



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

May 20, 2019

California Department of Managed Health Care
Office of Legal Services
Attention: Sarah Ream, Acting General Counsel
980 Ninth Street, Suite 500
Sacramento, CA 95814

Via e-mail: sarah.ream@dmhc.ca.gov

SUBJECT: Draft Guidance on Exemptions from the DMHC General Licensure Regulation

Dear Ms. Ream:

The California Hospital Association (CHA), representing more than 400 hospitals and health systems, is pleased to provide comments on the California Department of Managed Health Care's (DMHC) draft guidance on exemptions from DMHC's general licensure regulation. California hospitals are working to improve the quality and coordination of patient care and reduce costs. The draft guidance is an important first step toward striking the appropriate balance between ensuring consumer protection and promoting efficient, innovative health care delivery.

CHA appreciates the many conversations DMHC staff has had with CHA and our member hospitals and health systems over the past few weeks related to our concern that certain types of payment arrangements that involve little or no financial risk — but create financial incentives to increase quality, access and efficiency — are subject to licensure under the regulation.

We offer the following observations for additional consideration and future dialogue to ensure that health care providers have the flexibility to continue to utilize low-risk payment arrangements resulting in high-value care and lower health care costs for consumers.

I. Contracts/Arrangements that Do Not Need to be Filed with DMHC

CHA appreciates that, in its draft guidance, DMHC has determined a number of contracts, although technically falling under the ambit of the new regulation, do not need to comply at this time. These types of contracts are bundled payment, case rate, diagnosis-related group payment, and per diem arrangements. These are safe, low-risk payment arrangements that are common in California; CHA has emphasized these should be exempt from licensure in our comments throughout DMHC's rulemaking process.

CHA also appreciates DMHC's clarification that entities participating in a Centers for Medicare & Medicaid Services (CMS) accountable care organization (ACO), as well as arrangements in which the payer is a California Department of Insurance (CDI)-licensed insurer, do not need to file contracts with DMHC. Requiring licensure in these circumstances would be redundant and, in the case of CMS ACOs,

could undermine federal policy and impose outsized burdens on providers that are not otherwise engaged in any risk-bearing activities.

CHA requests that DMHC clarify the arrangements below are exempt from licensure:

- Upside-only arrangements – These are common payment arrangements that use quality metrics to incentivize providers to improve quality and patient satisfaction while reducing costs. In these arrangements, providers are not liable to repay any financial losses if care costs exceed budget.
- Clinically integrated networks (CINs) with only upside risk –CINs are not risk-bearing entities, are fully supported by their health system owner, and take no downside — not even roll-over — risk. CINs are largely engaged in clinical quality improvement and pay for performance bonuses around those efforts and should not be subject to licensure.
- Quality incentive programs – Providers commonly enter into arrangements where they receive additional payment for achieving certain quality metrics. In these arrangements, providers do not share in any loss or savings associated with the cost of providing services to subscribers or enrollees.
- Professional capitation-only division of financial responsibility (DOFR) agreements – Professional capitation DOFRs typically have some facility services embedded in them because of California’s ban on the corporate practice of medicine; these arrangements may not otherwise meet DMHC’s definition of professional risk. Examples include the facility component of radiation therapy, hemodialysis, and amniocentesis. Other services that are typically part of a professional capitation arrangement — such as diagnostic testing; infusion therapy, including chemotherapy; apheresis; and rehabilitation — may sometimes have a facility component, if performed at a hospital.
- Medicare Advantage (MA) contracts – MA contracts are heavily regulated by the federal government. Moreover, MA contracts involve no material additional risk than entities regulated by CMS or CDI. CHA is concerned that the inclusion of MA contracts will discourage physician participation in value-based arrangements for California’s aging population — a population expected to double over the next 20 years.

CHA appreciates that, for all other contracts that involve the assumption of global risk, DMHC is phasing in the exemption application process and temporarily expediting exemption requests to not only give entities time to comply, but also and ensure orderly implementation.

II. Expedited Processing of Exemption Request During Phase-In Period

CHA appreciates DMHC’s clarification that, during the phase-in period, entities that assume global risk will be required to file their global risk contracts within 30 days of execution by all parties and do not need to receive an exemption before finalizing or beginning performance under the contract. During the phase-in period, DMHC will automatically grant an exemption to submitted contracts. CHA requests additional clarification in the areas outlined below.

Duration of Phase-in Period

CHA appreciates that DMHC is phasing in the exemption application process and temporarily expediting exemption requests to give providers time to comply with the regulation. The phase-in period is July 1, 2019, to December 31, 2019. CHA requests that DMHC extend the phase-in period to July 1, 2020, to allow for additional education for both DMHC and providers on the regulation's scope and the types of arrangements that should be exempt. In addition, CHA requests that DMHC clarify whether the trigger date for the phase-in period is the "effective" date of the arrangement or the date the arrangement was "executed."

