

**STATE OF CALIFORNIA
DEPARTMENT OF MANAGED HEALTH CARE**

**TITLE 28, CALIFORNIA CODE OF REGULATIONS
DIVISION 1. THE DEPARTMENT OF MANAGED HEALTH CARE
CHAPTER 2. HEALTH CARE SERVICE PLANS
ARTICLE 2. ADMINISTRATION**

**SECTION 1300.49
GENERAL LICENSURE REQUIREMENTS**

INITIAL STATEMENT OF REASONS

(Control Number 2017-5220)

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, Rule 1300.49.¹

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” (health 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.”

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 health plan business.

Health and Safety Code section 1343 gives the Director the authority, through the adoption of rules or issuance of orders deemed necessary and appropriate, to exempt from the Knox-Keene Health Care Service Plan Act of 1975 (Health and Safety Code, sections 1340 et seq., hereinafter “Knox-Keene Act”) any class of persons or health plan contracts if certain conditions are met.

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 Act. For the purpose of rules and forms, the Director may classify persons

¹ All further regulatory (“Rule”) references are to California Code of Regulations, Title 28, unless otherwise indicated.

and matters within the Director's jurisdiction, and may prescribe different requirements for different classes.

Health and Safety Code section 1346 vests in the Director additional powers to administer and enforce the Knox-Keene Act, including the power to study, investigate, research, and analyze matters affecting the interests of health plans, subscribers, enrollees, and the public, and to promote and establish standards of ethical conduct for the administration of health plans.

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 persons in California without first securing a license from the Director of the Department, unless the person is exempted from the requirement by Health and Safety Code section 1343 or a rule adopted thereunder.

Health and Safety Code section 1375.1, subdivision (a)(2), requires a health care service 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 which, 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.

II. SPECIFIC PROBLEMS ADDRESSED AND NECESSITY OF REGULATION

Existing law defines a health plan pursuant to Health and Safety Code section 1345, subdivision (f). Health and Safety Code section 1375.1, subdivision (a)(1), states that a health plan shall assume "full financial risk" for the provision of covered health care benefits to enrollees or subscribers. However, "full financial risk" is not defined. As a result, provider groups that contract with health plans or other organizations to provide health care services to health plan enrollees assume at least some degree of risk for both professional and institutional (hospital) health care services (professional and institutional risk together is considered "global risk"). These provider groups otherwise meet the definition of a health plan pursuant to Health and Safety Code section 1345, subdivision (f), by arranging for health care services for health plan enrollees and accepting at least a portion of global risk. Without a clear definition of what types and levels of risk may be assumed, entities that meet the definition of a health plan may be operating without a license. This is a violation of Health and Safety Code section 1349, which makes it unlawful to receive advance or periodic consideration in connection with a health plan without first securing a license or an exemption. The regulation would state clearly that a person that accepts global risk receives "advance or periodic consideration" requiring licensure for purposes of Health and Safety Code section 1349.

In 2015 the California Court of Appeal, Second District, held that “the level of financial risk under a capitation agreement that causes a ‘risk bearing organization’ ... to become a ‘health care service plan’ ... is precisely the type of regulatory determination involving complex economic policy that should be made by the DMHC...” *Hambrick v. Healthcare Partners Medical Group, Inc.*, (2015) 238 Cal.App.4th 124, 149.

The addition of Rule 1300.49 is necessary to set the level of assumption of financial risk that triggers a requirement to obtain licensure by the Department.

Additionally, there are entities that contract only with other health plans to provide services to that health plan’s enrollees and subscribers. These entities do not pose as great a risk to the stability of the health care delivery system because their overall impact on the health care market is limited. However, they still meet the definition of a health plan under the Knox-Keene Act. Rule 1300.49 would provide a separate “restricted license” for these entities thereby limiting the confusion these entities have about the need for a license and the type of regulation that will be incurred.

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

The addition of Rule 1300.49 implements, interprets, and makes specific Health and Safety Code sections 1345, subdivision (f), 1375.1, subdivision (a), and 1349, which define a health plan and require health plans to assume full financial risk for arranging health care services for subscribers and enrollees.

