From: DMHC Licensing eFiling
Subject: APL 20–017 - General Licensure Regulation
Date: Thursday, April 16, 2020 4:52:52 PM

Attachments: APL 20-017 - General Licensure Regulation (4.16.2020).pdf; Revised General Licensure Reg Guidance issued 6.13.19 (updated 4.16.2020).pdf

Dear Health Plan Representative:

Please find the attached APL 20-017 in regards to general licensure requirements as well as the revised general licensure regulation guidance.

Thank you.

Gavin Newsom, Governor
State of California
Health and Human Services Agency
DEPARTMENT OF MANAGED HEALTH CARE
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ALL PLAN LETTER

DATE: April 16, 2020

TO: All Health Care Service Plans; All Risk Bearing Organizations

FROM: Sarah Ream, Acting General Counsel

SUBJECT: APL 20-017 – General Licensure Regulation: Extension of Phase-In Period For Expedited Exemption Requests

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On June 14, 2019, the Department of Managed Health Care (DMHC) issued All Plan Letter 19-014. The All Plan Letter provided guidance regarding the Department's recently adopted General Licensure Regulation. The General Licensure Regulation requires an entity that accepts any amount of global risk, as defined in the General Licensure Regulation, to obtain either: (1) a health care service plan license; or (2) an exemption from the licensure requirements.[1]

The All Plan Letter also provided for a "phase-in" period during which entities seeking an exemption from the licensure requirements could take advantage of an expedited exemption request process. The phase-in period provided by All Plan Letter 19-014 runs from July 1, 2019 through June 30, 2020.

Due to the uncertainty caused by the COVID-19 pandemic, **the DMHC is extending the phase-in period through December 31, 2020**.

The DMHC has updated the guidance document it issued with All Plan Letter 19-014 to reflect the extended phase-in period. The updated guidance document is attached to this All Plan Letter.

If you have questions or concerns regarding this APL, please contact Phuc Nguyen, Assistant Chief Counsel in the Office of Plan Licensing, at (916) 323-0416 or via email at phuc.nguyen@dmhc.ca.gov.

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[1] California Code of Regulations, title 28, section 1300.49.

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Guidance Regarding DMHC General Licensure Regulation

(Issued June 13, 2019; Revised April 16, 2020)

I. Background Regarding Regulation

The Department of Managed Health Care (DMHC) recently adopted a regulation that, among other things, defines various types of risk and requires entities that assume any amount of global risk to either obtain a license under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act) or receive an exemption[1] from the DMHC for the contract(s) under which the entity assumes global risk.[2]

The regulation defines the following terms that are relevant to this guidance:

- "Global risk," which means "the acceptance of a prepaid or periodic charge from or on behalf of enrollees in return for the assumption of both professional and institutional risk."
- "Institutional risk," which means "the assumption of the cost for the provision of hospital inpatient, hospital outpatient, or hospital ancillary services to subscribers or enrollees undertaken by a person, other than services performed pursuant to the person's own license…in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee."

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[1] The receipt of an exemption from the application of the general licensure regulation does not mean the DMHC "approves" the terms of the contract for other purposes. Notwithstanding the grant of an exemption, the DMHC may find that a contract violates other portions of the Knox-Keene Act if the contract conflicts with the requirements of the Act. Such conflicts could include, but are not limited to: the requirement that medical decisions be rendered by qualified medical providers unhindered by fiscal management; the requirement that medical decisions be made by qualified medical professionals acting within the scope of licensure; and, the requirement that enrollees have timely access to medically necessary care.

[2] This guidance does not address applications for licensure under the Knox-Keene Act. For questions regarding licensure, please contact the DMHC at duty.counsel@dmhc.ca.gov.

- "Professional risk," which means "the assumption of the cost for the provision of physician, ancillary, or pharmacy services undertaken by physicians or other licensed or certified providers to subscribers or enrollees in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee."

- "Prepaid or periodic charge," which means "any amount of compensation, either at the start or end of a predetermined period, for assuming the risk, or arranging for others to assume the risk, of delivering or arranging for the delivery of the contracted-for health care services for subscribers or enrollees that may be fixed either in amount or percentage of savings or losses in which the entity shares."

The regulation applies to any contract entered into, amended, or renewed on or after July 1, 2019. For purposes of this guidance, "Entity" refers to any person or organization that:

1. does not have a Knox-Keene Act license, or is not licensed as an insurer by the California Department of Insurance (CDI); and,

2. assumes any amount of global risk on a pre-paid or periodic basis, including a payment at the end of a contract or term.

