

## DEPARTMENT OF MANAGED HEALTH CARE

### FINAL STATEMENT OF REASONS

General Licensure Requirements

Title 28, Section 1300.49

Control No. 2017-5220

#### **Updated Informative Digest**

There have been no changes in applicable laws or to the effect of the proposed regulation from the laws and effects described in the original Notice of Proposed Regulatory Action.

#### **Update of Information Contained in the Initial Statement of Reasons**

##### *Update to the Economic Impact Analysis*

Based upon information obtained during the 3<sup>rd</sup> comment period from America's Physician Groups (APG), the Department has revised its Economic Impact Analysis to take into account additional organizations cited by APG<sup>1</sup> that may be exempt from licensure under the regulation.

The Department estimates that it may license up to two-thirds (2/3) of the estimated 67 ACOs in California and up to one-quarter (1/4) of the estimated 21 PHS. That is, the Department estimates that it could license approximately 44.67 ACOs and 5.25 PHS each year, assuming that they meet licensure requirements and are not granted exemptions. Additionally, based on Department data, the Department estimates it will continue to receive five (5) applications for licensure each year from other restricted health care service plan applicants. Therefore, it is expected that the first effective year of the proposed regulation could result in an aggregate impact of up to 55 entities seeking licensure (rounded up from 54.92).

Please note that the only number that has changed in this analysis is the number of estimated ACOs impacted by the regulation. As stated above, the Department is now estimating that 2/3 of the 67 ACOs will be impacted versus the previous estimation of 3/4, because of information received from APG during the 3<sup>rd</sup> comment period which ran from May 15, 2018 through June 1, 2018. APG noted that the Department relied upon a 2015 UC Berkeley report for its estimated number of ACOs in California. However, APG brought into question whether those 67 ACOs accept global risk payments and/or are Medicare ACOs. The Department agrees with APG that some of the ACOs considered in the study may not fall within the provisions of the proposed rule and

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<sup>1</sup> June 1, 2018 Letter from William Barcellona to Jennifer Willis, Senior Counsel, Department of Managed Health Care. A copy of this letter is included in the 3<sup>rd</sup> comment period letters within the rulemaking file.

therefore has reduced its estimate of the number of ACOs it may license as a result of the proposed rule. Again, it should be noted that these numbers are estimates.

The proposed regulation interprets, implements, and makes specific state law regarding the definition of a health plan and licensure of restricted licensees. The Department has determined that the regulation amendments will not have a significant statewide adverse economic impact directly affecting businesses. The costs associated with the regulation 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.

The overall cost for the regulation is estimated to be \$4,121,508. This number was reached by adding the one-time costs and ongoing costs associated with the regulation.

### **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 care service plan. The proposed regulation implements current practice regarding the Department's licensure of restricted health care service plans. 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 their application for licensure. Restricted health care service plans, on average, pay \$15,093 per application for licensure, whereas full-service health care service plans pay the maximum \$25,000 fee. PHS will likely receive full-service health care service plan licenses, whereas ACOs will receive restricted health care service plan licenses."

Therefore, it is expected that the first effective year of the proposed regulation, with five restricted health care service plans seeking licensure, as well as 44.67 ACOs and 5.25 PHS seeking licensure, will result in \$880,919.31 total costs.

Restricted health care service plans and newly licensed entities, such as ACOs and PHS, will also be responsible for paying ongoing annual fees based on the amount of covered lives for which they contract. Pursuant to Health and Safety Code section 1356, subdivision (b)(1), a licensed health care service plan, which includes a restricted health care service plan, 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 these entities. In 2016, the per member enrollment cost for full service health care plan was \$1.59. The total amount owed by each licensed entity will vary significantly depending on the total number of contracted enrollees the entity undertakes. Based on available data and the number of entities the Department estimates it will license, the Department estimates the proposed regulation will result in approximately \$3,240,588.76 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. Additionally, none of the businesses affected are small businesses. This regulation specifies requirements of existing sections 1345, subdivision (f), 1349, and 1371.5 of the Knox-Keene Act. The regulation clarifies existing state law. While it clarifies that entities that may not currently have either a license or an exemption from the licensure requirement from the DMHC to seek either a license or an exemption from the Department, the regulation is unlikely to cause new businesses to be created or eliminate existing businesses.

