

DATE: **October 27, 2017**

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

SUBJECT: General Licensure Requirements for Health Care Service Plans; adding section 1300.49 to title 28, California Code of Regulations; Control No. 2017-5220.

PUBLIC PROCEEDINGS:

Notice is hereby given that the Director of the Department of Managed Health Care (Department) proposes to adopt the proposed regulation under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act)¹ clarifying that the Knox-Keene Act definition of a health care service plan (health plan) includes an entity that takes on global risk (both institutional and professional risk) for services provided to health plan subscribers and enrollees. The proposed regulation would also set out requirements for a restricted health plan license that allows an entity to take on a small proportion of global risk and standards for obtaining an exemption from health plan licensing requirements. The regulation defines relevant terms concerning financial risk. Changes to the regulation are noted by underline.

This rulemaking action proposes to add section 1300.49 to title 28, California Code of Regulations (the Regulations). 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 Government Code section 11346.8(a). The written request for a 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

¹ The Knox-Keene Act is codified as Health and Safety Code section 1340 et seq.

Services, no later than **5 p.m. on December 11, 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: Jennifer Willis, Senior Counsel. Comments may be transmitted by regular mail, fax, email or via the Department's website:

Website: <http://www.dmhc.ca.gov/LawsRegulations.aspx#open>
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, **General Licensure Requirements for Health Care Service Plans, Control No. 2017-5220** in any of the above inquiries.

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

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OR

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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://www.dmh.ca.gov/LawsRegulations.aspx#open>.

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, subdivision (a), the Department "has charge of the execution of the laws of this state relating in to health care service plans... including, but not limited to, those laws directing the department to ensure that health care service plans provide enrollees with access to quality health care services and protect and promote the interests of enrollees."

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 plans and the health plan business.

Health and Safety Code section 1343 gives the Director authority through the adoption of rules or orders to exempt from the Knox-Keene Act any class of persons or health plan contracts when certain condition are met.

Health and Safety Code section 1344 grants the Director authority to adopt, amend, and rescind rules, forms, and orders necessary to carry out the provisions of the Knox-Keene Act, and to classify persons and matters within the Director's jurisdiction and prescribe different requirements for different classes.

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 services to 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 1349 makes it unlawful for any person to engage in business as a health plan in California, or to receive advance or periodic consideration in connection with a

health plan from or on behalf of person in California without first securing a license from the Director, unless the person is exempt from the licensure requirements under Health and Safety Code section 1343.

Health and Safety Code section 1375.1, subdivision (a)(2), requires a health plan to demonstrate that it is fiscally sound and has “assumed full financial risk on a prospective basis for the provision of covered health care services, except that a plan may obtain insurance or make other arrangements for the cost of providing to any subscriber or enrollee covered health care services...”

Health and Safety Code section 1399.5 declares the Legislature’s intent to apply the provisions of the Knox-Keene Act to an entity that, in return for a prepaid or periodic charge paid by or on behalf of a subscriber or enrollee, provides, administers or otherwise arranges for the provision of health care services, unless the entity is exempted under Health and Safety Code section 1343.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Purpose of the Regulation:

The purpose of this rulemaking action is to clarify licensure requirements for health plans. Specifically, the proposed regulation states that a person who accepts global risk (both institutional and professional risk) for services to subscribers or enrollees receives “advance or periodic consideration” from or on behalf of subscribers or enrollees, and shall seek a health plan license. The proposed regulation will also set out requirements for a restricted license for entities that do not market directly to consumers or employers but otherwise meet the statutory definition of a health plan. In addition, the regulation states specific criteria the Department may apply in considering a request for exemption from licensure requirements. Key terms defined by the regulation include global, professional, and institutional risk, as well as “risk.”

Summary of Existing Laws and Regulations:

Health and Safety Code sections 1345, subdivision (f), 1375.1, subdivision (a), and 1349 define a health plan and require health plans to assume full financial risk for the arrangement of health care services to subscribers and enrollees. “Full financial risk” is not defined. Health and Safety Code section 1343 authorizes the Director to exempt a class of persons or contracts from the Knox-Keene Act under certain conditions. Health and Safety Code section 1344 allows the Director to adopt rules, classify persons within the Department’s jurisdiction, and prescribe different requirements for different classes of persons. Health and Safety Code section 1399.5 declares the Legislature’s intent to apply the Knox-Keene Act to an entity that, in return for a prepaid or periodic charge paid by or on behalf of a subscriber or enrollee, provides, administers, or otherwise arranges for the provision of health care services, unless the entity receives an exemption from the Director.

Broad Objectives and Benefits of the Regulation:

Pursuant to Government Code section 11346.5(a)(3)(C), the broad objectives and benefits of this regulation are to clarify and make specific state law relevant to the licensure of health plans. The Department is proposing to adopt Rule 1300.49 to clarify that entities that take on global risk (risk for both institutional and professional services) receive “advance or periodic consideration” from or on behalf of subscribers and enrollees meet the definition of a health plan and shall seek a health plan license pursuant to section 1349 of the Health and Safety Code. The objective is to clarify that entities accepting global risk and thereby meeting the definition of a health plan are required to either obtain a license or an exemption.

