

DATE: February 10, 2017

ACTION: Notice of Rulemaking Action
Title 28, California Code of Regulations

SUBJECT: Adoption of Regulation, Title 28, California Code of Regulations, Section 1300.67.005, “Essential Health Benefits”; Control No. 2016-5191.

PUBLIC PROCEEDINGS

Notice is hereby given that the Director of the Department of Managed Health Care (Department) proposes to make final the emergency regulations under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), Title 28, California Code of Regulations (CCR), section 1300.67.005. This regulation was initially adopted as an emergency regulation and approved by the Office of Administrative Law and effective on November 28, 2016. Changes made to the text during the emergency period are noted in underline and strikeout. The Department is incorporating by reference the above mentioned emergency filing approved by OAL, File No. 2016-1117-01-E.

Before undertaking this action, the Director of the Department (Director) will conduct written public proceedings, during which time any interested person, or such person’s duly authorized representative, may present statements, arguments, or contentions relevant to the action described in this notice.

PUBLIC HEARING

No public hearing is scheduled. Any interested person, or his or her duly authorized representative, may submit a written request for a public hearing pursuant to Section 11346.8(a) of the Government Code. The written request for hearing must be received by the Department’s contact person, designated below, no later than 15 days before the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written statements, arguments or contentions (hereafter referred to as comments) relating to the proposed regulatory action by the Department. Comments must be received by the Department, Office of Legal Services, **by 5 p.m. on March 27, 2017**, which is hereby designated as the close of the written comment period.

Please address all comments to the Department of Managed Health Care, Office of Legal Services, Attention: Regulations Coordinator. Comments may be transmitted by regular mail, fax, email or via the Department's website:

Website: <http://wpsso.dmhc.ca.gov/regulations/#1>
Email: regulations@dmhc.ca.gov
Mail: Department of Managed Health Care
Office of Legal Services
Attn: Regulations Coordinator
980 9th Street, Suite 500
Sacramento, CA 95814
Fax: (916) 322-3968

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

Please identify the action by using the Department's rulemaking title and control number, **Essential Health Benefits, Control No. 2016-5192** in any of the above inquiries.

CONTACTS: Inquiries concerning the proposed adoption of these regulations may be directed to:

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AVAILABILITY OF DOCUMENTS

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

The Notice of Proposed Rulemaking Action, the proposed text of the regulation, and the Initial Statement of Reasons are also available on the Department's website at <http://wpsso.dmhc.ca.gov/regulations/#1> , under the heading "Open Pending Regulations."

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

AVAILABILITY OF MODIFIED TEXT

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

AUTHORITY AND REFERENCE

Pursuant to Health and Safety Code section 1341.9, the Department is vested with all duties, powers, purposes, responsibilities and jurisdiction as they pertain to health care service plans (health plans) and the health care service plan business.

Health and Safety Code section 1344 grants the Director authority to adopt, amend, and rescind regulations as necessary to carry out the provisions of the Knox-Keene Act, including rules governing applications and reports, and defining any terms as are necessary to carry out the provisions of the Knox-Keene Act.

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 1346 vests in the Director additional powers to administer and enforce the Knox-Keene Act, including but not limited to, the power to study, investigate, research and analyze matters affecting the interests of plans, subscribers, enrollees and the public and to promote and establish standards of ethical conduct for the administration of health plans.

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). Under the ACA, health plans offering individual and small group

contracts both inside and outside each state's health benefits Exchange are required to provide coverage of these EHB pursuant to ACA sections 1301 and 1302 (42 USC §18022), as well as Public Health Service Act section 2707 (42 USC § 300gg-6). In December 2011, the DHHS issued guidance for state implementation of EHB. The guidance authorized each state to select a benchmark plan from a list of options, and to establish EHB particular to that state. This guidance was codified at 45 Code of Federal Regulations (CFR) part 156.100 et seq., effective April 26, 2013. (78 Fed Reg. 12834, 12866.)

Pursuant to federal guidelines, the California legislature enacted Assembly Bill (AB) 1453, adopting Health and Safety Code section 1367.005, in September 2012. Health and Safety Code section 1367.005 established the California EHB-benchmark plan by selecting the Kaiser Small Group HMO 30 plan (Kaiser plan or base-benchmark plan) as the base-benchmark plan, and designated 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. Health and Safety Code section 1367.005 also established requirements for pediatric dental and vision benefits and coverage of habilitative and mental health services, and prohibits substitution of benefits for EHB coverage requirements.