Duration of Exemption

CHA appreciates DMHC's clarification that, upon receipt of the Request for Expedited Exemption, it will deem a contract to be exempt from the regulation and will issue an Order of Exemption. The draft guidance indicates that the duration of the exemption will be either: 1) the term of the contract, if a DMHC-licensed health plan is a party to the contract; or 2) one year from the date DMHC grants the exemption, if a DMHC-licensed health plan is not a party to the contract. CHA strongly requests that the department clarify that all exemptions granted 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.

Submission of Contracts

The draft guidance indicates that, during the phase-in period, entities assuming global risk must file with DMHC their global risk contracts within 30 days of execution of the contract by all parties. CHA requests DMHC clarify, for health plan contracts already filed with DMHC, providers do not need to submit the contract for review. DMHC-regulated plans have already filed these contracts with DMHC, so requiring providers to also file them would be duplicative, administratively burdensome for all parties involved, and unnecessary.

Confidentiality of Contracts

CHA appreciates DMHC's draft confidentiality request form provides a process for entities that want DMHC to treat the contract or any portion thereof as confidential. CHA requests DMHC automatically treat the entirety of all contracts submitted as confidential, without the need for a separate request. Contract language is confidential — the language itself can be hard fought and have a monetary value to a provider. CHA members are concerned that disclosing the information without assurance of confidentiality could lead to unfair negotiating advantage for payers.

III. Next Steps

Based on discussions with DMHC, it is CHA's understanding that DMHC will evaluate contracts submitted during the phase-in period and then reevaluate next steps to implement the regulation, including evaluating additional arrangements that may be exempt from licensure. CHA appreciates that DMHC has indicated it is open to continued stakeholder discussions during this time, as a number of outstanding concerns related to the scope of the regulation remain, as well as questions about DMHC's implementation process after the initial phase-in period. Included below are topics CHA would like to continue discussing with DMHC and other stakeholders over the next few weeks and months.

Quantitative Standards for Exemption

CHA requests DMHC provide clear, quantitative standards allowing a provider to determine whether it is entitled to an exemption from the licensure requirement. The regulation permits DMHC 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.” A provider cannot accurately predict whether the department will grant its request for an exemption because the criteria outlined in the regulation are too vague. Therefore, we urge DMHC to establish that a provider that participates in particularly low-risk payment arrangements that fall below quantitative risk thresholds — including institutional risk pools and non-Medicare ACOs — are presumptively exempt from the regulation.

Regulatory frameworks outside of California are instructive in demonstrating how such thresholds might be developed and applied. For example, CMS and the state of New York have determined provider risk-bearing arrangements in which less than 25 percent of payments are at risk are sufficiently low-risk and do not require the same level of oversight.¹ Below these thresholds, providers can take on risk without closer scrutiny by regulators. These standards show 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 payers 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 payers in a financially stable manner.

These payment arrangements are common tools to improve care quality and coordination while posing minimal to no risk to patients, payers, 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 exempt if they meet quantitative thresholds.

With that in mind, we urge the department to include the following presumptive exemptions based on the level of risk:

- (A) A person shall be presumptively eligible for an exemption under this subdivision (f) if at least one of the following is true:
 - (i) No more than 25% of the person’s maximum annual revenue from health care services from all payors is at risk.
 - (ii) No more than 25% of the person’s sponsoring affiliate’s maximum annual revenue from health care services from all payors is at risk.

¹ 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.

- (iii) No more than 25% of the person's tangible net equity is at risk across all payors with whom the person has entered into payment arrangements.
- (iv) No more than 25% of the person's sponsoring affiliate's tangible net equity is at risk across all payors with whom the sponsoring affiliate has entered into payment arrangements.
- (v) No more than 25% of the person's cash on hand is at risk across all payors with whom the person has entered into payment arrangements.
- (vi) No more than 25% of the person's sponsoring affiliate's cash on hand is at risk across all payors with whom the sponsoring affiliate has entered into payment arrangements.

To establish eligibility for a presumptive exemption based on level of risk, a person, provider, or other organization should be required simply to provide materials and information demonstrating its satisfaction of the applicable risk thresholds.

Exemption Process

The procedure by which the department evaluates exemption requests after the phase-in period should be designed to give providers clarity and finality. To give providers greater certainty around the 30-day time frame for the department to respond to requests for exemption, as outlined in the regulation, CHA urges 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 to clarify 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 be given until the latter of 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.

CHA appreciates the opportunity to provide comments on DMHC's draft guidance. We look forward to continued discussions with DMHC and stakeholders to ensure the regulation strikes the proper balance between protecting the public and encouraging value-based care. If you have any questions, please contact me at (916) 552-7543 or akemp@calhospital.org.

Sincerely,



Amber Kemp
Vice President, Health Care Coverage