The DMHC has determined that a number of contracts, although technically falling within the ambit of the new regulation, do not need to comply with the regulation at this time because the Director of the DMHC has determined it is in the public interest and not detrimental to the protection of subscribers, enrollees, or person regulated under this chapter, and the regulation of these contracts is not essential to the purposes of the Knox-Keene Act. These types of contracts are described in Section II below. Entities entering into these types of contracts do not need to file the contracts with the DMHC.

For all other contracts that involve the assumption of global risk, including those contracts that involve only "upside" risk, the DMHC is phasing in the exemption application process and temporarily expediting exemption requests to give Entities time to comply with the regulation and to ensure an orderly implementation of the regulation. **The phase-in period is July 1, 2019, ~~to June 30, 2020~~ through December 31, 2020**.

During the phase-in period, Entities that assume global risk must file with the DMHC their global risk contracts within 30 days of execution of the contract by all parties.[3] They do not need to receive an exemption from the DMHC before finalizing or beginning performance under the contract.

As discussed below, during the phase-in period, the DMHC will automatically grant an exemption to contracts submitted to the DMHC by Entities pursuant to this guidance.

[3] Neither the regulation nor this guidance relieves DMHC-license health plans from the obligation to file their contracts with the DMHC for review and approval as required by the Knox-Keene Act and its implementing regulations, including California Code of Regulations, title 28, section 1300.51.

The duration of the exemption is for either the term of the contract or two years, depending on whether a licensed health plan is a party to the contract.

II. Contracts/Arrangements That Do Not Need To Be Filed With The DMHC

A. Bundled Payment, Case Rate, Diagnosis-Related Group Payments, and Per Diem Arrangements.

The DMHC understands that some arrangements between DMHC-licensed health plans, hospitals, and/or provider groups involve:

- Bundled Payments
- Case Rates
- Diagnosis-Related Group (DRG) Payments
- Contracts for professional services provided in a hospital emergency department
- Per diem payments pursuant to which the provider (typically a hospital and/or provider group) assumes financial responsibility for providing or arranging for all services associated with an episode of care. In exchange for the bundled payment, the hospital/provider agrees to provide or arrange for all necessary care, including hospital services, professional services, and other attendant medical services, associated with the episode.
- Agreements between a DMHC-licensed health plan and a provider for professional capitation-only where, under the Division of Financial Responsibility (DOFR), the provider assumes financial responsibility for professional services that may be provided in a hospital facility (e.g., radiation therapy, hemodialysis, chemotherapy, amniocentesis, imaging services) but the provider does not share in any savings or losses the hospital may incur.

The arrangements identified above do not need to be filed with the DMHC at this time.[4]

B. CMS Accountable Care Organizations

The Centers for Medicare and Medicaid Services (CMS) supports a number of models of Accountable Care Organizations (ACOs) through which providers, hospitals and CMS contract to provide coordinated care to Medicare patients. CMS selected the organizations that participated or are participating in these ACO models.

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[4] If an arrangement/contract involves both bundled payments, case rates, DRG payments and/or per diems, plus other types of global risk sharing, such as risk pools or global budgets, the Entity assuming global risk must apply for an exemption.

Entities that are not DMHC-licensed health plans (e.g., medical groups, hospitals) do not need to submit their contracts pursuant to which they participate in a CMS ACO, as the DMHC finds those contracts to be outside the requirements of the regulation.[5] Entities do not need to file these contracts with the DMHC at this time.

C. Arrangements Where the Payer is a CDI Licensed Insurer

To the extent an Entity assumes global risk as defined under the regulation, and all of the consumers impacted by the global risk arrangement are covered by a CDI-licensed insurer, the DMHC has determined such arrangements to be outside the requirements of the regulation. Entities do not need to file these contracts with the DMHC at this time.

III. Expedited Processing of Exemption Requests During Phase-In Period

A. Prior DMHC approval is not required during the phase-in period of July 1, 2019 ~~to June 30, 2020~~ through December 31, 2020.

For all contracts involving any amount of global risk (other than the contracts/ arrangements discussed in Section II, above) that an Entity enters into or renews between July 1, 2019, and ~~June 30, 2020~~ December 31, 2020, the Entity or someone acting on the Entity's behalf, must submit a Request for Expedited Exemption to the DMHC by the later of:

- Thirty (30) days after all parties have executed the contract or renewal; or,
- Thirty (30) days after the effective date of the contract or renewal.

If an entity enters into, renews, or amends a contract that must be submitted to the DMHC for an exemption within the last 30 days of the phase-in period, or the contract has an effective date during the last 30 days of the phase-in period, the entity's submission of the contract and exemption request is timely if submitted within 30 days of execution or the effective date, even if the 30th day is later than ~~June 30, 2020~~ December 31, 2020.