In 2015, the California legislature enacted Senate Bill (SB) 43, which amended EHB coverage requirements of health care service plans based on upon amendments to the base-benchmark plan that was established under AB 1453. SB 43 amended section 1367.005 to select the Kaiser Small Group HMO 30 (2014) plan as the new base-benchmark plan. The adopted emergency regulation brought the current regulation into alignment with the Kaiser Small Group HMO 30 (2014) plan pursuant to SB 43. The Department proposes to adopt the emergency regulation as final without change. Health and Safety Code section 1367.005 grants the Director the authority to adopt and readopt emergency regulations, followed by final regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing federal law under ACA section 1301(a) (42 USC § 18021) requires any health plans certified to participate on the Exchange as a Qualified Health Plan (QHP)¹ to

¹ "The term 'qualified health plan' means a health plan that-- (A) has in effect a certification (which may include a seal or other indication of approval) that such plan meets the criteria for certification described in section 18031(c) of this title issued or recognized by each Exchange through which such plan is offered; (B) provides the essential health benefits package described in section 18022(a) of this title; and (C) is offered by a health insurance issuer that-- (i) is licensed and in good standing to offer health insurance coverage in each State in which such issuer offers health insurance coverage under this title; (ii) agrees to offer at least one qualified health plan in the silver level and at least one plan in the gold level in each such Exchange; (iii) agrees to charge the same premium rate for each qualified health plan of the issuer without regard to whether the plan is offered through an Exchange or whether the plan is offered directly from the issuer or through an agent; and (iv) complies with the regulations developed by the Secretary under section 18031(d) of this title and such other requirements as an applicable Exchange may establish." 42 U.S.C. § 18021.

provide EHB package defined in ACA section 1302(a) (42 USC § 18022). Existing federal law at PHSA section 2707 (42 USC § 300gg-6) also requires “health insurance issuers” offering coverage in the individual or small group market to ensure such coverage includes the essential health benefits package required under ACA section 1302(a). ACA section 1302(b) states that the DHHS Secretary shall define EHBs, so long as such benefits include the general categories listed in ACA section 1302(b).

In December 2011, the DHHS issued guidance for state implementation of EHB. The guidance authorized each state to select a benchmark plan from a list of options, and to establish EHB particular to that state. This guidance was codified at 45 CFR section 156.100 et seq., effective April 26, 2013. (78 Fed Reg. 12834, 12866.) Federal regulations permit states to select an EHB-benchmark package pursuant to 45 CFR parts 156.100 and 156.110, and require plans to provide EHB, including prescription drug benefits pursuant to 45 CFR part 156.122.

In California, jurisdiction over “health insurance issuers” is divided between regulation of health insurers and health care service plans by the California Department of Insurance (CDI) and the Department, respectively. The Department’s jurisdiction is determined by the Knox-Keene Act, which includes state mandates for benefit coverage. Existing California law at Health and Safety Code section 1367, subdivision (i), requires health care service plan contracts to provide to subscribers and enrollees all of the “basic health care services,” included in Health and Safety code section 1345, subdivision (b). Article 5 of the Knox-Keene Act includes standards for health care service plan contracts, including coverage mandates. For example, Health and Safety Code section 1367.51 requires that every individual or group health care service plan contract issued, amended, or renewed on or after January 1, 2000, provide coverage for certain equipment and supplies for the management and treatment of diabetes.

In response to federal guidance regarding EHB, through enactment of Health and Safety Code section 1367.005, the California Legislature selected the Kaiser plan as California’s base-benchmark plan and required all Knox-Keene Act benefit mandates enacted on or before December 31, 2011 to be covered as part of the EHB-benchmark package. Mandated benefits included as EHB are listed in Health and Safety Code section 1367.005(a)(2)(i) - (iv). Existing law at Health and Safety Code section 1367.005(a)(2)(v) requires that health plans cover as EHB all “other health benefits” offered by the base-benchmark plan in the first quarter of 2012 in addition to state mandated benefits. Existing law also requires coverage for pediatric vision and oral care (Health and Safety Code section 1367.005(a)(4) and (5), respectively), as well as mental health and habilitative services (Health and Safety Code section 1367.005(a)(2) and (3), respectively).

SB 43 amended Health and Safety Code section 1367.005 to select the Kaiser Small Group HMO 30 (2014) plan as the new base-benchmark plan. The proposed regulation

is identical to the recently-promulgated emergency regulation amending title 28, California Code of Regulations section 1300.67.005, regarding EHB.

