



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

December 17, 2018

California Department of Managed Health Care
Office of Legal Services
Attention: Jennifer Willis, Senior Counsel
980 Ninth Street, Suite 500
Sacramento, CA 95814

Via e-mail: regulations@dmhc.ca.gov

SUBJECT: General Licensure Requirements for Health Care Service Plans
Control No. 2017-5220

Fourth Comment Period

Dear Ms. Willis:

The California Hospital Association (CHA), representing more than 400 hospitals and health systems, is pleased to provide additional comments on the modified proposed general licensure regulations released by the Department of Managed Health Care on November 30, 2018. We appreciate the department's efforts to clarify how and why an entity may be granted an exemption from the licensure requirement, and we have several suggestions for further clarifications. We remain concerned that the proposed regulation would subject a number of providers to licensure based on the adoption of innovative — yet low-risk — payment models that were not the intended subject of regulation under the Knox-Keene Act. These include bundled payment arrangements, institutional risk pools and accountable care organizations (ACOs). We encourage you to revise the regulation to strike a balance between encouraging innovative, low-risk arrangements and engaging in necessary oversight. We hope our comments, detailed below, will assist you in this effort.

I. The procedure by which the department evaluates exemption requests should be designed to give providers clarity and finality.

We appreciate the department including, in the proposed regulation, a process for a provider or other entity to seek an exemption from the licensure requirement. This proposal identifies the information an applicant should provide and the department contact to whom a request should be made. In light of the mismatch between the requirements for a health care service plan under the Knox-Keene Act and the low-risk payment arrangements described in this letter, it is critical that the department provide a clear and efficient process for providers to obtain exemptions and inform providers of the outcome as soon as possible.

We urge the department to provide greater clarity around the procedures for seeking an exemption.

As drafted, the regulation leaves a number of questions unanswered. For example:

- When is a provider required to seek an exemption?
- What are a provider's rights while its request is pending?
- What is the status of a request for an exemption if the department does not respond within 30 days?
- Can a provider appeal if it disagrees with the department's decision?

Without this clarity, providers may be forced to put longstanding business relationships on hold or stop expanding their use of the payment arrangements described above. Therefore, we urge the department to create greater structural protections for providers engaged in the exemption request process. Accordingly, we believe a provider should have a 90-day grace period after a contract is issued, amended or renewed before being required to submit an application for licensure or request an exemption.

We strongly support the proposed requirement that the department respond to requests for exemption within 30 days (28 C.C.R. § 1300.49, paragraph (b)(3) (proposed)). To give providers greater certainty around this time frame, we urge the department to deem requests approved if the department does not act on the request within 30 days. We also urge the department to establish appeal rights for applicants whose request is denied, and note that the licensure requirement does not apply to an applicant while any appeal is pending. Finally, if an exemption request is denied and all appeals are unsuccessful, the applicant should have longer than the end of that calendar year or nine months from the date of the denial to unwind the arrangement. This will give providers whose requests for exemptions have been denied the opportunity to unwind payment arrangements for which a license or exemption is required without disrupting patient care. Finally, we urge the department to clarify that any effective date inserted in the regulation by the Office of Administrative Law shall be calculated pursuant to Government Code section 11343.4.

Specifically, we encourage the department to make the following additions and revisions to paragraph (b) of the regulation:¹

(2) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to any person upon review and a finding that the action is in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.

(3) A person requesting an exemption shall submit the following information for consideration by the Director:

...

¹ For clarity, our recommended insertions are underlined, recommended deletions are stricken, and language that we recommend moving is double-underlined. We have suggested separating the information submission requirement that currently appears in paragraph (b)(2) from the substantive standard that appears in that paragraph. We have also suggested moving additional procedural provisions, including the language that currently appears in paragraph (b)(2)(G), *after* all substantive bases for exemptions such that it would appear in paragraph (b)(7)(A). Finally, it appears that paragraph (b)(3) erroneously appeared twice, so we have revised the numbering accordingly.

~~(G) — Persons requesting an exemption shall submit the request to the following address: OPLInquiries@dmhc.ca.gov or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.~~

...

~~(3)(4)~~ When reviewing the information submitted under subdivision (b)~~(2)(3)~~ of this regulation, the Director shall consider the following criteria:

...

~~(3)(7)~~

(A) Persons requesting an exemption shall submit the request to the following address: OPLInquiries@dmhc.ca.gov or submit a hard copy to the Department of Managed Health Care, ATTN: Office of Plan Licensing, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.

