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California Regulators Publish Highly Anticipated Draft Regulations on Mandatory Pre-Transaction Notices for Health Care Entities

Article By:

Paul A. Gomez

Ashley N. Osak

Matthew T. Lin

Introduction

Last week, the Office of Health Care Affordability ("OHCA") published draft regulations to implement the requirements for California health care entities filing mandatory notices of material change under SB 184. The draft regulations can be found here. The draft regulations address many unanswered questions about SB 184's pre-transaction notice requirements by clarifying, among other issues, the timing of the notices, the types of entities and transactions subject to the notice requirements, the content of the notices, and the standards for conducting the more in-depth Cost and Market Impact Review ("CMIR"). The regulations as currently drafted will require extensive public disclosures on mergers, acquisitions and certain affiliations of California health care entities. Intentional or not, the OHCA's draft regulations may also have a chilling effect on health care transactions in California due to the extensive costs and exposure imposed by the notice requirements. The OHCA is receiving public comment on the regulations though the end of August with the goal of finalizing the regulations by January 1, 2024.

Background

As detailed in our previous article, SB 184 created the OHCA in 2022 with the goal of analyzing and regulating health care costs in California. For transactions occurring on or after April 1, 2024, SB 184 requires health care entities to provide public written notice to OHCA at least ninety (90) days prior to entering a transaction that involves the transfer of ownership or control over a material amount of the entity's assets or operations. These transactions may not close until after OHCA completes its review of the notices and (1) completes a CMIR or (2) declines to conduct a CMIR.

SB 184 also authorized OHCA to adopt regulations implementing the pre-transaction notice procedures through emergency rulemaking in order to fully establish the procedure before January 1, 2024. The emergency rulemaking process for these draft regulations will be expedited compared to

the rulemaking process typically employed for California regulations. The OHCA has proposed the following schedule for soliciting public comment and implementing the regulations:

- **August 15, 2023**: OHCA will host a public workshop to receive oral and written comments on the draft regulations. The notice of the workshop can be found here.
- **August 22, 2023**: The Health Care Affordability Board (the governing board within the OHCA) (the "Board") will discuss the draft regulation text and provide an oral summary of the public workshop.
- **August 31, 2023, 5:00 p.m. PT**: Deadline for submission of written comments on the draft regulations.
- **September 19, 2023**: The Board will hear an update on the status of the regulations.
- **October 2023**: OHCA will submit the regulations as an emergency rulemaking package to the Office of Administrative Law ("OAL").
- **January 1, 2024**: OHCA will begin receiving pre-transaction notices.

Overview

Given the expedited schedule for soliciting public comment on these regulations, it is critical for members of California's health care industry to be aware of the draft regulations' potential impact on future transactions. Here are some key questions that have been addressed by the draft regulations:

(1) When do entities have to submit notices of material change to OHCA?

The draft regulations would require notice of transactions at least ninety (90) days before "the date any parties' respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived." Although this wording could be clearer, the draft regulation would most likely require the notice to be provided at least ninety (90) days prior to the transaction closing or becoming otherwise effective.

(2) Who must file the notices?

The draft regulations would require the notices to be filed if (A) a health care entity involved in the transaction meets certain threshold requirements and (B) the transaction is a "material change" (defined below), unless the health care entity meets an exception listed under SB 184.

SB 184 broadly defines "health care entity" to include payors, providers and fully integrated delivery systems (each with further definition in the statute). The statute has limited exceptions for certain types of health care entities, such as nonprofit corporations subject to review by the California Attorney General. The draft regulations would narrow the scope of health care entities subject to the notice requirement—a health care entity would be subject to the notice requirements if: (1) it has annual revenue or California assets of at least $25 million; (2) it has annual revenue or California assets of at least $10 million and where the transaction involves an entity with annual revenue or California assets of at least $25 million; or (3) it is a health care entity located in or serving at least 50% of patients residing in a health professional shortage area.

Under the draft regulations, a transaction is a “material change” if certain circumstances exist. These circumstances include: (1) the transaction has a fair market value of at least $25 million; (2) the transaction is likely to increase annual revenue of a health care entity by at least $10 million or 20%; (3) the transaction involves disposition of at least 20% of the assets of any health care entity; (4) the transaction involves a change of control of a health care entity; (5) the transaction contemplates an entity negotiating or administering contracts with payors on behalf of one or more providers and involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, management services organization or other organization; (6) the transaction would form a new entity for provision of health care services in California that is projected to have at least $25 million in annual revenue or assets; (7) the transaction involves a health care entity joining, merging or affiliating with another health care entity, affiliation, partnership, joint venture or parent corporation where the health care entity has at least $10 million in annual revenue; (8) the transaction involves changing the form of ownership of a health care entity, including changes from a physician-owned to a private equity-owned entity or from a publicly-held to a privately-held entity; and (9) a health care entity that is party to the transaction has consummated any transaction regarding provision of health care services in California with another party to the transaction in the 10 years prior to the transaction subject to the notice. The draft regulations state that a transaction is not a “material change” if the health care entity already controls, is controlled by or is under common control with all other parties to the transaction, such as in a corporate restructuring.

