California's Health Care Transactions Review Law: Regulatory Revisions Effective Immediately

Article By:

Kathryn F. Edgerton

Deborah A. Daccord

Stephnie A. John

Pamela Polevoy

Effective immediately, on August 22, 2024, the Office of Health Care Affordability (OHCA) adopted revisions to the cost and market impact review (CMIR) regulations (<u>Revised Regulations</u>), which govern California's pre-closing health care transaction review process. As discussed in our <u>prior post</u>, certain health care entities must provide OHCA with notice of a transaction at least 90 days prior to closing. The Revised Regulations, among other things: (1) expand who must file a notice; (2) narrow the applicability of the health care professional shortage area threshold; (3) clarify calculation of California-derived revenue; (4) clarify confidentiality of expedited review request documents; and (5) add a required attestation. We describe these revisions to the CMIR regulations in detail below.

Who Must File a Material Change Transaction Notice (MCN) Expanded

The Revised Regulations expand the applicability of the MCN filing requirement beyond a health care entity that is "a party to" a material change transaction to encompass a health care entity that is "a subject of" a material change transaction. Pursuant to the Revised Regulations, a health care entity is a subject of a material change transaction if the transaction will result in the transfer[1] of the health care entity's assets, control, responsibility, governance, or operations, in whole or in part to one or more entities. Thus, a health care entity not party to a transaction may be required to file an MCN with OHCA if it is a subject of a material change transaction.

Further, the Revised Regulations expand the applicability of the MCN filing requirement to consider common deal structures where a non-health care entity is a party to a transaction with a health care entity. For example, prior to the revision, a physician organization with \$10 million in revenue[2] or California assets would not be required to file an MCN if the counterparty to the transaction was not a health care entity (e.g., venture fund). However, post-revision, the physician organization would meet the threshold to file an MCN if the venture fund owned or controlled a health care entity with \$25 million in revenue or California assets.

Applicability of Primary Health Care Professional Shortage Area Threshold Narrowed

Prior to the revision of the regulations, a health care entity met the threshold for filing an MCN if the health care entity was located in a primary health care professional shortage area (HPSA). Although it is simple to determine whether certain types of health care providers (e.g., hospitals, physician practices) are located in HPSAs, questions arise regarding how to determine whether other types of health care providers are located in HPSAs (e.g., pharmacy benefit managers, health insurers). The Revised Regulations bring welcomed clarity that the HPSA threshold applies to providers and fully integrated delivery systems only.

California-Derived Revenue Clarified

The Revised Regulations clarified that for the purposes of determining whether a transaction meets the circumstances for filing only, "annual California-derived revenue" means revenue from the provision of health care services in California. Clarity is still needed as to what the provision of health care services in California means with respect to certain types of health care entities (e.g., laboratories).

Confidentiality of Expedited Review Request Documents Clarified

Pursuant to the CMIR regulations, a health care provider may request expedited review of its MCN if one or more of the parties to the transaction is in severe financial distress, including grave risk of immediate business failure. The Revised Regulations make clear that the process to request confidentiality of documents submitted in support of an MCN apply to documents submitted in support of a request for expedited review as well. Further, if a request for confidentiality is denied, even partially, the submitting health care entity may withdraw its request for expedited review. This clarification is particularly important because of the extremely sensitive business nature of the information required to support a request for expedited review.

Attestation Added

The Revised Regulations add a requirement that a health care entity attest, under the penalty of perjury, that it used reasonable diligence to ascertain the information required for the MCN. Practically, this means that the parties to the transaction must coordinate and share information early in the diligence process to ensure that each party has the information necessary to determine whether an MCN is required, and if required, that each party can attest that it acted with reasonable diligence to ascertain the required information.

Final Considerations

Although the Revised Regulations bring some welcome clarity, many questions abound. For example, how will OHCA determine the meaning of "related health care services"? How will OHCA judge whether a prior transaction is "similar to" the proposed transaction? Buyers, sellers, and other stakeholders entering into transactions involving health care entities with California revenue or assets will need to continue to assess the impact of the CMIR process and plan well in advance of closing before proceeding.

[2] As defined in 22 CCR § 97435(d).

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