### **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 care service 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 care service plan. It is estimated that 55 (rounded) entities per year (5 restricted health care service plans, 44.67 ACOs, and 5.25 PHS) will be impacted by this regulation. Application for licensure and ongoing regulatory oversight by the Department requires specific fees to be paid by health care service plan applicants and licensees, as required under existing law contained in Health and Safety Code section 1356. It is estimated that the total fees due from new restricted health care service plan licensees will be \$880,919.31. Additionally, it is estimated that these entities will be required to pay annual ongoing fees in the amount of \$3,240,588.76. Because this regulation reduces confusion over licensure 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 care service 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.

The Department made the following non-substantive amendments:

- The Department has amended the reference to the date of the proposed form, "Restricted Health Care Service Plan Statement," from "dated March 2018" (located in subdivision (c)(1)(C)) to "dated May 2018" to accurately track the last time the form was amended and noticed to the public during the 3<sup>rd</sup> comment period in May 2018.
- The Department made non-substantive changes to subdivision (c)(1)(B) renumbering from (c)(1)(C) because of previous edits.
- The Department made non-substantive edits to subdivision (c)(2) to clarify the proposed rule. It divided (c)(2) into (c)(2) and (c)(2)(A), (c)(2)(B), and (c)(2)(C) to divide up the requirements for restricted health care service plans and allow for easier reading and understanding by the impacted stakeholders.
- The Department also made changes to conform to previous edits as discussed under the substantive amendments below. For example, the Department changed "restricted licensee" to "restricted health care service plan" to match the term used throughout the proposed rule and used in practice at the Department for consistency.
- The Department made non-substantive edits to subdivision (d) by changing "limited licensee" to "limited health care service plan" to be consistent with terminology used throughout the proposed rule and in practice at the Department.
- Non-substantive changes to punctuation have been made.

The Department made the following substantive amendments:

- The Department amended the definition of "global risk" in subdivision (a)(1) by changing "assumption" to "acceptance" and adding "prepaid or periodic charge from or on behalf of enrollees" for consistency with the definition of a health care service plan in Health and Safety Code section 1345(f)(1). Reference to the definition of health care service plan is important as, pursuant to this proposed rule, an entity which accepts global risk and meets the definition of a health care service plan must seek licensure or an exemption from licensure from the Department. Prepaid or periodic charge is defined later in the proposed rule to add clarity to the definition and ensure that impacted stakeholders clearly understand whether they would fall under the definition.
- The Department amended the definition of "institutional risk" in subdivision (a)(2) by adding a reference to "prepaid or periodic charge paid by or on behalf of the subscriber or enrollee" to refer to the definition of a health care service plan in Health and Safety Code section 1345(f)(1). Adding this language also clarifies in

what way and on whose behalf the payment must be made to fall within the scope of the regulation.

- The Department simplified the definition of “limited health care service plan” in subdivision (a)(3). The original term was “limited license health care service plan,” but “license” was removed because the word did not add any necessary meaning to the definition.
- The reference to the “license with waivers” in subdivision (a)(3) was amended to “person with a health care service plan license with waivers” in order to make it clear that it is a person holding the license for a health care service plan which is subject to waivers. The term “person” is defined in Health and Safety Code section 1345 and is an understood term within the industry and this helps clarify the meaning of the definition for impacted stakeholders. Because the Department added that the limited license health care service plan is issued to a “person,” the Department deleted that the limited health care service plan is issued to a “health care service provider or its affiliate” because keeping this language would be confusing and prevent the clarity provided by the previous amendment.
- To ensure the definition in (a)(3) is consistent with the rest of the proposed rule, the reference to “financial risk” and additional detail regarding professional and institutional risk was deleted. This adds brevity to the definition and ensures that it is more easily understood by impacted stakeholders.
- The Department deleted the definition of “person” in the original subdivision (a)(4) because person is already defined in Health and Safety Code section 1345 and therefore does not need to be duplicated in this subdivision.
- In the new subdivision (a)(4), the Department defined “prepaid or periodic charge.” This definition was added because it is found in the definition of health care service plan in Health and Safety Code section 1345(f)(1). Using language from the definition of health care service plan is important for this rule because the proposed regulation will be read in conjunction with the definition of health care service plan under the Knox-Keene Act. The definition of prepaid or periodic charge explains that a fixed amount or percentage of savings or losses, paid at the start or end of a predetermined period, qualifies as a prepaid or periodic charge. This clarifies any ambiguity as to which entities could be impacted by the proposed regulation.
- The Department amended the definition of “professional risk” in subdivision (a)(5) to add a reference to the acceptance of a prepaid or periodic charge by or on behalf of enrollees in order to refer back to the definition of health care service plan in Health and Safety Code section 1345(f)(1). Adding this language also clarifies in what way and on whose behalf the payment must be made for consistency in the proposed regulation and within the Knox-Keene Act.
- The Department deleted the definition of “risk” in original proposed subdivision (a)(6) because “risk” alone is not used and so a definition became unnecessary and confusing. Rather, “institutional risk” and “professional risk” are defined since