An "evergreen" renewal is a renewal for purposes of this guidance. In the event a contract for which the DMHC previously granted an exemption renews via an evergreen clause, the party(ies) must submit the renewed contract within 30 days of the date the contract renewed. However, short-term renewals of 90 days or less, without other material changes to the contract, do not need to be filed with the DMHC.

Upon receipt of the Request for Expedited Exemption, the DMHC will deem the contract to be exempt from the requirements of the regulation and will issue an Order of Exemption.

[5] DMHC-licensed health plans should continue to submit their provider contracts to the DMHC for review and approval per the requirements of the Knox-Keene Act.

The duration of the exemption will be either:

- the term of the contract, if a DMHC-licensed health plan is a party to the contract; or
- if a DMHC-licensed health plans is not a party to the contract, the earlier of two years from the date the DMHC grants the exemption or the renewal or amendment of the contract.

B. Non-substantive contract amendments do not need to be filed.

If the parties to a contract make non-substantive amendments to a contract that do not affect the risk arrangements between the parties and the DMHC previously issued an Order of Exemption regarding the contract, the contract amendments do not need to be submitted to the DMHC for an exemption.

Notwithstanding the above, the types of contract amendments that must be submitted to the DMHC for an exemption include, but are not limited to:

- changes to the risk sharing arrangements described in the contract
- extensions to the duration of contract
- amendments regarding the parties to the contract

C. Which Entities must file the Request for Expedited Exemption?

In a contract where only one party assumes global risk, only the party assuming global risk needs to receive for an exemption. Below are two examples of contracts that would need to be filed with the DMHC and the Entities that would need to receive an exemption.

- Example: A hospital and provider group have a contract under which the *provider group* will receive a bonus/shared savings if certain targets are met. The contract does not contain a similar provision for the hospital. In this example, the provider group is assuming global risk but the hospital is not, because the hospital is at risk only for the services it provides. Therefore, the provider group must receive an exemption for the contract but the hospital does not need an exemption.
- Example: A hospital and a provider group set a global budget to provide care (institutional and professional) for a population of consumers. The hospital and provider group will share any savings achieved if the total expenditure for the population is less than the global budget. In this example, both the hospital and the provider group have assumed global risk and each must receive an exemption.

The DMHC received a number of questions about whether one party to a contract may file contracts on behalf of another party to the contract—e.g., may a hospital file contracts on behalf of the provider groups it contracts with? The answer is "yes" during the phase-in period. The DMHC has modified the Request for Expedited Exemption Form (**see attachment to this guidance**) in contemplation that one entity might submit exemption requests on behalf of another entity.

The DMHC also received feedback that some entities would like to submit multiple contracts with one submission. During the phase-in period entities may do this. The DMHC has also modified the Request for Expedited Exemption Form to allow for multiple contracts to be submitted at once.

D. What must an Entity file to obtain an expedited exemption?

To obtain an expedited exemption, the Entity, or a person acting on the Entity's behalf (e.g., an attorney, another party to the contract), must submit to the DMHC:

1. A copy of the executed contract.
2. The Request for Expedited Exemption Form or a cover letter that includes all of the information requested in the form.

E. What if the Entity wants the contract, or a portion thereof, to be treated as confidential?

If the Entity wants the DMHC to treat the contract or any portion thereof as confidential, in addition to submitting the contract and the Request for Expedited Exemption Form, the Entity must also:

1. Submit a justification for confidential treatment that includes the basis for the request and the time period for which the Entity wants confidential treatment. The DMHC has created a Request for Confidentiality form submitters may use to request confidential treatment. **The form is attached to this guidance.**
2. If the Entity seeks confidential treatment for a portion of the contract (e.g., payment rates), submit a copy of the contract with the confidential information redacted and a copy of the contract without redactions. The DMHC will treat the redacted version of the contract as public and subject to requests under the California Public Records Act.

During the phase-in period, the Entity **should not submit** to the DMHC any other information required under the regulation (e.g., financial statements, geographic service areas, percentage of annualized income from institutional risk, estimated number of enrollees) at the time the Entity submits the request for an expedited exemption.

F. Where should the Entity submit its request for an expedited exemption?

Submit the information outlined above to the DMHC either by emailing the information to OPLInquiries@dmhc.ca.gov or mailing the information to the DMHC addressed as follows: Department of Managed Health Care, ATTN: Office of Plan Licensing, Exemption Request, 980 9th Street, 5th Floor, Sacramento, CA 95814.

Please direct questions regarding this guidance to Sarah Ream, Acting General Counsel, at (916) 324-2522 or sarah.ream@dmhc.ca.gov.