STATE OF CALIFORNIA
DEPARTMENT OF MANAGED HEALTH CARE
TITLE 28, CALIFORNIA CODE OF REGULATIONS
SECTION 1300.67.005

INITIAL STATEMENT OF REASONS

ESSENTIAL HEALTH BENEFITS

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 California Code of Regulations, Title 28, section 1300.67.005 (hereinafter "Rule 1300.67.005"), as amended by the emergency regulatory action approved on November 28, 2016 (see OAL File Number: 2016-1117-01-E). The Department proposes to permanently adopt the emergency regulations, without change. The Department is also hereby incorporating by reference, the above mentioned emergency regulatory filing.

I. AUTHORITY

California Health and Safety Code section 1341, subdivision (a), authorizes the Department to regulate "health care service plans." Health and Safety Code Section 1345, subdivision (f)(1), defines a "health care service plan" as "any person who undertakes to arrange for the provision of health care subscribers or enrollees, or to pay for or to reimburse any part of the cost of those services in return for a prepaid or periodic charge paid by or on behalf of subscribers or enrollees."

Health and Safety Code section 1344 grants the Director 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).

Federal law, under the Patient Protection and Affordable Care Act (ACA), requires the Secretary of the Department of Health and Human Services (DHHS) to define "essential health benefits" (EHB), which are a minimum standard for health benefit coverage required under ACA sections 1301 and 1302 (42 USC §§ 18021 and 18022), as well as Public Health Service Act (PHSA) section 2707 (42 USC § 300gg-6). In December of 2011, the DHHS issued guidance for state implementation of EHB. The guidance authorized each state to select a base-benchmark plan from a list of options to establish EHB particular to that state. This guidance was codified at 45 Code of Federal Regulations (CFR) parts 156.100, et seq. (78 Fed. Reg. 12834, 12866).

Pursuant to those federal guidelines, the California legislature enacted Assembly Bill (AB) 1453, adopting Health and Safety Code section 1367.005 (Section 1367.005 of the Act), in September of 2012. Section 1367.005 of the Act established the California EHB

benchmark plan by selecting the Kaiser Small Group HMO 30 plan (Kaiser plan or base-benchmark plan) as that plan was offered during the first quarter of 2012. Section 1367.005 of the Act also designates state benefit mandates enacted prior to December 31, 2011, and "other health benefits," which are services and devices not required under state law but nonetheless covered by the base-benchmark plan in the first quarter of 2012, as required EHB. Section 1367.005 of the Knox-Keene Act also supplements the base-benchmark plan by establishing requirements for pediatric dental and vision benefits and coverage of habilitative and mental health services.

More recently, in 2015, DHHS directed states to select a new base-benchmark plan from options offered during the first quarter of 2014, and to supplement that base-benchmark as necessary to achieve coverage in all ten broad, federally-defined benefit categories (such as pediatric oral and vision care). (80 Fed. Reg. 10813, February 27, 2015). Accordingly, the California Legislature enacted Senate Bill 43 (SB 43) in order to define the new base-benchmark plan as the Kaiser Small Group HMO 30, as that plan was offered during the first quarter of 2014, and to update the EHB standards for rehabilitative/habilitative health care services and devices, pediatric benefits, and other EHB standards in accordance with the federal law and guidance.

Health and Safety Code section 1367.005 grants the Director the authority to adopt and readopt emergency regulations, followed by final regulations.

II. SPECIFIC PROBLEMS ADDRESSED AND NECESSITY OF REGULATION

The amendments to Rule 1300.67.005, which the Department now proposes to make permanent without change, are necessary to interpret, implement and make specific the requirements for health plan coverage of EHB under Health and Safety Code section 1367.005, as amended by SB 43.

By enacting SB 43, California chose a new base-benchmark plan, thereby updating California's EHB. Specifically, California chose as its new base-benchmark plan the Kaiser Foundation Health Plan Small Group HMO 30 plan, as this plan was offered during the first quarter of 2014. SB 43 similarly updated the pediatric oral and vision benefits that supplement the base-benchmark plan and constitute the EHB standard for the pediatric oral and vision care benefit categories. Finally, SB 43 implemented certain federal rules and guidance regarding EHB requirements for habilitative services, nondiscrimination, and pediatric services. The benchmark plan, as supplemented, generally defines the scope of EHB within a state.

