Proskauer

California Releases Proposed Regulations on Health Care Transaction Notice Requirements

Health Care Law Brief on **August 10, 2023**

On July 27, 2023, California's Office of Health Care Access and Information (the "Office") released its long-awaited proposed regulations on the notice requirements for material health care transactions in California. The anticipated regulations follow the passing of SB 184 on June 30, 2022, which, in part, created the Office and granted it the authority to collect and analyze data related to health care costs, specifically via monitoring mergers and acquisitions in the health care industry. Following the lead of states like New York, whose wide-range health care transaction requirements were discussed in a previous blog post, California seeks to address the increasing costs of health care services by imposing significant notice and review requirements for mergers and acquisitions beginning in 2024.

Beginning on January 1, 2024, the proposed regulations require a health care entity engaging in a "material change" transaction (defined below), to provide the Office with at least **90 days' advance notice** of any transaction that will be entered into on or after April 1, 2024.

Health Care Entities

In the initial draft of the proposed regulations, the Office broadly defines a "health care entity" to include a payer, provider, or a fully integrated delivery system,[1] as well as pharmacy benefit managers, management services organizations ("MSOs"), and "any affiliates, subsidiaries, 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."[2] The proposed regulations stipulate that MSOs qualify as "payers" for purposes of the regulations. Exempt from the regulations are physician organizations with less than 25 physicians, unless determined to be a high-cost outlier. [3]

"Material Change" Transactions

A health care entity is required to file a written notice of transaction (the "Notice of Transaction") with the Office if: (a) the health care entity meets certain threshold requirements *and* (b) the transaction is a "material change" pursuant to any of the circumstances listed thereafter.

The threshold requirements include:

- A health care entity with annual revenue of at least $25 million or that owns or controls California assets of at least $25 million; or
- A health care entity with annual revenue of at least $10 million or that owns or controls California assets of at least $10 million and is involved in a transaction with any health care entity satisfying subsection (a) above; or
- A health care entity located in or serving at least 50% of patients who reside in a health professional shortage area, as defined under Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations.

A "Material Change" requiring filing includes:

- A transaction concerning the provision of health care services that is assessed to have a fair market value of $25 million or more.
- A transaction likely to increase annual revenue of any health care entity that is a party to the transaction by at least $10 million or 20% of annual revenue at normal levels of operation or utilization.
- A transaction that involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 20% or more of the assets of any health care entity in the transaction.
- A transaction involving a transfer or change in control, responsibility, or governance.
- A transaction where an entity is negotiating or administering contracts with payers on behalf of one or more providers where the transaction involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, management services organization, or other organization.
- A transaction involving the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health services in California that is projected to have at least $25 million in annual revenue at normal or stabilized levels of utilization or operation or have control of assets related to the provision of health care services valued at $25 million or more.

- A transaction involving a health care entity joining, merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services where any health care entity has at least $10 million in annual revenue.
- A transaction that changes the form of ownership of a health care entity that is a party to a transaction, including but not limited to change from a physician-owned to private equity-owned and publicly held to a privately held form of ownership.
- A transaction where a health care entity has been a party to a transaction regarding the provision of health care services in California with another party in the transaction within ten years prior to the current transaction.

Notably, not all "material change" thresholds focus on financial considerations, such as subsection (e), which focuses on the negotiations and administration of payor contracts.

There are also exemptions form the foregoing thresholds. A material change does not occur if the health care entity already controls or is directly or indirectly, through intermediaries, controlled by, all other parties to the transaction. Further, transactions already subject to review by the California Department of Insurance, Attorney General, and Department of Managed Health Care, along with county transactions, are exempt from notice requirements, but may be referred by the foregoing agencies to the Office for review.

Form and Content of Public Notice

As currently drafted, the proposed regulations require a filed Notice of Transaction that includes, but is not limited to, the following information and documentation: (i) a description of all involved parties (including ownership type, governance and operation structure, and geographic areas of service); (ii) a description of the transaction (including proposed date of the transaction closure, general public impact or benefits of the transaction, narrative on the expected competitive impacts of the transaction); (iii) material contracts and pre-and-post closing conditions; (iv) post-transaction balance sheet for any surviving or successor entity service and financial statements of *all* parties to the transaction from *three* years prior to the transaction; and (v) locations and revenue information.

All information provided to the Office by the submitter of the Notice of Transaction, will be treated as a public record, unless the submitter designates documents or information as confidential and the Office accepts the confidential designation at their discretion. The Office deems a Notice of Transaction complete when all of the required information has been submitted to the Office.

Upon such a determination, the Office will then conduct a 60-day preliminary review to determine whether the agreement or transaction must undergo a Cost and Market Impact Review ("CMIR"). In its assessment of whether to conduct a CMIR, the Office will consider factors relating to a health care entity's business and relative market position (including changes in size and market share in a given service/geographic region), prices for services compared to other providers for the same services, equity, cost, access, and other factors the Office determines to be in the public interest. The Office will also consider the benefits of the material change to consumers of health care services, the potential of lessening competition in a particular market, and the effect on the quality of health care services to the community affected by the transaction.

Upon completion of a CMIR, the Office will make factual findings and issue a preliminary report to the parties. Within 10 business days of the issuance of such preliminary report, the parties to the transaction and the public *may* submit written responses to the findings. The Office will then issue a final report of its findings within 30 days of the close of the comment period, unless this time period is extended by the Office for good cause. **Notably, agreements or transactions subject to a CMIR may not be implemented until 60 days after the Office issues its final report.**

Public Comment and Impact

The Office will be receiving public comments on these proposed regulations until August 31, 2023, and has scheduled a public workshop to discuss the regulations on August 22, 2023. The proposed regulations are expected to have a significant impact on the occurrence and timing of mergers, acquisitions, and corporate affiliations involving California health care entities. Private equity investors and other key stakeholders should be aware of the implications of the CMIR process and may also need to build into the transaction documents a process for preparing notice documents and providing the Notice of Transaction review process. Requirements similar to those proposed in California have been, and will continue to, take effect.

Proskauer will be monitoring and providing updates on any finalized regulations, as well as all other forthcoming and proposed state regulations affecting transactions.

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[1] Cal. Health & Saf. Code § 127500.2(k).

[2] Cal. Code Regs. tit. 22 § 97431(g)(4).

[3] Organizations that are considered high-cost outliers provide services at substantially higher rates when compared to the statewide average for the same services. The cost of delivering the same services in a geographic region will be considered to the extent that a cost substantially deviates from the statewide average and reflects higher costs in that region unrelated to the market dominance of providers in that region or unrelated to the ownership, management, or asset structure chosen by the organization. Cal. Health & Saf. Code § 127500.2

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Related Professionals

- **Vinay Kohli**
  Partner