The proposed regulation adopts, without change, the emergency regulation, and does the following:

- Updates the reference to the Kaiser Small Group HMO 30 as it was offered during the first quarter of 2014 rather than 2012;
- Updates the regulation's EHB Filing Worksheet in order to reference the correct supplementary plan for the pediatric vision EHB (the "BCBS Association, 2014 FEP BlueVision – High Option") and the correct supplementary plan for the pediatric dental EHB ("the same health benefits for pediatric oral care cover under the dental benefit receive by children under the Medi-Cal program as of 2014, including the provision of medically necessary orthodontic care provided pursuant to the federal CHIPRA of 2009");
- Clarifies that with regard to the pediatric oral EHB, the required coverage includes the Medi-Cal "Early Periodic Screening, Diagnosis, and Treatment" (EPSDT) benefit. Adopting this language clarifies and implements the statutory requirement for the pediatric dental EHB to include "the same health benefits for pediatric oral care coverage under the dental benefit received by children under the Medi-Cal program as of 2014 [...]." EPSDT benefits can result in coverage notwithstanding a benefit limit, such as a frequency limit, when the service is medically necessary pediatric dental coverage, as required by SB 43;
- Implements SB 43 by requiring health plans to file the EHB compliance worksheet for Department review no later than the date that the QHP product filings are required to be submitted;
- Clarifies the specific end date for "pediatric" EHB benefits, relative to an enrollee's nineteenth birthday;
- Removes the *per se* age limit on aphakia lens coverage, because such a limit must be clinically justified to avoid violating state and federal antidiscrimination laws;
- To reflect the new benchmark plan, strikes the description of "physical, occupational, and speech therapy" benefits from the regulation's subdivision regarding Skilled Nursing Facility care, and move it to the newly proposed subdivision regarding habilitative and rehabilitative services;
- Adds proposed subdivision (d)(12) for habilitative and rehabilitative services, and describe the coverage required under the new Kaiser benchmark plan and SB 43's provisions related to habilitative services;
- To reflect the new benchmark plan, adds proposed subdivision (d)(13) regarding coverage for clinical trials; and
- Updates the EHB Filing Worksheets to reflect the amendments described above.
- Updates the Prescription Drug Benefit Worksheet to reflect the new benchmark plan's number of drugs in each United States Pharmacopeia (USP) category and class, thus ensuring prescription drug EHB coverage in accordance with state and federal law.

COMPARABLE FEDERAL LAW (Govt. Code § 1346.5(a)(3)(B))

The proposed regulation is consistent with and facilitates state implementation of federal health care reform law. Under the ACA, section 1301 (42 USC § 18021) and PHSA section 2707 (42 USC 300gg-6) require that individual and small group health plans and insurers, both inside and outside the state Exchange, provide EHB as required by ACA section 1302(b) (42 USC § 18022). In February 2013, DHHS finalized regulations that delegate authority to each state to identify a benchmark plan according to criteria specified in 45 CFR parts 156.100 and 156.110. Federal regulations at 45 CFR parts 156.115 and 156.122 require health plans to comply with state EHB requirement. In response to federal guidance regarding EHB, through enactment of Health and Safety Code section 1367.005, the California Legislature selected the Kaiser plan as California's base-benchmark plan and required all Knox-Keene Act benefit mandates enacted on or before December 31, 2011 to be covered as part of the EHB-benchmark package. The filing requirement contained in the proposed regulation is also consistent with these federal laws and regulations regarding EHB.

POLICY STATEMENT OVERVIEW – BROAD OBJECTIVES AND BENEFITS OF THE PROPOSED REGULATION (Govt. Code § 1346.5(a)(3)(c))

The Department's broad objective served by promulgating this regulation is to clarify benefits that must be covered as part of EHB under Health and Safety Code section 1367.005. By clarifying the benefits required as part of EHB, the Department will ensure consistent and efficient implementation of EHB requirements. The proposed regulations will benefit health plans and health consumers by providing a transparent and consistent approach to implementation of state and federal EHB requirements.

The proposed regulation is necessary as it adopts the amendments already promulgated as an emergency regulation. It updates the benchmark plan from 2012 Kaiser Small Group HMO 30 to the 2014 Kaiser Small Group HMO 30. This updates what health plans must cover and what coverage consumers must be provided. The update will help consumers by ensuring health plans are accountable to the public, as well as the Department for compliance with EHB coverage requirements.

CONSISTENCY AND COMPATIBILITY WITH STATE REGULATIONS (Govt. Code § 11346.5(a)(3)(D))

The Department compared the proposed regulation to existing state regulations. The proposed regulation is neither inconsistent nor incompatible with existing state regulations. The Department evaluated the proposed amendments to the regulations for any related regulations in this area and found that these are the only regulations that deal with essential health benefits required under the Knox-Keene Act.