While Section 1367.005 of the Knox-Keene Act identifies California's new base-benchmark plan, the statute does not specify benefits contained in each of the broad categories listed in subsection (a), especially "other health benefits" identified in subsection (a)(2)(A)(v). Accordingly, it is necessary to update Rule 1300.67.005 to remove inconsistencies between the rule and the statute created by SB 43's amendments, and to implement SB 43 by specifying any "other health benefits" that are not otherwise required to be covered under the Knox-Keene Health Care Service Plan Act of 1975 (Health and Safety Code § 1340, et seq., hereinafter "the Act").

To clarify and implement the updated benchmark standard, the Department compared the original benchmark plan to the updated, 2014 benchmark plan, as it was offered in the first quarter of 2014, and amended Rule 1300.67.005 for consistency with SB 43's updated EHB standard and federal guidance regarding provision of EHB.

The proposed regulation is necessary to ensure health plans offer consistent benefits among health plan contracts and products, as well as to provide transparency to the public regarding the benefits that must be covered, and to implement the updated EHB standard in a manner that allows the Department to efficiently determine compliance. The amendments that the DMHC now proposes to adopt as final are identical to those approved as emergency regulations on November 28, 2016.

Specific Problems Addressed, and Necessity of Regulations

The amendment to subdivision (b) of Rule 1300.67.005 addresses the problem that the previous version of the Rule contained an obsolete compliance filing deadline of "July 15, 2013," which has passed. The Rule is amended to update the deadline for filing the EHB Filing Worksheet. This implements the statute by establishing an appropriate deadline for the filings demonstrating compliance with the updated EHB standards. It is necessary to schedule the EHB compliance filing so that it will not interfere with the Department's review of Qualified Health Plan (QHP) filings, for sale on the California health benefits exchange (also called "Covered California").

The amendment to subdivision (c)(2) of Rule 1300.67.005 addresses the problem that the old Rule was inconsistent with the statute, as amended by SB 43, because the old Rule referenced the old base-benchmark plan (the Kaiser Small Group HMO 30 as it was offered during the first quarter of 2012). It is necessary to update the reference to California's base-benchmark plan, as defined in section 1367.005 of the Act. This change implements existing law.

The amendment to subdivision (c)(3) of Rule 1300.67.005 addresses the problem that it was previously ambiguous as to exactly when a health plan enrollee "ages out" of pediatric benefits. This amendment is necessary to clarify the date on which an enrollee ages out of pediatric oral and vision benefits, consistent with related federal law regarding pediatric EHB (45 CFR section 156.115(a)(6)).

The amendment to subdivision (d)(4)(B) of Rule 1300.67.005 addresses the problem that a benchmark plan's *per se* age limit on aphakia contact lenses, without clinical justification, may run afoul of federal law and guidance regarding impermissible discrimination. It is necessary to strike this limit to ensure that plans to not employ such limits without appropriate justification. This has also been amended to relocate a comma, for greater clarity.

The amendment to subdivision (d)(10)(C)(ix) of Rule 1300.67.005 addresses the problem that the new base-benchmark plan restructured its Evidence of Coverage (the document that describes covered health benefits), creating disparity in the structure of the base-benchmark plan and the Rule. It is therefore necessary to amend the Rule to strike the description of "physical, occupational, and speech therapy" benefits from the Rule's subdivision regarding Skilled Nursing Facility care, and to move this benefit to the newly proposed subdivision regarding Habilitative and Rehabilitative services. This clarifying change reflects the structure of the new base-benchmark plan.

The purpose of the addition of subdivision (d)(12) of Rule 1300.67.005 is twofold: (1) it implements federal law specific to the benefit category of habilitative health care services, and (2) it implements, clarifies, and makes specific the coverage of rehabilitative and habilitative services and devices under the benchmark plan, consistent with federal and state law.

Initially, federal law did not define habilitative services, so California established its own definition in Health and Safety Code section 1367.005(p). Later, however, federal regulators finalized a federal definition that was broader than California's definition. California's previous (pre-SB 43) definition was narrower because it included devices and services necessary only to "partially or fully [acquire] or [improve] skills and functioning…" and it expressly excluded certain services from the definition. In contrast, the federal definition of habilitative services includes the additional concept of *keeping* skills and functioning, it does not contain express exclusions, and it adds specific examples of habilitative services. The federal regulation also specifies that on or after January 1, 2017, limits on habilitative and rehabilitative services shall not be combined [see 45 C.F.R. section 156.115(a)(5)]. Accordingly, SB 43 amended state law in order to align with the broader federal definition and incorporate the new prohibition on combined limits [see Health and Safety Code section 1367.005(a)(3) and (p)(1)].