these terms are used throughout the proposed regulation and defining these terms adds clarity and understanding for entities impacted by the proposed rule.

- The Department added a definition of “restricted health care service plan” in subdivision (a)(6). This definition is necessary because, while restricted health care service plans were often referenced in the proposed rule, the term was not defined and the lack of a definition could cause confusion. The definition encompasses the current definition of a health care service plan while adding that the restricted health care service plan is restricted in that it may not directly market, solicit, or sell health care service plan contracts under the terms of its license. Information from the originally proposed subdivision (c)(1) is contained in this definition.
- The Department amended subdivision (b)(1) of the proposed rule by removing the reference to “advance or periodic consideration” and instead adding language that a person who assumes global risk shall obtain a health care service plan license. Because the proposed rule now refers to “prepaid or periodic charge” as found in the definition of a health care service plan, reference to Health and Safety Code section 1349 advance or periodic consideration is not necessary in the subdivision and could be confusing for impacted stakeholders. This amendment clarifies that it is the acceptance of global risk which can trigger the requirement to seek licensure from the Department as a health care service plan.
- The Department added a reference to Health and Safety Code section 1343 in subdivision (b)(2) to make it clear the ability for a person to seek and the Director to grant an exemption is the same process contained in the already existing statute in the Knox-Keene Act. Additionally, the language was amended to add that the Director can consider any information the Director deems relevant, including “but not limited to” certain information that the requestor may provide to the Director to support the request. This clarifies that any relevant information may be considered if it is submitted by the requester. This is necessary because the Department wants to encourage any entity seeking an exemption to provide any information they deem relevant under the proposed rule and Health and Safety Code section 1343.
- The Department amended subdivision (b)(2)(A) – (F) to clarify the information the Director will consider when determining whether an exemption request shall be granted.
  - In 1300.49(b)(2)(A), the Department added that the Director will consider the financial statements from the entity, as this will help the Department determine whether the entity is financially stable and the amount of risk it assumes, key parts of the exemption that must be considered for public safety and the stability of the healthcare market place.
  - In 1300.49(b)(2)(B), the Department moved the reference to the contract for the assumption of global risk to subdivision 1300.49(b)(2)(C). Moving this provision clarifies the regulation because it divides the provision into

two separate subdivisions, making it clear they are two separate considerations for an exemption request.