(B) The Director shall issue the decision on the request for exemption from licensure under this section within 30 days of receipt of the request by the Department. An applicant for exemption shall be deemed exempt from this section while the Department's decision on its request is pending. If the Department does not issue a decision on a request for exemption from licensure within 30 days of its receipt of the request, the request shall be deemed approved.

(8)

(A) The Department's decision to grant or deny a request for exemption shall be subject to review by the Director pursuant to Health & Safety Code section 1397, paragraph (a). An applicant for exemption shall be deemed exempt from this section while the Director's decision is pending pursuant to this subdivision.

(B) The Director's decision shall be subject to judicial review pursuant to Health & Safety Code section 1397, paragraph (b). An applicant for exemption shall be deemed exempt from this section while judicial review on the appeal of a denial of an exemption upheld by the Director is pending pursuant to this subdivision.

(9) An applicant whose request for exemption is denied shall not be subject to this section until January 1 of the calendar year following the date the denial becomes final or nine months from the date the denial becomes final, whichever comes later. For the purposes of this subdivision (b)(11), a denial shall not be final until any appeals under subdivision (10)(A) and/or (10)(B) above are exhausted, if applicable.

...

(e) This section shall apply only to contracts issued, amended, or renewed or significantly modified on or after [Date to be inserted by OAL pursuant to Gov. Code § 11343.4].

II. The department should provide clear, quantitative standards that allow a provider to determine whether it is entitled to an exemption from the licensure requirement.

We appreciate the department's efforts to respond to the Office of Administrative Law's concern that earlier drafts of the proposed regulation did not provide sufficient clarity as to the standard for obtaining an exemption from the licensure requirement. We support the department's decision to grant applicants an exemption upon the director's finding that doing so is "in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act"

(28 California Code of Regulations (“C.C.R.”) § 1300.49, paragraph (b)(2) (proposed)). This standard, which is drawn from Health & Safety Code Section 1343, ensures that the department focuses on the circumstances where its licensing and oversight activities are necessary to protect the public interest.

However, as drafted, the exemption process would still require the department to engage in a subjective decision-making process to determine whether an exemption for a particular person or organization would be “in the public interest and not detrimental to the protection of subscribers, enrollees or persons regulated under the Knox-Keene Act.” Even with the criteria provided in the new draft regulation, a provider cannot accurately predict whether the department will grant its request for an exemption because the proposed criteria are too vague. **Therefore, we urge the department to identify circumstances in which a person, provider or other organization is presumptively exempt from the licensure requirement and to identify payment arrangements that are not subject to this regulation.** Applications for exemption under these categories should be subject to a streamlined review to confirm that the applicant participates in the types of safe, low-risk payment arrangements that are common in California and that we have emphasized in our comments throughout this rulemaking process.

For example, the department should establish that a provider that participates in particularly low-risk payment arrangements that fall below quantitative risk thresholds is presumptively exempt from the licensure requirement. Regulatory frameworks outside of California are instructive in demonstrating how such thresholds might be developed and applied. For example, the Centers for Medicare & Medicaid Services (CMS) and the state of New York have determined that provider risk-bearing arrangements in which less than 25 percent of payments are at risk are sufficiently low-risk that the arrangement does not require the same level of oversight.² Below these thresholds, providers can take on risk without closer scrutiny by the regulators. These standards show that other state and federal regulators have limited their oversight activity to arrangements that present more significant levels of risk-taking. California’s providers have decades of experience sharing risk with payors to incentivize high-value care, resulting in the most sophisticated health care market in the country. **The department’s oversight and regulation is, therefore, unnecessary when providers take on modest amounts of risk, when providers have the wherewithal to manage the risk they have taken on, or when the provider has a proven track record of sharing risk with payors in a financially stable manner.**

The department’s regulatory oversight is also unnecessary when a provider participates in certain payment arrangements pursuant to state or federal law, and under careful regulation by the Medicare or Medi-Cal programs. For example, as hospitals that participate in Medicare, many of our members are required to or voluntarily participate in various CMS bundled payment initiatives, like the Comprehensive Care for Joint Replacement (CJR) model or the Medicare Shared Savings Program, both

² CMS allows a Medicare Advantage organization to pass risk on to physicians or physician groups by way of a “physician incentive plan.” See 42 C.F.R. § 422.208. The arrangement is subject to additional regulation if it involves “substantial financial risk.” “Substantial financial risk,” in turn, is defined by reference to a number of quantitative risk-taking thresholds, such as facing withholds or liability greater than 25% of total payments.

