California Regulators Publish Draft Regulations on Health Care Pre-Transaction Notice Requirements

August 29, 2023

As detailed in our previous article, the California Health Care Quality and Affordability Act ("SB 184" or the "statute") established the Office of Health Care Affordability ("OHCA" or the "Office"), whose portfolio is to collect and report data that are informative to the legislature and the public regarding health care expenditures and cost trends in order to develop data-informed policies and enforceable cost targets. The statute gives OHCA the authority to analyze health care mergers, acquisitions, affiliations and other transactions involving regulated health care entities. SB 184 requires the Office to adopt implementing regulations before January 1, 2024, when it is slated to begin receiving notice filings. Last month, OHCA responded with its draft regulations (the "Draft Regulations"),[1] which we summarize below.

SUMMARY OF OHCA'S DRAFT REGULATIONS

Regulated Health Care Entities

SB 184 broadly defines "health care entity" to include payors, providers and fully integrated delivery systems. The Draft Regulations appear to expand the statute's definition of "health care entity" to include: (i) pharmacy benefit managers; (ii) management services organizations ("MSOs"); and (iii) any affiliates or other entities that control, govern or are financially responsible for the health care entity or that are subject to the control, governance or financial control of the health care entity. This last clause would seem to capture any entity up the chain from the actual health care company, including private equity and other financial investors. The Draft Regulations set thresholds to determine which types of health care entities could be required to file the notice described in the statute. These thresholds include a health care entity that:

- has an annual revenue[2] of at least $25 million or owns or controls California assets of at least $25 million;

---

1 The Regulations are available here.

2 The Regulations limit the calculation of "annual revenue" to California-derived revenue.

- has an annual revenue of at least $10 million or owns or controls California assets of at least $10 million and is involved in a transaction with any health care entity with annual revenue of at least $25 million or that owns or controls California assets of at least $25 million; or

- is located in or serving at least 50% of patients who reside in a health professional shortage area.

Circumstances Constituting a "Material Change"

SB 184 requires a health care entity that meets any of the thresholds described above to provide notice to OHCA of a transaction that constitutes a "material change." In their current form, the Draft Regulations delineate nine broad circumstances that trigger SB 184's notice requirements, including transactions: (i) with a proposed market value of at least $25 million or more; (ii) that implicate 20% or more of a health care entity's assets or revenue or are likely to increase a health care entity's annual revenue by at least $10 million; (iii) that change the form of ownership of a health care entity from physician-owned to private equity-owned or public to private; or (iv) that involve a change of control, defined as 10% or more of the control or governance of a health care entity. Defining a change of control in this context as a mere 10% change will obviously pick up a large swath of smaller investment transactions, and investors and others will need to keep this in mind if the Draft Regulations are adopted as written.

Notice Requirements

Transacting parties are required to notify OHCA 90 days before "entering into the agreement or transaction," which the Draft Regulations clarified to mean the date a party's respective rights vest in a binding agreement or all the contingencies to the agreement are met or waived. While this language is not entirely clear, it appears to require parties to notify the OHCA 90 days before closing, not signing. Notifying parties would be required to provide the Office a substantial amount of information, including detailed descriptions of: (i) the parties to a transaction; (ii) the transaction itself; (iii) any other investigations into, or proceedings involving, the transaction (e.g., other state or federal agency investigations or court proceedings); and (iv) any prior transactions involving a notifying health care entity during the preceding 10 years. All information and documentation provided to the Office under the requirements of SB 184 are submitted under penalty of perjury.

Timing of OHCA's Review

SB 184 provides OHCA with 60 days after receipt of a notice of a material change to decide whether to conduct a cost and market impact review ("CMIR"). The Draft Regulations would allow the Office to toll such initial review period while other state or federal agencies or courts are reviewing the transaction. Should OHCA decide to

conduct a CMIR, the Draft Regulations afford the Office 90 days to complete its review and issue a preliminary report, which the Office may extend by 45 days should it need additional time. The Draft Regulations also provide that OHCA may toll either of the 90-day or 45-day time periods while it waits for the parties to comply with its requests for additional information. The issuance of the preliminary report would be followed by a 10-business-day public comment period, after which the Office would be required to issue its final report within 30 days, unless it extends this time for good cause.