- Because 1300.49(b)(2)(C) now contains the reference to the contracts for the assumption of global risk as explained above, each subsequent provision needed to be renumbered correctly because of the addition of this separate criteria.
- The Department added 1300.49(b)(2)(F), which states that the Department will consider how the entity taking global risk will impact the public interest or protection of the public consistent with Health and Safety Code section 1343. This consideration is important to the Director's determination of whether an exemption should be granted to the requester, as the Department is concerned with the potential impact of an exemption on consumer protection and the public interest. Highlighting these criteria will help guide entities to provide appropriate information in any request for an exemption from the Department.
- As stated in the non-substantive changes section, above, the Department made non-substantive changes to the language in subdivision (c)(1)(A) to conform to other changes made in the proposed rule. For example, the Department referred to the "restricted health care service plan" rather than the "restricted licensee" to conform to previous edits as explained above and to ensure consistency of language throughout the proposed regulation.
- The Department amended originally proposed subdivisions (c)(1)(A) and (c)(1)(B) to conform to language used throughout the regulation, including in the definition of restricted healthcare service plan in subdivision (a)(6). The new (c)(1)(A) is a more clear statement defining the function of a restricted health care service plan for the purposes of the proposed regulation.
- The Department, in (c)(2)(A), simplified the language to remove the reference to "health care service plan or specialized health care service plan" because it was not necessary, as the language already refers to section 1351 and the statute uses these terms. The Department clarified that the application for licensure shall specify which functions are the responsibility of the full service health care service plan and which are the responsibility of the restricted health care service plan, removing the reference to "delegation" of functions which could be confusing to the impacted stakeholders. Changing this language clarifies that the entire scope of the Knox-Keene Act provisions will be covered by either the health care service plan or the restricted health care service plan with which it contracts and both parties are subject to its requirements.
- In order to clarify the requirements for restricted health care service plan applications in a more distinctive manner for easier reading, the Department added new subdivision (c)(2)(B) which contains language from the originally proposed subdivision (c)(2). Non-substantive edits were also made, such as referring to "restricted health care service plan" rather than "restricted licensee." This change adds consistency of language throughout the proposed regulation.

- New subdivision (c)(2)(C) contains information from the originally proposed (c)(2) and (c)(3). The Department renumbered and reordered the originally proposed subdivisions for clarity and easier reading. Additional changes were made, such as renaming the “Division of Financial Responsibility Statement” to be the “Restricted Health Care Service Plan Statement.” This change was made because the Division of Financial Responsibility Statement is an already existing form and using the same name may have caused confusion with impacted stakeholders. The new name will also make the purpose of the form clear.
  - The new name of the form was changed throughout the proposed regulation for consistency.
  - The date of the form was also changed to May 2018 to accurately track the last time the form was amended in the 3<sup>rd</sup> comment period.
- The originally proposed subdivision (c)(2) is now partially contained in subdivision (c)(3). The Department made non-substantive edits to the new subdivision (c)(3) to conform to changes made in the rest of the proposed rule, such as changing the name of the form to “Restricted Health Care Responsibility Statement.” As mentioned above, dividing the originally proposed subdivision (c)(2) makes the proposed rule more clear and easier for impacted stakeholders to read and follow its requirements.
- The Department made non-substantive edits to subdivision (c)(4), such as changing the reference to “restricted licensee” to “restricted health care service plan.” Also, the Department changed the language to state that entities “currently licensed” by the Department may continue to engage in business rather than entities that were “previously licensed” by the Department. The language was amended to clarify these impacted licensees may continue to operate under the terms of their existing license.
- The Department added subdivision (e) to clarify that this section shall only apply to contracts issued, amended, or renewed on or after the effective date of the regulation. This is necessary in order to ensure that the provisions in the proposed rule are not erroneously applied retroactively.

### **Update of Material Relied Upon**

No material other than the public comments, the Notice of Proposed Regulatory Action, the 15-day Comment Period documents, the Final Statement of Reasons, and the Final Text of the Regulations have been added to the rulemaking file since the time the rulemaking record was opened, and no additional material has been relied upon.

### **Mandate on Local School Agencies and School Districts**

The Department has determined that the proposed regulation will not impose a mandate on local school agencies or school districts.

### **Comparable Federal Law**

The Department has reviewed federal law and determined that there is no comparable federal law for this regulation.

### **Alternatives to the Proposed Regulation**

As discussed in the Initial Statement of Reasons, the Department considered various alternatives to the proposed regulation during the informal rulemaking process. Further, the Department determined during the rulemaking process that the alternatives considered would not be more effective in carrying out the purposes for which the regulation is proposed, would not be as effective and less burdensome to regulated entities, and would not be more cost-effective in implementing the requirements of Health and Safety Code sections 1345, 1349 and the entirety of the Knox-Keene Act.

### **Summary of and Responses to Comments**

The Department's summary and responses to comments received are contained in tabs H, L and P of the rulemaking record.