The addition of Rule 1300.49, subdivision (a), is necessary to provide clarity to the definition of a health plan by making specific the definition of risk and related terms. The subdivision codifies industry terms of art: professional risk is the financial risk for professional medical services, while institutional risk is the financial risk for hospital inpatient, hospital outpatient, or hospital ancillary services. Current law allows providers that assume only professional risk to register as a risk-bearing organization (RBO) pursuant to Health and Safety Code section 1375.4. RBO registration and financial solvency provisions were added by Senate Bill (SB) 260 (Stats. 1999, c. 529) to address the problem of provider groups that contracted to assume financial risk for health care services of subscribers and enrollees but became insolvent, threatening to disrupt delivery of health care to consumers. Rule 1300.49 does not change the RBO financial solvency rules, but it clarifies that entities that take on any portion of institutional risk, risk associated with covered hospital inpatient, hospital outpatient, and hospital ancillary services, need to be licensed.

Additionally, although the term “risk” is used in the Knox-Keene Act, it is not defined. Rule 1300.49, subdivision (a), defines “risk” and the type of risk that triggers the requirement for licensure. Rule 1300.49 will clarify and implement the licensing requirements laid out in the Knox-Keene Act. As the court stated in *Hambrick*, the Department is uniquely situated to determine the level of risk requiring licensure. In consideration of the overarching duty of the Department to safeguard the health care

delivery system, the Department has determined that, unless otherwise provided, any assumption of global risk, as defined in Rule 1300.49, requires licensure.

Subdivision (a)(1) – Global risk. This definition is added to clarify that global risk is the assumption of both professional and institutional financial risk. This will prevent confusion in the health care marketplace and avoid potential enforcement actions against those entities that contract for this type of risk without a license.

Subdivision (a)(2) – Institutional risk. This definition is added to clarify that assumption of the risk of payment for hospital inpatient, hospital outpatient, or hospital ancillary services is considered institutional risk. However, assumption of responsibility for institutional services that are provided within the entity's internal operations for services which the entity is licensed to perform is not considered institutional risk. An entity that assumes risk only for services that it provides itself does not risk substantial claims payment liability.

Subdivision (a)(3) – Limited license. This definition is added to clarify that existing holders of limited licenses may continue to engage in business as provided in subdivision (b)(3) of Rule 1300.49. This prevents confusion by these entities over whether they need to apply for a different type of license with the Department in order to continue their current operations.

Subdivision (a)(4) – Person. This definition is added to clarify that a person includes a corporation, association, or other entity, as defined by the Knox-Keene Act.

Subdivision (a)(5) – Professional risk. This definition is added to clarify that the assumption of the cost of health care services provided by physicians and other providers is considered professional risk.

Subdivision (a)(6) – Risk. This definition is added to clarify that risk is the assumption of the cost for covered health care services rendered to enrollees or subscribers.

Subdivision (b)(1), clarifies that the phrase in section 1349 “to receive advance or periodic consideration in connection with a plan from or on behalf of a person in this state” includes the acceptance of global risk. Subdivision (b)(2) clarifies that the Director may exempt certain entities from the requirements of a health plan license, pursuant to Health and Safety Code section 1343, subdivision (b), and lists the factors the Department will consider in determining whether an entity may be exempt from the requirements of a health plan license.

This provision will clarify the licensure requirements of the Knox-Keene Act. The Department will use fewer resources responding to licensure inquiries and taking enforcement actions against entities that claim they do not have to seek a license. Additionally, the ability to apply for an exemption will allow entities that accept only a small portion of global risk, have only a minor market share, and/or operate in well served areas and are, therefore, less likely to disrupt the market and access to health care services in the event of failure, to obtain an exemption from the licensure

requirement.

Rule 1300.49, subdivision (c), allows entities that do not market directly to consumers or employers, but otherwise meet the definition of a health plan as defined in Health and Safety Code section 1345, subdivision (f), to seek a restricted license if they contract with a health plan to accept global risk. This type of license requires an entity to apply for licensure and submit to the regulation of the Department, but also allows the entity to declare that certain provisions of the Knox-Keene Act will continue to be the responsibility of the contracting health plan, thus limiting the extent of the entity's regulation by the Department. Additionally, this ensures that enrollees and subscribers of restricted licensees receive the same consumer protections as those that are enrolled in a fully licensed health plan.

Rule 1300.49, subdivision (c)(2), requires an applicant for a restricted license to file a health plan application for license, as required in Rule 1300.51. In addition, Rule 1300.49, subdivision (c)(3), requires the applicant to submit a "DMHC Division of Financial Responsibility Form," incorporated by reference, that will disclose which health plan functions will remain the sole duty of the full licensed health plan with which the restricted licensee contracts and which functions will be the responsibility of the restricted licensee. The restricted licensee is required to maintain its own contracted provider network that ensures adequate access to services delegated to the license under the DMHC Division of Financial Responsibility Form.

