California Proposes Regulations for Health Care Entity Pre-Transaction Notices

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On July 31, 2023, the California Office of Health Care Affordability ("OHCA") published proposed regulations requiring health care entities to notify OHCA 90 days before engaging in certain types of common transactions (the "Proposed Regulations"). The Proposed Regulations implement part of the California Health Care Quality and Affordability Act, which was passed last year, and created OHCA. This statute gave OHCA broad responsibility for controlling the growth of health care costs in California, including requiring it to review certain health care transactions occurring on or after April 1, 2024. Comments on the Proposed Regulations are due by August 31, 2023.

The Proposed Regulations mandate a two-step process: (1) 90-day advance notice to OHCA of any material change in the ownership or control of a covered entity's assets or operations, and (2) an extensive "cost and market impact" review of these transactions, if and when OHCA determines the material change is likely to have a significant impact on market conditions or costs. The submitter must wait for OHCA to complete its review and issue its final report before the submitter consummates the transaction, but OHCA cannot block the transaction.

Health care entities will be required to comply with OHCA's notice and possible review obligations as early as January 1, 2024 in order to provide the required 90 days' prior notice of an agreement or transaction occurring on or after April 1, 2024.

Although the Proposed Regulations add details, significant questions remain. In particular, the Proposed Regulations would appear to require notice (and potential review) of a broad range of activities that occur frequently in the ordinary course of business, potentially adding considerable costs and delays.

Here are some of the key provisions of the Proposed Regulations.

1. **The Proposed Regulations both expand and narrow the categories of "health care entities" subject to OHCA's material change notice and possible cost and market review**.

The notice and review requirements apply to certain agreements or transactions involving a "health care entity," which includes: (i) payers, such as Knox-Keene plans; (ii) providers, including health facilities, clinical laboratories, and physician organizations; and (iii) fully integrated delivery systems. (Certain categories of agreements or transactions are exempted from OHCA's notice requirement, such

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as those reviewed by other regulatory agencies).

The Proposed Regulations would ***narrow*** this scope to cover only such health care entities (i) with annual revenue or California assets of at least $25 million, (ii) with annual revenue or California assets of at least $10 million involved in a transaction with a health care entity with annual revenue or California assets of at least $25 million, or (iii) that are located in or serve at least 50% of patients residing in a "health professional shortage area."

However, the Proposed Regulations would ***expand*** the definition of "health care entity" to include: (i) management services organizations; and (ii) any affiliates, subsidiaries, or other entities that control, govern, or are financially responsible for the health care entity or that are subject to the health care entity's control, governance, or financial control.

Under this broad language, entities that do not directly provide or pay for health care services may come under the regulations as affiliates of a health care entity.

Note, the health care entity bears the obligation to submit the notice to OHCA, not the non-health care entities involved in the transaction, which may impact how OHCA notice and review compliance obligations arise in future deals. Further, it appears that if multiple health care entities are party to a transaction, but the transaction results in a material change for only one of the entities, all the other health care entity parties still need to provide notice.

2. **The Proposed Regulations define "material change" broadly, and may include activities occurring frequently in the ordinary course of business**.

The Proposed Regulations would include the following, among others, as constituting a material change that requires notice to OHCA:

- Any transaction involving the sale, transfer, lease exchange, option, or encumbrance, or other disposition of 20% or more of the assets of any health care entity in the transaction (this appears to cover any loan, when the borrower pledges its assets as security);
- Any transaction involving a transfer or change in control, responsibility, or governance of the submitter (the Proposed Regulations appear to include even a change of minority membership, and arguably even a change in a single member of a board of directors or other governing body);
- Any change in the "form of ownership" of a health care entity (potentially a change such as converting from a corporation to a limited liability company would be covered);
- Any transaction that contemplates an entity negotiating or administering contracts with payers on behalf of one or more providers, and involves an accountable care organization, management services organization, or other organization (this could include any instance of an entity negotiating an agreement with an ACO, or negotiating with a payor on behalf of itself and an affiliate); and
- Any transaction regarding provision of health care services in California that occurs within 10 years of a prior transaction with another party to the current transaction.

