The "Prescription Drug Name" column shall include all covered dosage forms and strengths for each prescription drug. <del>If, if</del> there are differences in tier placement, quantity limit, prior authorization, step therapy, or other utilization restrictions or plan benefit offerings for a prescription drug based on its differing dosage forms or strengths, <del>the</del>. <u>The</u> categorical list of prescription drugs shall include separate rows for the dosage forms and/or strengths of the prescription drug to clearly identify the differences.</p>	<p>DECLINED. The Department determined that dosage forms and strengths of prescription drugs are important for consumers in understanding their prescription drug benefits. Often dosage and strengths influence an enrollee's access to the prescription drug. The dosage of the drug may also influence the tiering of prescription drugs and the enrollee must understand this fact when reviewing his or her formulary. Information that impacts utilization controls and tiering is required to be included in the formulary template under Health and Safety Code section 1367.205(b)(2)(A).</p>
1-36	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>d. We recommend revision of subdivision (e)(6) to include an exception for plans that only manage Medi-Cal patients. For managed care plans that are strictly Managed Medi-Cal only, a drug tier that includes cost sharing does not apply.</p>	<p>ACCEPTED. The Department has made the proposed amendments to the regulation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-37	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>e. In subdivision (e)(7), we request that the Department confirm that plans can keep their formatting based on their system limitations in order to accomplish the requirements of this paragraph. Currently, some plans have headers in their template and indicate via an X if the drug is subject to step therapy, prior authorization, or quantity limit. Requiring plans to change format based on their system limitations presents an unnecessary burden and will require additional capital and resources to make the required changes.</p> <p>We also request that the requirement in the last sentence of subdivision (e)(7) be eliminated or made optional.</p>	<p>DECLINED. One of the goals of SB 1052 is to create a template that is uniform and easily comparable between different health plans. The Department is balancing the need of the health plans along with the need of the consumers in setting forth the format of the prescription drug formulary as required under SB 1052. Further, the Department worked extensively with the CDI to ensure that the formulary templates required under SB 1052 are as streamlined and consistent as the law allows placing as little of a financial burden on the health plans as possible.</p>
1-38	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p>f. Subdivision (e)(8) requires that the annotated legend or key to all abbreviations, symbols and notations used in the formulary appear on each page of the categorical list. Capturing such a legend on every page may not fit within the system limitations of the plan and will be costly to implement. Thus, we request that this requirement be eliminated or made optional.</p> <p>If the requirement is not eliminated or made optional, we request that the Department clarify that plans need not go down to the detail of defining terms like "tab," "cap," "mg," etc. We also request that the Department confirm that plans do not need to provide a key if an abbreviation is already defined within the forward language.</p>	<p>DECLINED. The CHCF study has determined that one of the basic methods to help consumers navigate and understand drug formularies is to provide a key or legend on each page that explains the abbreviations and symbols used in the formularies. To meet the consumer friendly goal of SB 1052, the Department has required this information be contained in the health plan formulary.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-39	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>VI. Index (Subdivision (f))</b></p> <p>The proposed regulations require that the formulary include an index of prescription drugs. As stated previously, we request that the index be made optional. Many plans do not currently include an index in their formularies and question whether this can be added based on system limitations with how the document is developed.</p>	<p>DECLINED. One of the goals of SB 1052 is to make the formulary more accessible and understandable for consumers. The Department determined an alphabetical index allows a consumer to locate a particular drug or section of the formulary if helpful and necessary and meets the purpose of SB 1052. Further, the Department worked extensively with the CDI to ensure that the formulary templates required under SB 1052, including the index requirement, are as streamlined and consistent as the law allows placing as little of a financial burden on the health plans as possible.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

