

Bracing For Calif.'s New Health Transaction Framework

By **Jordan Grushkin and Matthew Goldman** (January 18, 2024)

As anticipated over the course of 2023, the cost and market impact review, or CMIR, regulations promulgated by the California Office of Health Care Affordability have been approved and are now in effect.

The final regulations were submitted by OHCA on Dec. 8, 2023, and approved by the California Office of Administrative Law on Dec. 18.

These regulations, in combination with the related statutory provisions in S.B. 184, set forth the framework for OHCA's authority to receive advance notice of and review a large scope of healthcare transactions in the coming months, reflecting a dramatic change to California's healthcare regulatory landscape.

To refresh and update stakeholders regarding the CMIR regulations, this article will provide an overview of the key components and practical considerations regarding this new reporting regime.

Who is subject to the CMIR process?

Healthcare Entities

Under S.B. 184, health care entities, which include payors, providers and fully integrated delivery systems, are potentially subject to OHCA's CMIR authority.

Under the law, payors include fully licensed Knox-Keene Act healthcare service plans, licensed health insurers, third-party administrators, publicly funded healthcare programs and pharmacy benefit managers.

Providers include physician organizations, including medical groups comprised of 25 or more physicians, medical foundations, restricted Knox-Keene plans and risk-bearing organizations; health facilities, including hospitals, nursing facilities, intermediate care facilities and hospices; outpatient clinics, including ambulatory surgery centers and specialty clinics; clinical laboratories; and imaging centers.

OHCA considered deeming management services organizations as healthcare entities subject to the CMIR process, but they were not included as healthcare entities in the final regulations.

However, the regulations do include parents, affiliates or subsidiaries of a payor that act in California on behalf of a payor and (1) control, govern or are financially responsible for the payor; (2) are subject to the control, governance or financial control of the payor; or (3) in the case of a subsidiary, are a subsidiary acting on behalf of another subsidiary.

Physician organizations with fewer than 25 physicians can be considered a healthcare entity if they are determined to be a high-cost outlier.

Entities Subject to the Process



Jordan Grushkin



Matthew Goldman

While healthcare entities are broadly defined, only the following entities are required to notify OHCA under the CMIR process:

- Healthcare entities with at least \$25 million in California-derived annual revenue or that own or control at least \$25 million of California assets;
- Healthcare entities with at least \$10 million in California-derived annual revenue or at least \$10 million of California assets and are involved in a transaction with a \$25 million healthcare entity; and
- Healthcare entities located in a designated primary care health professional shortage area in California, as defined under federal law.

Parties should closely examine these monetary thresholds in assessing the applicability of the law, but the last threshold regarding designated primary care health professional shortage areas also should not be ignored, as such areas include significant geographic portions of the state.

What types of transactions are within scope of OHCA's purview?

Material Change Transactions

Transactions need to be considered material change transactions to be within the scope of the CMIR process. Under the law, a wide variety of transactions are considered material change transactions, including, most notably, deals involving:

- A transaction value of at least \$25 million and provision of healthcare services;
- An increase in a healthcare entity's annual California revenue by at least \$10 million or 20%;
- The transfer of 25% or more of the assets of the filing party;
- A filing party's transfer of control, responsibility or governance, which include 25% or greater ownership or control changes; or
- The formation of a new entity for the provision of healthcare services projected to have at least \$25 million in annual California revenue or assets.

When reviewing these prongs, it is also important to understand what OHCA considers to be a transaction.

Under the regulations, a transaction includes mergers, acquisitions, affiliations or agreements affecting the provision of healthcare services in California, that involve a transfer of assets or transfer of control, responsibility or governance of the assets or operations of a healthcare entity.

Accordingly, certain transactions involving services relationships, for example, and not including asset or control changes, could potentially fall out of the scope of the CMIR process, depending on the details. Ultimately, assessing whether a transaction fits within the CMIR framework will be a fact-intensive inquiry.

Exceptions

Despite the broad applicability of the CMIR framework, the law does contain certain exceptions.

Indeed, the final regulations specify that the following are not considered material change transactions: (1) transactions in the usual and regular course of the healthcare entity; and (2) situations in which the healthcare entity already controls, is controlled by, or is under common control with, all other parties to the transaction, such as a corporate restructuring.

S.B. 184 also exempts agreements or transactions involving Knox-Keene healthcare service plans, where such agreements or transactions are subject to the review of the state Department of Managed Health Care for cost impact or market consolidation; involving insurers where such agreements or transactions are subject to the review of the state Department of Insurance; where a county is purchasing, acquiring or taking control of an entity to ensure continued access in that county; and involving nonprofit corporations where such agreements or transactions are subject to the review of the attorney general.

However, the statutes and regulations do not provide further specification regarding the exact scope of these exemptions, and thus it is unclear, for example, whether the inclusion of a Knox-Keene licensee in a larger underlying transaction would exempt an entire transaction from the CMIR process.