Rule 1300.49, subdivision (d), is necessary to provide clarity to existing limited health plan licensees. This subdivision allows those currently licensed health plans that have received limited exemptions to the Knox-Keene Act to retain those licenses, but does not provide future opportunities for entities to seek limited licenses.

SPECIFIC PURPOSE AND NECESSITY OF THE *DMHC DIVISION OF FINANCIAL RESPONSIBILITY FORM*.

The *DMHC Division of Financial Responsibility Form* (Form), dated June 1, 2017, incorporated by reference into section 1300.49, subdivision (b)(3), of the regulation, requires restricted licensees to disclose whether the restricted license or the full-service health plan is responsible for compliance with specific provisions of the Knox-Keene Act. The form allows the restricted licensee to clearly set out how health plan responsibilities will be divided between the restricted licensee and the fully licensed health plan under a plan-to-plan contract. The adoption of the form will clarify that restricted licensees are not exempt from any provision of the Knox-Keene Act, and that subscribers and enrollees receiving services from restricted licensees receive the full protection of the Knox-Keene Act.

Specifically, the Form requires the following information:

- Column 1 "Categories of Services" — This column lists the specific category of services that must be covered. The main categories are: Primary Care Services; Hospital Services; Specialty Physician Services; Mental Health Services; Mental Health Facilities; Clinic/Urgent Care Services; Ancillary Provider Services; Dental

Services; and Vision/Optomety Services. Each main category lists subcategories. For example, Specialty Physician Services includes the subcategories Anesthesiology and Diagnostic Radiology, among others. This addition is necessary to allow the Department to readily identify which specific categories of health care the restricted licensee has contracted to cover and ensure that enrollees are receiving adequate access to care.

- Column 2, "Service Provided by Restricted Licensee"— This addition is necessary to identify which provider services the restricted licensee is responsible for covering, listed for each specified provider type. This allows the Department to easily identify the health care coverage obligations of the restricted licensee for each type of service ensuring that enrollees are provided appropriate access to care.
- Column 3, "Service Provided by Full Service Plan" — This addition is necessary to identify which provider services the full service licensee is responsible for covering, listed for each specific provider type. This allows the Department to easily identify the health care coverage obligations of the full service plan to ensure that enrollees are provided appropriate access to care.
- Column 4, "Service Provided by Other Plan or Entity" — This addition is necessary to identify health care services for which entities other than the restricted licensee or full service plan are responsible. This allows the Department to easily identify the entity responsible for covering these services, listed by provider type.
- Column 5, "Notes" — This addition is necessary to allow the restricted licensee to provide any necessary further coverage information, listed by provider type. This allows the Department to easily access additional information concerning the division of responsibility between the restricted licensee and other entities and allows the restricted licensee to provide any additional explanation to the proposed service provider structure.

Pursuant to Government Code section 11346.3, subdivision (d), the Department has made a finding that the reporting requirement contained in the regulation is necessary for the health, safety, or welfare of the people of the state that the regulation apply to businesses.

IV. DOCUMENTS RELIED UPON

- Health and Safety Code sections 1341, 1341.9, 1343, 1344, 1345, 1346, 1349, 1367, 1367.03, 1375.1, 1375.4, 1375.9, and 1399.5;
- California Code of Regulations, title 28, section 1300.51, 1300.67.2, 1300.67.2.1, 1300.67.2.2, and 1300.75.2;
- *Hambrick v. Healthcare Partners Medical Group, Inc.*, (2015) 238 Cal.App.4th 124; and,
- The DMHC Division of Financial Responsibility Form.

V. REASONABLE ALTERNATIVES TO THE REGULATION

The Department has determined that, due to the need to clarify licensure requirements for entities that assume financial risk for health care services, there are no reasonable

alternatives to this regulation.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations and amendments during the written comment period. As part of this process, the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department 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 will not have a significant statewide adverse economic impact directly affecting businesses. The economic impact on private businesses was calculated as follows:

The proposed adoption of Rule 1300.49, subdivision (b), interprets, implements, and makes specific state law regarding the definition of a health plan. The addition of Rule 1300.49 makes clear that entities that accept global risk must seek licensure or an exemption from licensure as a health plan. Additionally, the proposed regulation codifies current practice regarding the Department's licensure of 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, billed on a monthly basis as fees accrue by the Department, for review and processing of the application for licensure. Therefore, it is expected that the first effective year of the proposed regulation will result in an aggregate impact of 5 restricted licensees seeks licensure x \$15,093 (the average cost of a restricted licensee application fee), or \$75,465 total for the first year.