One purpose of the addition of the proposed Rule's subdivision (d)(12), which specifies that "[c]overage shall be in accordance with subdivisions (a)(3) and (p)(1) of section 1367.005…" is to similarly implement the amended, broader definition of habilitative services and to implement the prohibition on combined limits, as required by the federal EHB regulation. The benefit of this addition is that health plans will comply with both state and federal law, and will indicate in the Rule's Filing Worksheet the specific locations within the health plan documents that demonstrate compliance with these standards, which will facilitate efficient compliance review by the Department. The proposed Rule's proposed (d)(12)(B), which requires health plans to include a disclaimer that the limits for rehabilitative and habilitative services shall not be combined, will also implement this standard and have the benefit of ensuring that consumers are aware of this protection. Finally, subdivision (d)(12)'s clear description of the rehabilitative and habilitative service coverage requirement will help ensure that consumers receive coverage in accordance with the newly-broadened standards.

In addition to the federal regulation's standards for the habilitative services EHB, discussed above, federal law more generally requires that nongrandfathered individual

and small group plans offer coverage in each of the EHB benefit categories in accordance with the state's benchmark plans [see 45 C.F.R. § 156.115(a)(1)]. California law echoes this requirement to offer coverage in accordance with the benchmark plan [see Health and Safety Code section 1367.005(a)(2)(A), especially subclause (v)].

Accordingly, the purpose of the addition of the proposed Rule's subdivision (d)(12)(A)((i)-(iii) is to specify the coverage of rehabilitative and habilitative services under the benchmark plan, as of the first quarter of 2014. This implements state and federal law, and has the benefit of ensuring that plans understand the required scope of coverage in this benefit category. The term "rehabilitative and habilitative health care services" is ambiguous and without this specification, could be subject to widely varying interpretations by health plans, leading to disparate coverage across California. Therefore, the benefits of proposed subdivision (d)(12)(A)(i)-(iii) include that California health plans will provide consistent baseline coverage for this EHB, consistent with the benchmark plan, as required by state and federal law. The addition of subdivision (d)(13) of Rule 1300.67.005 addresses the problem that the Rule did not include a clear description of the existing requirement for coverage in connection with a clinical trial, as reflected in the new base-benchmark plan. This addition is necessary to clarify the existing requirement for coverage in connection with a clinical trial, and to reflect the description of that coverage in the new base benchmark plan.

The amendments to subdivision (g) of Rule 1300.67.005 address the problem that the EHB Filing Worksheet did not include the changes in the new base-benchmark plan. It is necessary to amend the worksheet to align it with the amendments in the rest of the Rule, and with the updated benchmark standard. For greater clarity, subdivision (g) also has nonsubstantive amendments for consistent formatting.

The amendments to section #10 of subdivision (g) of Rule 1300.67.005 address the problem that the Rule referenced the old supplementary pediatric oral and vision services benefits, rather than the supplementary pediatric oral and vision care EHB defined under the Act as amended by SB 43. This amendment is therefore necessary to remove inconsistency with the statute, and to implement and clarify existing law by updating the references to the supplementary pediatric benefits. This subdivision further clarifies that, with regard to the pediatric oral EHB, the required coverage includes the Medi-Cal "Early Periodic Screening, Diagnosis, and Treatment" (EPSDT) benefit. The proposed language clarifies and implements the statutory requirement for the pediatric dental EHB to include "the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014 […]." Finally, this subdivision addresses the problem that some health plans have misunderstood whether the pediatric vision EHB includes low-vision benefits by providing necessary clarification on that point.

The amendments to subdivision (g) of Rule 1300.67.005, regarding the Prescription Drug Benefit chart, address the problem that the Rule is inconsistent with the updated benchmark plan drug count. The amendment is necessary to reflect the new base-benchmark plan's number of drugs in each drug category and class, as determined by

federal regulators.

III. SPECIFIC PURPOSE AND BENEFITS OF THE AMENDMENTS TO THE REGULATION

The purpose of the amendment to subdivision (b) of Rule 1300.67.005 is to update and implement the updated EHB requirement and clarify the process the Department will use to conduct its compliance review. The benefits of this amendment are that health plans will clearly understand the deadline to file compliance documents and that the Department will complete its compliance review in an efficient manner that does not interfere with Covered California activities.

The purpose of the amendment to subdivision (c)(2) of Rule 1300.67.005 is to implement SB 43 by referencing California's new base-benchmark plan. The benefit is that the regulation will be clear and consistent with the underlying statute.

The purpose of the amendment to subdivision (c)(3) of Rule 1300.67.005 is to clarify the specific end date for "pediatric" EHB benefits, relative to an enrollee's nineteenth birthday. The benefit of clarifying that pediatric oral and vision EHB benefits at the end of the month in which the enrollee turns 19 years of age is that it will ensure consistency with federal law and resolve ambiguity regarding when an enrollee ages out of pediatric EHB coverage.