1-40	<p>Stephanie L. Shirkey, California Association of Health Plans (CAHP)</p> <p>Sunshine Moore, America's Health Insurance Plans (AHIP)</p>	<p><b>VII. Summary</b></p> <p>CAHP, AHIP, and our member plans appreciate the opportunity to provide these comments. Overall, we are concerned that the proposed rulemaking would result in a lengthy and overly complicated document that defeats the purpose of the law it intends to implement. We also think that the rulemaking needs some revision for accuracy, clarity, and implementation feasibility and would benefit from modification to mirror Medicare requirements. We look forward to working with you to improve the rulemaking to achieve those purposes.</p>	<p>No specific change requested. Thank you for your comment.</p> <p>It should be noted that SB 1052 specifically states, "In developing the template, the department and Department of Insurance shall take into consideration existing requirement for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services." (Health &amp; Saf. Code §1367.205.) The Department has taken into consideration the existing Medicare formulary. In fact, the Department utilized the Centers of Medicare and Medicaid Services' "2017 Part D Model Formulary (Abridged and Comprehensive)" as the foundation for the proposed formulary template as requested under the statute.</p> <p>Further, the Department worked extensively with the CDI to ensure that the formulary templates required under SB 1052 are as streamlined and consistent as the law allows placing as little of a financial burden on the health plans as possible.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-41	Anthony Wright, Health Access California	<p>Health Access California, the statewide health care consumer advocacy coalition working for affordable and quality health care for all Californians, offers comments on the departments rulemaking action on the subject of the Standard Prescription Drug Formulary Template, Control No. 2017-5229.</p> <p>Health Access supports the overall design of the Standard Prescription Drug Formulary Template, and would like to note areas where the regulations could be clarified to better inform consumers of their rights to prescription drug coverage.</p> <p>Several of our comments relate to the newly enacted SB1021 (Wiener, Chapter 787, Statutes of 2018). We recognize that the proposed regulations were issued almost concurrent with the Governor’s signature of that measure and that the law does not take effect until January 1, 2019. Since the Governor has now signed SB1021 and since it will be in effect at the time these regulations take effect, we suggest a number of changes to conform the proposed regulations to the newly enacted law.</p>	<p>No specific change requested. Thank you for your comment.</p> <p>It should be noted that SB 1052 specifically states, “In developing the template, the department and Department of Insurance shall take into consideration existing requirement for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services.” (Health and Safety Code section 1367.205.) The Department has taken into consideration the existing Medicare formulary. In fact, the Department utilized the Centers of Medicare and Medicaid Services’ “2017 Part D Model Formulary (Abridged and Comprehensive)” as the foundation for the proposed formulary template as requested under the statute. Moreover, the Department has also considered and revised the existing formulary based on the comments received during the first comment period as well as the stakeholder meetings held prior to the finalization of the proposed template formulary.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-42	Anthony Wright, Health Access California	<p><b><u>Comments on Proposed Regulations</u></b></p> <p><b>Include Updates on Consumers’ Cost-Sharing in Informational Section of Formulary</b></p> <p>As part of the Standard Prescription Drug Formulary Template, SB 1052 (Torres, Chapters 575, Statutes of 2014) requires that DMHC and the Department of Insurance “evaluate a way to include on the template...cost-sharing information for drugs subject to coinsurance.”<sup>1</sup> We recommend that the Department also include in the formulary a description of the limit on cost-sharing for prescription drugs as required by Section 1342.73 of Health and Safety Code and Section 10123.1932 of the Insurance Code and SB 1021, which provides that consumers’ co-pays continue be capped at \$250 for a 30-day supply of a prescription drug. This addition would also be consistent with the department’s description included in the template formulary of the limit on cost sharing for orally administered anti-cancer drugs as required by Section 1367.656 of the Health and Safety Code.