Cost and Market Impact Review

OHCA may consider a host of factors in its determination of whether to conduct a full CMIR, including: (i) the transaction's impact on the accessibility and quality of health care services and on competition; (ii) consumer concerns; and (iii) whether the parties to the transaction have engaged in prior transactions involving health care services. Should OHCA ultimately decide to conduct a CMIR, the Office would examine many of the same factors relating to a health care entity's business and its relative market position and any other factors the Office deems relevant and in the public interest.

KEY TAKEAWAYS

- **Dealmaking Implications**. Although the Office does not have the authority to block or challenge health care transactions, if adopted in their current form, the Draft Regulations may nonetheless have an adverse effect on health care dealmaking in California. The broad scope of transactions and targets subject to review is poised to overwhelm OHCA's limited resources as well as create a significant administrative burden for affected stakeholders. Additionally, the review process may cause substantial delays, during which time material facts to a transaction could change and jeopardize the deal. California health care entities should factor a potentially lengthy review process into their overall transaction timeline as well as consider the additional time and costs of preparing regulatory notices.

- **Focus on Private Equity**. By expanding the definition of "health care entity" to include MSOs as well as any entity that controls, governs or is financially responsible for a health care entity, as well as highlighting transactions that result in a change of ownership from physician-owned to private equity-owned, the Office appears to be signaling its intent to focus on private equity investments in the California health care market.

- **Confidentiality**. SB 184 requires the parties to a covered transaction to submit a large volume of highly sensitive information; the public disclosure of such information, as SB 184 requires through the Office's preliminary and final reports,

could cause substantial harm to the parties and jeopardize the transaction. The Draft Regulations appear to address this important issue by allowing parties to submit requests for confidential treatment of information submitted to the Office, minimizing potential harm related to disclosures required by the statute.

- **No Reimbursement Cap**. SB 184 permits OHCA to seek reimbursement from transacting parties for all actual, reasonable and direct costs related to its review and evaluation of material change transactions, including administrative costs. The Draft Regulations do not set a cap on such reimbursement amounts; therefore, transacting parties will be unable to determine the cost of a transaction, and moreover, transactions between smaller parties may face disproportionately high fees.

- **No Expedited Review**. Although SB 184 provides OHCA with a 60-day initial review period, it instructs OHCA to adopt regulations "that expedite [review] timelines, as warranted, depending on the nature of the agreement or transaction." The Draft Regulations, however, do not implement an expedited review process, even in the case of a financially distressed health care entity looking for an emergency capital infusion.[3]

The Draft Regulations are still in draft form and are subject to change: the public comment period closes on August 31, 2023, at 5:00 PM PT.[4] OHCA plans to submit the Draft Regulations as an emergency rulemaking package to the Office of Administrative Law in October 2023 and, as stipulated by SB 184, will begin receiving transaction notices on January 1, 2024.[5]

* * *

We will continue to monitor the status of the Draft Regulations and will provide an update when they are finalized. Please do not hesitate to contact us with any questions.

---

[3] Other states, such as Oregon, have implemented expedited review processes. The regulations promulgated by the Oregon Health Authority ("OHA") explicitly lay out regulations for "Emergency and Exempt Transactions" that contemplate exempting a covered transaction where an emergency "immediately threatens health care services; and the transaction is needed to protect the interests of consumers and to preserve the solvency of an entity." The OHA regulations are available here.

[4] Comments can be submitted to 2020 West El Camino Avenue, Suite 1200, or to CMIR@hcai.ca.gov.

[5] If the Regulations are approved by the Office of Administrative Law ("OAL"), they will become effective for 180 days when the OAL files them with the Secretary of State. OHCA could make the Regulations permanent by adopting them through the regular rulemaking process during the 180-day emergency period.

Andrew L. Bab
Partner, New York
+1 212 909 6323
albab@debevoise.com

Jennifer L. Chu
Partner, New York
+1 212 909 6305
jlchu@debevoise.com

Kevin Rinker
Partner, New York
+1 212 909 6569
karinker@debevoise.com

Kim T. Le
Counsel, San Francisco
+1 415 738 5706
kle@debevoise.com

Michael L. Cederblom
Associate, New York
+1 212 909 6043
mlcederblom@debevoise.com

Hannah R. Levine
Associate, New York
+1 212 909 6095
hrlevine@debevoise.com