The purpose of the amendment to subdivision (d)(4)(B) of Rule 1300.67.005 is to implement federal guidance regarding discriminatory benefit limits on EHB. An age limit on an EHB must be clinically justified to avoid violating state and federal anti-discrimination laws. The benefit of removing the *per se* limit on aphakia lens coverage is that it will ensure that if the plan imposes an age limit on this EHB, the limit is clinically justified, consistent with federal law and guidance. Additionally, relocating the comma will clarify the regulation.

The purpose of the amendment to subdivision (d)(10)(C)(ix) of Rule 1300.67.005, which relocates the reference to the physical, occupational, and speech therapy benefit, is to implement and clarify SB 43 by making the Rule reflect the structure of the new base-benchmark plan. The benefit of updating the structure of the Rule to reflect the new base-benchmark plan's description of "habilitative and rehabilitative services" is that it will provide greater clarity and implement the EHB requirement in accordance with the benchmark plan's coverage, as required by state and federal law.

The purpose of the addition of subdivision (d)(12) of Rule 1300.67.005 is to implement, clarify, and make specific the habilitative and rehabilitative services and devices EHB. The benefit of specifying that the coverage must be in accordance with the new base-benchmark plan is that health plans will provide consistent baseline coverage for this EHB. The benefit of specifying that the habilitative and rehabilitative services coverage must comport with the statutory definition, as amended by SB 43, specifying that limits

for habilitative and rehabilitative services shall not be combined, and specifying that the health plan must include related disclaimers in the plan documents, is that the Rule will ensure that plans give the Department the information necessary to determine compliance efficiently, using the EHB Filing Worksheet.

The purpose of the addition of subdivision (d)(13) of Rule 1300.67.005 is to clarify the existing requirement for coverage in connection with a clinical trial, and reflect the description of this benefit, as set forth in the new base-benchmark plan. The benefit is that the Rule will more clearly describe the required coverage of clinical trials, thus ensuring that health plans provide and health plan enrollees receive the required health coverage.

The purpose of the amendments to subdivision (g) of Rule 1300.67.005 is to clarify the Rule by ensuring that the Worksheet is consistently formatted, and ensuring that the Worksheet reflects the amendments to the rest of the Rule. The benefit is that these amendments will make the Worksheet more clear and user-friendly, and will help to ensure efficient review by the Department.

The purpose of the amendments to section #10 of subdivision (g) of Rule 1300.67.005 is to implement existing law by clarifying the benefits that supplement the base-benchmark plan and define California's pediatric oral and vision care EHB. The amendments to this subdivision also clarify that the pediatric vision EHB includes but is not limited to low-vision benefits, which has the benefit clarifying an issue that has been a point of confusion among some health plans. The amendments also clarify that, with regard to the pediatric oral EHB, the required coverage includes the Medi-Cal EPSDT benefit. This new language clarifies and implements the statutory requirement for the pediatric dental EHB to include "the same health benefits for pediatric oral care covered under the dental benefit received by children under the Medi-Cal program as of 2014 […],"[1] and has the benefit of clearly communicating the coverage requirement to health plans. The EPSDT benefit can result in coverage notwithstanding a benefit limit, such as a frequency limit, when the service is medically necessary for the child, so this clarification will result in the benefit of appropriate, medically necessary pediatric dental coverage, as required by SB 43.

The purpose of the amendments to subdivision (g) of Rule 1300.67.005, regarding the Prescription Drug Benefit chart, is to implement SB 43 by reflecting the new base-benchmark plan's drug count in each drug category and class, as determined by federal regulators. The benefit of these amendments is that they will ensure that health plans understand the required minimum EHB drug coverage, and that the Department's compliance review is efficient and based on the operative standard (i.e., base-benchmark plan as it was offered during the first quarter of 2014).

[1] Health & Saf. Code § 1367.005, subdivision (a)(5).