It is possible that OHCA may issue further guidance on similar fact patterns. Moreover, S.B. 184 permits the attorney general, the Department of Managed Health Care and the Department of Insurance to refer transactions to OHCA for a CMIR.

What does the notice and review process entail?

Timeline and Review Standards

Applicable healthcare entities seeking to close a material change transaction on or after April 1 will need to provide OHCA with a complete notice of the transaction at least 90 days prior to the closing of the transaction.

Once filed, OHCA must notify the submitter within 45 days if it determines that a CMIR will not be conducted. OHCA must notify the submitter within 60 days of the filing if OHCA intends to conduct a CMIR.

This timeline is tolled while OHCA awaits additional information from the parties or if the transaction is under review by another government agency. Filing parties may appeal OHCA's decision within 10 days of OHCA's determination, and OHCA will then have 5 days to decide to uphold the original determination or grant a waiver.

In deciding whether to conduct a CMIR, OHCA will weigh certain factors, including, for example, whether the transaction may result in negative impact on availability or accessibility of healthcare services or on costs for payors, purchasers or consumers.

Other notable factors include whether the transaction may lessen competition or create a monopoly in geographic service areas affected by the transaction or entrench or extend a dominant market position of a healthcare entity.

If OHCA decides to conduct a CMIR, it must complete the review within 90 days of its determination, which period can be extended for one additional 30-day period and tolled while OHCA awaits additional information from the parties or if the transaction is under review by another government agency.

Upon completion of the CMIR, OHCA will issue a preliminary report of its findings and the parties and the public may submit comments within 10 days of the preliminary report. OHCA will issue a final report within 15 days of the close of the comment period. Parties may not close the transaction until 60 days following the issuance of the final report.

In sum, there is a potential for a 9-month timeline from the initial filing to complete the CMIR process, not including any filing preparation time or tolling of the timeline.

There is a limited process for expedited review. The submitter must demonstrate, with a detailed explanation and underlying documentation, either that one of the parties to the transaction is undergoing severe financial distress, i.e., a grave risk of immediate business failure, and the transaction is necessary to ensure continued healthcare access in the relevant markets, or there is a substantial likelihood of a significant reduction in the provision of critical healthcare services within one or more geographic regions.

Disclosure Requirements

Parties subject to the CMIR process will need to file through OHCA's online portal.

Filing materials include a broad range of information and disclosure materials, including, among other things, a description of the transaction and identification of the parties involved, summary of expected post-transaction impacts on services and related organizational and operational changes, detailing of prior merger and acquisition activity involving the parties in the last 10 years, definitive transaction agreements and certified financial statements for the prior three years.

Parties should keep in mind that only the submission of a complete filing — meaning, all information and documentation required under Section 97438 of the regulations — will commence the 45- to 60-day initial review process previewed above.

Parties also should understand that information included in the notice is treated as a public record unless the submitter requests confidentiality for such information and OHCA accepts such designation. Marked-confidential versions of definitive transaction agreements, compensation documents, contract rates and valuation documentation are deemed confidential and nonpublic.

Practical Takeaways for Stakeholders

The CMIR process marks a significant overhaul to California's healthcare regulatory landscape, and most parties looking to consummate transactions in the California healthcare space in 2024 will need to take into account and potentially navigate this new regulatory process.

For parties wishing to avoid going through the CMIR process, it may be advisable to attempt to close transactions in advance of the April 1 date.

For transactions where such a closing timeline is not possible or potentially could slip past April 1, parties now should be carefully reviewing the transaction components in conjunction with the regulations to determine whether notice of a material change transaction will be needed.

And if such notice is needed, parties may be wise to begin the process of collecting and preparing information and documentation needed to submit a complete notice of material change transaction, including assessing the need to seek confidentiality for certain materials.

Moreover, definitive transaction agreements involving transactions closing on or near April 1 should contemplate appropriate closing conditions and contingencies in the event the transaction fails to close prior to April 1.

Parties should also be prepared from an operational perspective that transactions may face substantial delays in the ability to close, given the potential timeline in the CMIR regulations, and it is certainly possible that OHCA could experience backlogs which exacerbate the regulatory timeline.

On the other hand, it remains to be seen how aggressive tOHCA will be in subjecting all in scope parties and transactions to the CMIR process.

OHCA is entitled to specific performance, injunctive relief and other equitable remedies a court deems appropriate for enforcement of any of the requirements of the law.

That being said, whether OHCA decides to focus its CMIR role toward certain types of transactions over others (e.g., those it views as more likely to be cost-drivers) or be more willing to grant waivers for certain transactions (such as those involving cost-saving components, like value-based reimbursement arrangements) are a few of the key enforcement-related questions that could have answers or more clarity in the coming months.

Jordan Grushkin is an associate and Matthew Goldman is a partner at Sheppard Mullin Richter & Hampton LLP.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of their employer, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.