New York subjects managed care organizations’ agreements with provider groups to reduced scrutiny if less than \$1 million of payments to the provider are at risk under the agreement or, if the total amount of payments at risk exceeds \$1 million, no more than 25% of projected annual payments to the provider are at risk. See Provider Contract Guidelines for Article 44 MCOs, IPAs and ACOs, available at https://www.health.ny.gov/health_care/managed_care/hmoipa/docs/guidelines.pdf.

of which are considered “alternative payment models” under federal law. It is unnecessary to require that a provider seek licensure as a health care service plan so that it may accept payment under any of the alternative payment models, each of which is subject to a complex and robust regulatory scheme and oversight. Requiring licensure in these circumstances is redundant, and could undermine federal policy and impose outsized burdens on providers that are not otherwise engaged in any risk-bearing activities.

We also urge the department to establish that certain types of payment arrangements — including bundled payment arrangements, institutional risk pools, and ACOs — are presumptively exempt from this regulation unless the department determines that special circumstances warrant licensure. These payment arrangements are common tools to improve the quality and coordination of care while posing minimal to no risk to patients, payors and providers. These arrangements may also be regulated under other schemes, as in the case of a health system that operates an ACO for its own employees under the health system’s self-funded plan that is subject to ERISA. These safe, common arrangements should be presumptively exempt from the licensure requirement.

With that in mind, we urge the department to insert the following as a new paragraph (b)(5):

(5)

(A) A person is presumptively exempt from the licensure requirement if the person is a provider and at least one of the following is true:

(i) No more than 25% of the provider’s maximum potential revenue from health care services from all payors is at risk;

(ii) No more than 25% of the provider’s tangible net equity (TNE) is at risk across all payors with whom the provider has entered into payment arrangements; or

(iii) No more than 25% of the provider’s cash on hand is at risk across all payors with whom the provider has entered into payment arrangements.

(B) A payment is not considered at risk for the purposes of this subdivision (b)(5) if the payment is:

(i) Received under an alternative payment model, as that term is defined in 42 U.S.C. 1395/(z)(3)(C);

(ii) Received from an entity that contracts directly with the United States government to provide services under the Medicare program or an entity that contracts directly with the State Department of Health Care Services to provide services under the Medi-Cal program;

(iii) A bundled payment for a specified set of services provided within ninety (90) days or less that relate to a single episode of care;

(iv) Received in connection with participation in an institutional risk pool;

(v) Received in connection with participation in an accountable care organization;

(vi) Received pursuant to a payment arrangement that has not been materially modified for three (3) or more years where the provider has not sustained a loss of more than 10% of the provider’s maximum potential revenue under that arrangement over the last three (3) years;

(vii) Not subject to downside risk; or

(viii) Received under an arrangement in which the provider is paid a per-member, per-month amount by a licensed health care service plan solely for services that the provider is authorized by law to provide (i.e., the provider takes capitated professional risk only or capitated institutional risk only, but does not take global risk).

(C) The calculation made pursuant to subdivision (b)(5)(A) shall take into account any applicable insurance held by the provider, including reinsurance and/or stop-loss coverage.

In order to establish eligibility for a presumptive exemption pursuant to this new paragraph (b)(5), a person, provider or other organization should be required simply to provide materials and information demonstrating its satisfaction of the applicable presumptive exemption category or categories. To that end, we recommend inserting the following as paragraph (b)(6):

(6)

(A) Pursuant to section 1343 of the Health and Safety Code, the Director shall grant an exemption from this section to a person described under paragraph (b)(5) unless the Department determines there is a compelling reason to deny the request for exemption.

(B) A person requesting an exemption pursuant to subdivision (b)(5) shall not be subject to the requirements of subdivision (b)(3) and shall instead submit materials and information to the Director demonstrating that it is entitled to exemption under the applicable requirement(s).

We also urge the department to clarify that an exemption granted to a person or organization would remain in effect unless and until there is a material change in the type of payment arrangements in which the person or organization is engaged. This would relieve the department of the burden of considering each new payment arrangement into which exempt persons and organizations enter. If a person or organization enters into new payment arrangements that do not materially differ from the payment arrangements in place when the person or organization was granted an exemption, there is no need for the department to revisit its analysis. To that end, we recommend inserting the following as a new paragraph (b)(10):

(10) An exemption granted under this subdivision (b) shall remain in effect unless and until there is a material change in the nature of payment arrangements in which the exempt person is engaged.

For the purpose of clarity, we also suggest inserting the following definitions under paragraph (a):

(7) “Accountable care organization” shall refer to an arrangement in which one or more providers, paid pursuant to a fee schedule, are held accountable for a patient population’s care over a predetermined period of time by way of incentive payments that are tied to the providers’ performance on quality metrics and/or the providers’ ability to control costs for that patient population by, among other things, comparing the actual cost of care to a target budget.