IV. DOCUMENTS RELIED UPON

- Health and Safety Code sections 1344, 1367.005;
- 28 CCR section 1300.67.005;
- 45 CFR sections 156.100, 115, 156.122, 156.125;
- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Proposed Rule;
- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule;
- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017- Final Rule;
- Kaiser Small Group HMO 30: Kaiser Permanente for Small Businesses Evidence of Coverage for Sample Group Agreement, EOC Number: 4 [2014];
- Kaiser Small Group HMO 30: Kaiser Permanente for Small Businesses Evidence of Coverage for Sample Group Agreement, EOC Number: 10 [2012];
- Kaiser California Soft Goods Formulary;
- Kaiser California Durable Medical Equipment Formulary;
- Kaiser Permanente Living Donor Guidelines – California Regions;
- Kaiser Foundation Health Plan – California, Utilization Management (UM) Criteria for Transgender Surgery;
- Health Family Program/CHIP Regulation Benefits vs. Medi-Cal Dental Services Scope of Benefits;
- BCBS Association 2014 FEP BlueVision- High Option;
- Medi-Cal Dental Program Provider Handbook;
- Centers for Medicare and Medicaid Services, Prescription Drug EHB-Benchmark Plan Benefits By Category And Class ([published under the "2017 EHB Benchmark Plan Information" link at https://www.cms.gov/cciio/resources/data-resources/ehb.html#California); and,
- The Department's Economic Impact Analysis (contained herein).

V. REASONABLE ALTERNATIVES TO THE REGULATION

The Department has determined that, due to the need for consistency between the existing EHB Rule and the underlying statute, and the need for consistent coverage of EHB by Department-regulated health plans, there are no reasonable alternatives to implement the specific benefits required under section 1367.005. Furthermore, Health and Safety Code section 1367.005 authorized the Department and the California Department of Insurance (CDI) to enact emergency regulations to implement EHBs, with an expectation that each agency would formalize those emergency regulations in accordance with the APA.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations and amendments at the above-mentioned hearing or during the written comment period. As part of this process, the Department must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, would be as

effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

VI. ECONOMIC IMPACT

The Department has determined that the regulation amendments will not have a statewide adverse economic impact directly affecting businesses because the amendments to the regulation are implementing current law, as revised by SB 43 and will benefit health plans, providers and consumers by making specific the requirements under State law. The California Legislature enacted SB 43 in order to define the new base-benchmark plan as the Kaiser Small Group HMO 30, as that plan was offered during the first quarter of 2014, and to update the EHB standards for rehabilitative/habilitative health care services and devices, pediatric benefits, and other EHB standards in accordance with the federal law and guidance. Pursuant to the legislation, plans shall update their EHB standards to meet the standards contained in the Kaiser Small Group HMO 30 as the plan was offered during the first quarter of 2014. This regulation clarifies what changes were contained in the Kaiser Small Group HMO 30 to assist health plans in meeting the statutory requirements and therefore will not negatively impact businesses including plans.

VII. ECONOMIC IMPACT ANALYSIS

Creation or Elimination of Jobs within California

The proposed adoption of the amendments to Rule 1300.67.005 interpret, implement, and make specific state law enacted by SB 43, which updated California's EHB standard. The EHB standard has been in effect since 2014, and SB 43 merely updated that EHB standard. The updates to California's EHB are not major and are required by law, and will not create or eliminate jobs within the State of California.

Creation of New Businesses or Elimination of Existing Businesses within the State of California

This proposed adoption of the amendments to Rule 1300.67.005 will neither create new businesses nor eliminate existing businesses. The EHB requirement has been in effect since 2014. The state was recently required by federal guidance and regulations under the ACA to select a new EHB base-benchmark package. The state complied with these requirements by enacting SB 43, which identified the new base-benchmark plan and supplementary benefits. These regulations specify benefits required by Section 1367.005 of the Act, and do not create any new requirements for businesses in California. Additionally, these regulations only apply to health plans licensed under the Act. Individual and small group health plans are subject to federal law under the ACA, and are required to comply with state and federal law related to EHB. Therefore, this regulation will not affect the creation of new or elimination of existing businesses in the State of California.

Expansion of Businesses or Elimination of Existing Businesses Within the State of California

This regulation is intended to clarify and make specific the existing State law for health plans under the Act. These plans are subject to federal law under the ACA, and are required to comply with state and federal rules related to providing coverage for EHB. The EHB requirement has been in effect since 2014, and these proposed adoptions simply update that standard. Therefore, the DMHC determined this regulation will not significantly affect the expansion of businesses currently doing business within the State of California.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulatory action will provide health consumers with a transparent mechanism to determine those benefits that are required to be covered as EHB in California. Health plan enrollees will also have better access to EHB because the requirements of the law will be clear and transparent for plans, resulting in more consistent baseline coverage. By clarifying the specific benefits that are required as part of the California base-benchmark plan, this regulation ensures consistency between health plans and health plan contracts, which allows consumers to better compare options both inside and outside the California Health Benefits Exchange. The Department does not anticipate this regulatory action will have any impact on worker safety, or the state's environment.