In addition, Rule 1300.49 would set out criteria for obtaining an exemption from the licensure requirement for entities that accept global risk. An exemption may be granted by the Director upon review and consideration of financial viability reports, the percentage of institutional risk taken on by the entity, the number of subscribers and enrollees involved, and the service area in which the entity operates.

Rule 1300.49 also clarifies the standards for obtaining a restricted license, under which the licensed full-service health plan the restricted licensee contracts with would retain financial responsibility for certain types of services provided to the full-service health plans subscribers or enrollees.² The restricted licensee could accept prepaid or periodic payments for both institutional and professional services only from a licensed health plan, and could not market, solicit, or sell health plan contracts to individual members of the public or to employers. Additionally, Rule 1300.49 also adopts “DMHC Division of Financial Responsibility Form,” (Form) as dated June 1, 2017, which requires restricted licensees to disclose whether the restricted licensee or full-service health plan is responsible for specific provisions of the Knox-Keene Act. The Form makes clear that restricted licensees are not exempt from any provision of the Knox-Keene Act and that subscribers and enrollees receiving services from these restricted licensees receive the full protection of the Knox-Keene Act. A restricted licensee would have to maintain its own provider network that ensures adequate access to all services delegated to the licensee under the DMHC Division of Financial Responsibility Form. “Limited licenses” obtained before financial solvency requirements were adopted in 2000 would remain in effect.

Finally, Rule 1300.49 would define key terms, including risk, global risk, institutional risk, and professional risk. The purpose of adding these definitions is to clarify and add transparency to existing health plan licensure requirements and to prevent confusion amongst impacted entities.

Evaluation of Consistency/Compatibility with Existing State Regulations:

The Department evaluated the proposed regulation for any other possible related regulations and has found that the regulation is consistent with other regulations concerning licensure and

² A full-service health plan is one that provides or arranges for the provision of basic health care services as defined in the Health and Safety Code section 1345, subdivision (a) or the essential health benefits pursuant to Health and Safety Code section 1367.005.

financial solvency, including Rules 1300.51 and 1300.75 et seq. Therefore, the regulation is neither inconsistent nor incompatible with existing state regulations.

Forms Incorporated by Reference:

The “DMHC Division of Financial Responsibility Form,” as dated June 1, 2017, is incorporated by reference pursuant to Title 1, California Code of Regulations, section 20(c)(3) and as cited to in the proposed regulation, section 1300.49, subdivision (c)(3).

DISCLOSURES REGARDING THE PROPOSED ACTION:

- Mandate on local agencies and school districts: None.
- Cost or Savings to any State Agency: 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.
- Other non-discretionary cost or savings imposed upon local agencies: None.
- Direct or Indirect Costs or Savings in Federal Funding to the State: None.
- Costs impacts to representative private persons or business/Significant statewide adverse economic impact directing affecting business, including the ability of California businesses to compete with businesses in other states: Although the proposed action will directly affect business statewide the Department concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant. The proposed regulation makes specific existing state law and codifies current practice in regards to restricted licensees. On average, the Department receives five (5) applications per year from restricted licensee applicants. Applicants for licensure pay fees up to \$25,000 for review and processing of the application for licensure. It is anticipated that the first effective year of the proposed regulation will result in an aggregate impact of 5 restricted licensees seeking licensure x \$15,093 (the average cost of a restricted licensee application fee), or \$75,465 total for the first year. These restricted licensees will also be responsible for paying annual fees typically in the average amount of \$24,137.

- Health plans are not considered a small business under Government Code Section 11342.610, subdivisions (b) and (c).

RESULTS OF THE ECONOMIC IMPACT ANALYSIS (Government Code section 11346.3, subdivision (b)):

Creation or Elimination of Jobs Within the State of California:

The proposed adoption of Rule 1300.49, subdivision (b), interprets, implements, and makes specific state law regarding the definition of a health plan. Additionally, the proposed regulation codifies current practice regarding the Department’s licensure of restricted licensees. On average, the Department expects that approximately five (5) entities per year will apply for a

restricted license resulting in an aggregate impact of \$75,465 total for the first year. Additionally, it is expected that restricted licensees will pay, on average, \$120,685 in aggregate ongoing annual costs. Despite these costs, the Department determined that this amendment will not significantly affect the creation or elimination of jobs within the State of California.

Creation of New Businesses or Elimination of Existing Businesses Within the State of California:

Expansion of Businesses Currently Doing Business Within the State of California:

It is not anticipated that the proposed regulation will directly result in expansion of businesses currently doing business in the State of California.

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

BUSINESS REPORT:

The proposed regulation is intended to clarify and make specific the existing state law for health plans under the Knox-Keene Act. The provisions of the regulation are necessary for the health, safety or welfare of the people of the state.

CONSIDERATION OF ALTERNATIVES:

Pursuant to Government Code section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified or brought to the attention of the Department would be more effective in carrying out the purpose for which the above action is proposed or 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 provisions 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.