3. **Complying with the notice requirements may be onerous and expensive** .

The proposed notice requirements are likely to be burdensome and costly. The Proposed Regulations include a long list of specific information and documents a health care entity must provide when submitting notice to OHCA of a material change.

The notice would need to include: (i) a description of the transaction, including its goals, summary of its terms, a statement as to why the transaction is necessary or desirable, its public impact, competitive impacts, and actions or activities to mitigate potential adverse impacts on the public; (ii) a description of other prior transactions that affected or involved the provision of health care services involving any of the health care entities in the proposed transaction that occurred in the last 10 years; and (iii) a description of the potential post-transaction changes, including with respect to competition within 20 miles or any physical facility offering comparable patient services. This would require pre-filing research, analysis and documentation, and many health care entities likely would enlist assistance from outside professionals to prepare materials required for the

notice.

Additionally, the Proposed Regulations would also require health care entities to submit information about any other entities involved in the material change, including their governance and operational structure, annual revenues, certain patient services data, copies of financial statements, and other information and documents. Consequently, health care entities would need to coordinate and obtain cooperation from these parties in order to comply with the proposed notice requirements.

All of the notice and related information and documents would be submitted to OHCA under penalty of perjury, which would place a premium on accuracy and completeness. In addition, all information and documents submitted to OHCA would be treated as a public record unless the submitter designates the documents or information as "confidential" and OHCA accepts this designation.

4. **Triggering OHCA's cost and market review may result in significant delays in a proposed agreement or transaction.**

An agreement or transaction subject to OHCA's "cost and market" impact review will likely face considerable delays. OHCA has 60 days from the date it receives a complete notice of a material change to determine whether a cost and market impact review is required, though the Proposed Regulations would give OHCA the authority to toll the 60-day period, for example, when waiting for additional requested information or while the transaction is pending review by another state or federal agency or court. OHCA may then take up to an additional 135 days to complete its preliminary review, not including time for OHCA to receive the parties' and the public's comments on the preliminary report, or to issue its final report. An agreement or transaction subject to cost and market review cannot be implemented until at least 60 days after OHCA issues its final report.

OHCA has the option to refer its findings to the California Attorney General for its own independent investigation. Parties might hesitate to proceed with a transaction after referral to the California Attorney General.

5. **Key Takeaways of the Proposed Regulations and Next Steps**

Although the Proposed Regulations are not yet finalized, health care entities and their business partners should begin thinking now about the possible impacts of the notice and review obligations on transactions currently under consideration. A few key takeaways—

- If possible, health care entities should complete their transactions before April 1, 2024.
- Health care entities should understand how routine governance changes or other changes in the ordinary course of business could trigger OHCA notice and possible review obligations.
- Consider how agreements and transactions should address possible OHCA notice and review. For example, consider addressing the parties' obligations if the transaction is delayed due to a review, or referred to the California Attorney General.
- Health care entities should consider submitting robust initial notices to OHCA, including explaining the transaction's impact on market competition, health care costs and statewide cost targets, and identifying benefits to patients and health care services – in short, why the material change will not result in any significant negative impact on competition or costs, and thus should not trigger a "cost and market" review.
- Health care entities and their business partners should consider the increased likelihood that transactions with greater impact on market competition may be scrutinized by the Attorney General for possible antitrust or unfair competition concerns.
- While the Proposed Regulations answer some open questions about the process, many uncertainties remain. Interested parties should consider submitting comments in in an effort to have their concerns addressed in the final regulations.

OHCA is accepting written comments on the Proposed Regulations until 5:00 PM PST on August 31, 2023. Additionally, OHCA is hosting a public workshop on the Proposed Regulations, to receive oral and written comments, on August 14, 2023, starting at 10:00 AM PST (virtual and physical attendance options). OHCA submits its final proposed regulations in September 2023.

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