(3) What information must be included in the notice?

The draft regulations would require the notices to include narratives describing the transaction and supporting documentation. The information required in both the narratives and the documentation would be extensive.

The narrative information would include descriptions of the entities to the transaction, such as the name, address, geography served, entity type, corporate structure, applicable California licenses and annual revenue. The narrative would also provide details about the transaction, including the goals of the transaction, a summary of the terms of the transaction, a statement of why the transaction is necessary or desirable, a description of the general public impact or benefits of the transaction, a description of the expected competitive impacts of the transaction and a description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public. The narrative would include a statement on whether the proposed transaction had been subject to any court proceeding, a description of the current services provided by the health care entity and the expected impacts on services post-transaction, descriptions of any transaction in the prior 10 years involving the health care entities in the proposed transaction that affected or involved the provision of health services, and a description on the post-closing structure’s impact on the health care entity’s operations. In addition, the entity providing notice would also describe any pending or planned material changes occurring between the submitting entity and any other entity in the 12 months following the date of the notice.

The noticing health care entity would also be required to submit supporting documentation. Each narrative answer would have to be supported with citations to the supporting documents. The draft regulations would also require: copies of the current agreement(s) and term sheet(s) governing the transaction; contact information for signatories to the agreement; if applicable, pro forma post-transaction balance sheet(s) for any surviving or successor entity; organization charts for all entities to the transaction pre- and post-transaction; certified financial statements for the prior three (3) years for all entities party to the transaction; corporate documents for all parties to the transaction; if applicable, a copy of the Premerger Notification and Report Form, with attachments, submitted to the

Federal Trade Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976; any documentation related to the mitigation of any potential adverse impacts of the transaction on the public; and any analytic support and/or documents supporting the narrative responses.

Note that these notices would be public and submitted under penalty of perjury.

(4) Will health care entities be able to protect confidential information when submitting notices?

The draft regulations would provide some protections for confidential information. All information would be treated as public by default, although the submitting entity could designate all or some of a document as confidential. Stock purchase agreements, financial documents, compensation documents, contract rates and unredacted resumes marked as confidential would be treated as confidential by OHCA automatically. The draft regulations would require all other documents marked as confidential to be supported by a redaction log explaining the need for confidentiality and the time for which confidential treatment of the information is necessary. Bases for confidentiality would include: (1) the proprietary nature of the information contained; (2) that confidentiality of the information serves the public interest; and (3) that the information is confidential by law. OHCA would determine whether to treat documents as confidential. If a document is deemed confidential, the entity providing notice would still be required to submit an unredacted copy of the document to OHCA, but OHCA would remove the confidential document or redact the confidential portions of document from the public file.

(5) What does OHCA do after receiving the notices?

OHCA must inform the noticing health care entity of its decision to conduct a CMIR within 60 days of receipt of the complete notice, although this deadline may be tolled in certain circumstances. In deciding whether to conduct a CMIR, the draft regulations would allow OHCA to consider the transaction's potential to: (1) negatively impact the availability or accessibility of health care services, including the ability to offer culturally competent care; (2) negatively impact costs on payers, purchasers or consumers, including the ability to meet health care costs targets established by the Board; (3) lessen competition or create a monology in a geographic service area; (4) affect a general acute care or specialty hospital; (5) negatively impact the quality of care; and (6) if the transaction is between a California health care entity and an out-of-state entity, increase the price of care or limit access to health care services in California.

If OHCA decides to conduct a CMIR, it must complete the CMIR within ninety (90) days of its decision, although that deadline may also be tolled in certain circumstances. The draft regulations would allow OHCA to consider the following non-exclusive factors when conducting a CMIR: (1) the transaction's effect on the availability or accessibility of health care, including the accessibility of culturally competent care; (2) the transaction's effect on the quality of care; (3) the transaction's effect of lessening competition or creating a monopoly; (4) the transaction's effect on any health care entity's ability to meet health care cost targets established by the Board; (5) whether the parties to the transaction have been parties to other transactions below the thresholds requiring a notice of material change; (6) consumer concerns; and (7) any other factor OHCA determines to be in the public interest.

After the CMIR, OHCA will publish a preliminary report and allow public comment for 10 business days. OHCA will issue a final report on its findings within 30 days of the close of the comment period, unless that deadline is extended for good cause. If OHCA conducts a CMIR on a transaction, the

transaction may not be implemented until 60 days after OHCA issues its final report.

Conclusion

Members of the California health care industry should pay close attention to this summer's developments of the draft regulations to anticipate its impact on transactions beginning in 2024. As currently drafted, OHCA's review process will likely affect the occurrence of and timing related to mergers, acquisitions and affiliations involving California health care entities. Any entities considering such transactions will have to consider the impacts on the review process, including additional time and money spent on preparing the notices, the time spent in waiting for OHCA to complete initial review and potentially a CMIR, and the impacts of the publicity of such transactions. They should also plan carefully and invest in the time needed to preemptively address the factors that OHCA may review in more detail when submitting the initial required notice.

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