(8) “Downside risk” shall refer to an arrangement in which one or more providers are paid using a fee schedule, but may be required to repay an amount to a payor at the end of a predetermined period if total payments for health care services under the arrangement exceed a target budget applicable to that arrangement. An arrangement does not subject a provider to downside risk if a deficit from spending exceeding a target budget accrues only against future surpluses under the arrangement, but does not require repayment to the payor.

(9) “Institutional risk pool” shall refer to a payment arrangement in which fee-for-service payments for hospital services for a particular set of patients are compared to a target and any surplus is disbursed to the physicians caring for those patients after a predetermined period of time, but only to the extent the patients’ costs for institutional services fall below the predetermined target, and any shortfall is accrued against future surpluses and does not create a payment obligation by the physicians.

(10) “Payor” shall have the meaning set forth in Health & Safety Code section 1395.6.

(11) “Provider” shall have the meaning set forth in Health & Safety Code section 1345.

III. As drafted, the proposed regulation is inconsistent with the Knox-Keene Act and unworkable, and the department should re-engage with stakeholders prior to finalizing it.

As we described in our earlier comment letters, we are concerned that certain types of payment arrangements that involve little or no financial risk — but create financial incentives to increase quality, access and efficiency — would be subject to licensure under the proposed regulation. These include bundled payment arrangements where the payment provides for both professional and institutional services; institutional risk pool arrangements; and integrated care arrangements, such as ACOs, including those with zero downside risk. **Under payment arrangements like these, many of our members provide high-quality care in a cost-effective manner while accepting minimal or no financial risk.**

These evolving payment arrangements typically encourage providers to coordinate care, improve quality and stay within a target budget. The arrangement might be limited to a narrowly defined set of services linked to an episode of care, in the case of a bundled payment arrangement, or a population’s care during a defined time period, as in the case of an institutional risk pool arrangement and many integrated care arrangements. However, these arrangements generally do **not** require a provider to be responsible for the entirety of a patient’s care in exchange for a capitated payment, nor do they require providers to take on such significant risk that the provider’s financial stability may be threatened. As such, these arrangements pose no threat of harm to consumers. However, under the plain language of the proposed regulation, it appears that these common, safe and valuable payment arrangements would be subject to licensure.

The Knox-Keene Act was intended to ensure health plans are able to deliver on their promise to arrange health care services after accepting a pre-paid charge from enrollees. The payment arrangements described above were not contemplated by the drafters of the Knox-Keene Act; shared savings arrangements, episodic payments and other value-based payments simply do not resemble the capitated arrangements that were the drafters’ focus and do not involve prepaid or periodic payments.

Furthermore, the department's Statement of Reasons provides little insight as to why it seeks to sweep in such a broad array of arrangements and disrupt California's health care marketplace. Moreover, regulating such arrangements as "health care service plans" would be inconsistent with the Knox-Keene Act's existing regulatory framework. **The proposed regulation does not address this inconsistency. Rather, it leaves unanswered a number of questions about whether an entity that participates in these innovative payment arrangements could obtain a license and satisfy the obligations of licensure on an ongoing basis without transforming its care model into a traditional health maintenance organization.** Indeed, it is unclear whether the department intends for such arrangements to continue under its oversight, or if the proposed regulation would operate as an indirect prohibition of these payment arrangements. If the department is unwilling to revise the regulation to narrow the scope of arrangements for which licensure will be required, then it should at least adopt the recommendations set forth above to ensure that exemptions from licensure are granted for the many common, low-risk arrangements that might now come within the newly expanded range of payment arrangements requiring a license.

We urge the department to elicit stakeholder feedback and to refine this regulation prior to making it final. We strongly encourage the department to engage in a collaborative process with the payor, provider and patient communities to formulate a regulatory framework that strikes the proper balance between protecting the public and encouraging value-based payment systems. The federal negotiated rulemaking process set forth in 5 U.S.C. sections 561 *et seq.* provides a model for stakeholders representing various interests to come together to inform an agency's rulemaking process. If implemented as currently written, the proposed regulation is likely to pose substantial operational challenges. We believe the department would benefit from a formal process for obtaining stakeholder input and improving the regulation.

CHA appreciates the opportunity to provide comments on the modified regulation. If you have any questions, please contact me at (916) 552-7543 or akemp@calhospital.org.

Sincerely,

A handwritten signature in black ink that reads "Amber Kemp". The signature is written in a cursive style with a large, looping initial "A".

Amber Kemp
Vice President, Health Care Coverage