</p> <hr style="width: 20%; margin-left: 0;"/> <p><sup>1</sup> SB 1052 (Chapter 575 of 2014).</p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p> <p>The Department’s provisions in the formulary regarding cost sharing were designed to capture the requirements set forth in Health and Safety Code section 1342.71(f). However, Senate Bill 1021 removed the sunset date and created a new section of the requirements previously set forth in this section. The newly created Health and Safety Code section 1342.73 was effective January 1, 2019. The Department’s formulary implements the requirements.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-43	Anthony Wright, Health Access California	<p><b>Align Drug Tiering Definitions with Existing Law</b></p> <p>AB 339 (Gordon, Chapter 619, Statutes of 2015) prohibited health plans from placing most or all of the drugs to treat a particular condition on the highest cost tier of a formulary, preventing discrimination based on a health condition. For example, before AB 339, Kaiser had placed all the drugs to treat HIV/AIDS on the highest tier of the formulary, reducing compliance with the AIDS drug treatment regimen, putting at risk not only the health of individual consumers but also the health of the community. We thank you for ensuring consistency with this provision in H&amp;S Code Section 1342.71. However, SB 1021 clarified this provision to also prohibit health plans offered to individuals and small employers from having drug formularies with more than four tiers.</p> <p>We recommend that the description of the drug tiers in the formulary on page 6 of the draft template standard formulary, be amended as reflected below to align with existing set standards for tiers in drug formularies as required by Section 1342.71 as well as Section 1342.73 of Health and Safety Code, and which also reflects the clarification to be enacted by SB 1021 on January 1, 2019.</p> <p><u>(6) A description of the drug tiers in the formulary, if the drugs are grouped into tiers. The description shall include tier numbers designating the tiers and shall accurately describe the types of prescription drugs that are placed in each tier. The same description shall be used in the corresponding coverage documents. The description shall explain how to determine the following: (i) which prescription drugs on the formulary are</u></p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p> <p>The Department's provisions in the formulary regarding cost sharing were designed to capture the requirements set forth in Health and Safety Code section 1342.71(f). However, Senate Bill 1021 removed the sunset date and created a new section of the requirements previously set forth in this section. The newly created Health and Safety Code section 1342.73 was effective January 1, 2019. The Department's formulary implements the requirements.</p>
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

		<p><u>preferred drugs; and (ii) the cost sharing for each drug tier, including any applicable dollar maximum amounts for products subject to section 1342.71 and section 1342.73 of the Health and Safety Code. If the formulary has four tiers and is subject to section 1342.71 and section 1342.73 of the Health and Safety Code, drugs shall be placed in tiers consistent with the drug tier definitions in that subdivision.</u></p>	
2-44	Anthony Wright, Health Access California	<p><b>Clarify the Definition of “Formulary” to include Medically Necessary Drugs</b></p> <p>Under Section 2 of the informational section of the template formulary, the definition of “formulary” must be clarified to reflect existing law under statute. H&amp;S Code 1342.71 (c) provides that a health care service plan will cover all medically necessary prescription drugs, including nonformulary drugs. Additionally, Section 1367.205 (b) (2) (D) also requires that the template educate enrollees on how to obtain prescription drugs not listed in the health plan’s drug formulary that are deemed medically necessary by their clinician. To help clarify this in the formulary for consumers, we recommend that the definition of “formulary” be amended as follows:</p> <p><u>(l) “Formulary” is the complete list of drugs preferred for use and eligible for coverage under a health plan policy, and includes drugs covered under the prescription drug benefit of the health plan policy, including medically necessary drugs. Formulary is also known as a prescription drug list.</u></p>	DECLINED. The Department has defined “formulary” as set forth in Health and Safety Code section 1367.205(c) for consistency.