COMPARABLE FEDERAL LAW

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). Under the ACA, health plans offering individual and small group contracts both inside and outside each state’s health benefits Exchange are required to provide coverage of these EHB pursuant to ACA sections 1301 and 1302 (42 USC §18022), as well as Public Health Service Act section 2707 (42 USC § 300gg-6). In December 2011, the DHHS issued guidance for state implementation of EHB. The guidance authorized each state to select a benchmark plan from a list of options, and to establish EHB particular to that state. This guidance was codified at 45 Code of Federal Regulations (CFR) part 156.100 et seq., effective April 26, 2013. (78 Fed Reg. 12834, 12866.)

BUSINESS REPORT

All cost impacts, known to the Department at the time of the notice of proposed was submitted to the Office of Administrative Law, that a representative or private person or business would necessarily incur in reasonable compliance with the proposed action: NONE.

PURPOSE OF THE REGULATIONS

The Department is proposing to make permanent the amendments to Rule 1300.67.005. This is 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.

LOCAL MANDATE

The Department has determined the regulations will not impose a mandate on local agencies or school districts, nor are there any costs requiring reimbursement by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

ALTERNATIVES CONSIDERED

Pursuant to Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention 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.

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

REPORTING REQUIREMENT

With the exception of the already *existing* reporting requirement of the EHB Filing Worksheet, there are no additional reporting requirements resulting from the proposed regulation.

SUMMARY OF FISCAL IMPACT

- Mandate on local agencies and school districts: None
- Cost or Savings to any State Agency: None
- Direct or Indirect Costs or Savings in Federal Funding to the State: None
- Cost to Local Agencies and School Districts Required to be Reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None
- Costs to private persons or businesses directly affected: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- Effect on Housing Costs: None
- Other non-discretionary cost or savings imposed upon local agencies: None

DETERMINATIONS

The Department has made the following initial determinations:

The Department has determined the regulation will not impose a mandate on local agencies or school districts, nor are there any costs requiring reimbursement by Part 7 (commencing with Section 17500) of Division 4 of the Government Code. As specified in Section 6 of AB 2179, no reimbursement is required.

The Department has determined the regulation will have no significant effect on housing costs.

The Department has determined the regulation does not affect small businesses. Health care service plans are not considered a small business under Government Code Section 11342.610(b) and (c).

The Department has determined the regulation will not significantly affect the creation or elimination of jobs within the State of California.

The Department has determined the regulation will not significantly affect the creation of new businesses or the elimination of existing businesses within the State of California.

The Department has determined the regulation will not significantly affect the expansion of businesses currently doing business within the State of California.

The Department has determined the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Department has determined that this regulation will have no cost or savings in federal funding to the state.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS (Government Code § 11346.3(b))

A. Creation or Elimination of Jobs Within the State of California

The proposed regulation is identical to the recently enacted emergency regulations amending title 28 of the California Code of Regulations regarding EHBs that implemented the provisions of SB 43. This regulation updates the benchmark plan from 2012 Kaiser Small Group HMO 30 to the 2014 Kaiser Small Group HMO 30 and updates the pediatric oral and vision EHB supplementation. Given the nature of the proposed regulation and the minimal changes it makes to the existing law, the regulation will not create or eliminate jobs within the State of California.

B. Creation of New Businesses or the Elimination of Existing Businesses Within the State of California

This proposed regulation will neither create new businesses nor eliminate existing businesses. The state is required by federal guidelines and regulations under the ACA to select an EHB-benchmark package. The state complied with these requirements by enacting AB 1453, and selecting a base-benchmark plan. This regulation simply updates the benchmark plan from 2012 Kaiser Small Group HMO 30 to the 2014 Kaiser Small Group HMO 30 and updates the pediatric oral and vision EHB supplementation. This regulation is identical to the recently promulgated emergency regulation amending title 28, California Code of Regulations section 1300.67.005 relating to EHB. Additionally, the regulation only applies to health plans licensed under the Knox-Keene Act. Individual and small group health care service plans are subject to federal law under the ACA, and are required to comply with state and federal law related to EHBs. Therefore, the regulation creates no additional requirements that would affect the creation of new or elimination of existing businesses in California.

C. Expansion of Businesses Currently Doing Business Within the State of California

This regulation is intended to clarify the existing State law for health plans under the Knox-Keene Act. This regulation does not create any new requirements and only updates the existing law and provides further clarification. The Knox-Keene licensed plans are subject to federal law under the ACA, and are required to comply with state and federal rules related to providing coverage for EHBs. Therefore, the Department determined this regulation will not significantly affect the expansion of businesses currently doing business within the State of California.

D. 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 essential health benefits in California. Plan enrollees will also have better access to EHB because the requirements of the law will be clear and transparent for plans. By clarifying the specific benefits that are required as part of the California 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.