Restricted Licensees will also be responsible for paying ongoing annual fees based on the amount of covered lives they contract for. Pursuant to Health and Safety Code section 1356, subdivision (b)(1), a licensed plan, which includes a restricted licensee, shall pay the Department \$10,000 plus an amount calculated on a per enrollee basis for the costs and expenses incurred by the Department associated with the regulation of health plans. In 2016, the per enrollment cost for full service health plans was \$1.59. The total amount owed by each restricted licensee will vary significantly depending on the total number of enrollees the licensees contracts for. On average, the typical restricted licensee contract for 15,272 covered lives and pays \$24,137 in annual fees. The proposed regulation will result in approximately \$120,685 in ongoing annual costs.

These fees are necessary and reflect the Department's costs to protect consumer interests and ensure access to quality health care. This licensure requirement will not create a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

VII. ECONOMIC IMPACT ANALYSIS

Creation or Elimination of Jobs within California

The proposed adoption of Rule 1300.49, subdivision (b), interprets, implements, and makes specific state law regarding the definition of a health plan. The addition of Rule 1300.49 makes clear that entities that accept global risk must seek licensure or an exemption from licensure as a health plan. Additionally, the proposed regulation codifies current practice regarding the Department's licensure of 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, billed on a monthly basis as fees accrue by the Department, for review and processing of the application for licensure. Therefore, it is expected that the first effective year of the proposed regulation will result in an aggregate impact of 5 restricted licensees seeks licensure x \$15,093 (the average cost of a restricted licensee application fee), or \$75,465 total for the first year.

Restricted Licensees will also be responsible for paying ongoing annual fees based on the amount of covered lives they contract for. Pursuant to Health and Safety Code section 1356, subdivision (b)(1), a licensed plan, which includes a restricted licensee, shall pay the Department \$10,000 plus an amount calculated on a per enrollee basis for the costs and expenses incurred by the Department associated with the regulation of health plans. In 2016, the per enrollment cost for full service health plans was \$1.59. The total amount owed by each restricted licensee will vary significantly depending on the total number of enrollees the licensees contracts for. On average, the typical restricted licensee contract for 15,272 covered lives and pays \$24,137 in annual fees. The proposed regulation will result in approximately \$120,685 in ongoing annual costs.

These fees are necessary and reflect the Department's costs to protect consumer interests and ensure access to quality health care. Because the addition of Rule 1300.49 clarifies and makes specific existing law and practice for health plans, 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

This proposed adoption of Rule 1300.49 will neither create new businesses nor eliminate existing businesses. This regulation specifies requirements of sections 1345, subdivision (f), 1349, and 1371.5 of the Knox-Keene Act, and does not create any new requirements for businesses in California, but merely clarifies existing state law. Additionally, this regulation only applies to health plans that must be licensed under the Knox-Keene Act. 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 Knox-Keene Act. The addition of Rule 1300.49 makes clear that entities that accept global risk must seek licensure or an exemption from licensure as a health plan. It is estimated that 5 entities per year will be impacted by this regulation. Application for licensure and ongoing regulatory oversight by the Department requires specific fees to be paid by health plan applicants and licensees, as laid out in existing law, Health and Safety Code section 1356. It is estimated that the total fee that will be due from new licensees will total \$75,465. Additionally, it is estimated that these entities will be required to pay annual ongoing fees in typically in the amount of \$120,685 total. Because this reduces confusion over licensure requirements, rather than creating new requirements, the Department determined this regulation will not significantly affect the expansion or elimination 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 plans and provider organizations with a transparent mechanism to determine whether licensure is required by the Department. Clarifying the licensure requirements of the Knox-Keene Act enhances the health and welfare of California resident's by ensuring that entities that are taking on global risk are not operating without the necessary oversight of the Department. This protects against potential insolvency and puts in place necessary protections against disruption in the health care delivery system. The Department does not anticipate this regulatory action will have any impact on worker safety, or the state's environment.