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-45	Anthony Wright, Health Access California	<p><b>Include Notice of Consumer’s Rights to Lowest Cost Alternative in Informational Section</b></p> <p>SB 1021 (Chapter 787 of 2018) also codifies a DMHC regulation which additionally caps drug co-pays at the retail price, if the retail price is lower than the co-pay amount. It also extends these protections to Insurance Code products as well as ensuring that the amount paid by the consumer applies toward the consumer’s deductible, if any, and maximum out-of-pocket limit. This is also required by Section 1367.47 of Health and Safety Code, Section 4079 of Business and Professions Code, and Section 10123.65 of the Insurance Code through AB 2863 (Nazarian, Chapter 770 of 2018). This law also helps ensure consumers pay the lowest price for a covered prescription drug by requiring pharmacies to inform consumers at the point of sale if the retail price is lower than their copayment for their prescription. AB 2863 also provided that whichever price the consumer pays, what the consumer pays counts toward the deductible, if any, and the maximum out-of-pocket annual limit.</p> <p>Consumers should be informed about these new rights when reading their formulary’s informational section to help ensure they pay the lowest available cost-sharing, and to help them understand that their co-payment will contribute towards meeting their annual maximum out-of-pocket limit. The formulary already includes other important notices in the informational section, such as the definitions of “out-of-pocket cost” on page 5, and should include updated information on co-payments as part of the information consumers receive regarding the out-of-pocket costs associated with acquiring their prescription drugs.</p>	DECLINED. The Department understands the concerns; however, the Department determined that providing this information will not necessarily add to consumers’ understanding of the formulary and would add burdensome requirements to the health plans. Health and Safety Code section 1367.47 provides the maximum a health plan may require an enrollee to pay is the lesser of the applicable cost sharing amount and the retail price. This information is not required in the formulary under Health and Safety Code section 1367.205 and would be duplicative.
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**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-46	Anthony Wright, Health Access California	<p><b>Include Information on Prescription Drugs Administered/Provided Under the Medical Benefit</b></p> <p>SB 1052 was also clear in that enrollees must be educated about the difference between drugs administered or provided under a health care service plan's medical benefit and drugs prescribed under a health care service plan's prescription drug benefit and must also educate enrollees about how to obtain coverage information about drugs that are not covered under the plan's prescription drug benefit. We ask the DMHC to please also include this information, as required by Health and Safety Code Section 1367.205 (b) (2) (C), as part of informational section of the template formulary.</p>	<p>DECILNED. The Department has included subdivision (d)(8) of the formulary as required by Health and Safety Code section 1367.205(b)(2)(C). As noted by the commenter, this provision requires enrollee education about drugs covered under a health plan's prescription drug benefit and drugs covered under a health plan's medical benefit.</p>
2-47	Anthony Wright, Health Access California	<p><b>Additional Comments:</b></p> <ul style="list-style-type: none"> <li>• <b>Clarify Health Plans Requirements on Enrollee Customer Service</b></li> </ul> <p>We also ask that the informational section which as currently written requires that plans provide customer service during "normal business hours," be clarified to be consistent with H&amp;S Code 1368, which allows grievances to be received "by telephone, by facsimile, by email, or online through the plan's Internet Web site," which may be submitted by an enrollee outside of "normal business hours" and we ask that the formulary remain consistent with what the Knox Keene Act requires of health plan grievance systems under H&amp;S Code 1368 (a)(4)(B)(i).</p>	<p>ACCEPTED. The Department has made the proposed amendment to the regulation.</p>

**DEPARTMENT OF MANAGED HEALTH CARE**  
**Standard Prescription Drug Formulary Template (2017-5229)**  
**Responses to Comments for**  
**Comment Period #1, September 28, 2018 – November 13, 2018**

2-48	Anthony Wright, Health Access California	<p>• <b>Help Consumers Understand Descriptions of Prescription Drugs</b></p> <p>We ask that the department include a key that explains what the different type faces indicate (e.g. <i>all bold and italicized lowercase</i> letters refer to the generic name of the brand name drug). These keys should apply for the description of listed drugs on page 6-7, and the “prescription drug name” information on pages 9-10 of the template formulary.</p>	DECLINED. Information regarding the typeface and font is already included as part of the annotated legend or key to all abbreviations, symbols and notations. Font and typeface are considered a type of notation and therefore the Department determined it is not necessary to separate them out from the existing requirement in the regulation.
2-49	Anthony Wright, Health Access California	<p>Health Access California appreciates the DMHC’s continued work in protecting consumers’ access to prescription drugs. We respectfully request that you modify the proposed regulations to reflect existing law and consumer protections enacted after 2014. Health Access California respectfully requests that the DMHC consider these comments.</p> <p>Thank you for your consideration.</p>	<p>No specific change requested.</p> <p>The Department has noted updates to the law as required under the Knox-Keene Act and SB 1052. Thank you for your comment.</p>