

**Alert | California Government Law & Policy/  
Health Care & FDA Practice**



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## California's Recent Proposed Regulations Include Significant Requirements for Health Care Transactions

### Go-To Guide:

- California's Office of Health Care Affordability (OHCA) issued proposed emergency regulations as directed by recently enacted California law (part of Senate Bill 184 passed on June 30, 2022) which authorized OHCA to review certain health care transactions in an effort to combat rising health care costs and promote competition. A proposed transaction cannot be implemented until 60 days after OHCA issues a final report unless it waives conducting a cost and market impact review (CMIR).
- Written notice must be filed with OHCA at least 90 days prior to the health care entity entering into the agreement or transaction, which the proposed emergency regulations defines as the date any parties' respective rights vest in a binding agreement or all deal contingencies are met or waived.
- The proposed regulations expand the type of health care entities subject to the notification requirement to include pharmacy benefit managers, management service organizations (MSOs), any health care entity entering into a transaction with a physician organization with fewer than 25 physicians, and any entity that controls, governs, or is financially responsible for the health care entity or is subject to the control, governance, or financial control of the health care entity.
- The proposed regulations define thresholds for who must file a material change notification (MCN), add circumstances of "material change" transactions where a MCN must be filed, describe the information, content and documentation required for submission to OHCA for review, and establish

the timelines with respect to OHCA’s decision to conduct a CMIR, issuance of a preliminary report, public comment to same, and issuance of a final report.

- The proposed regulations go into effect Jan. 1, 2024, subject to change based on public comment received prior to Aug. 31, 2023. California’s new law applies to transactions involving health care entities entered into on or after April 1, 2024. While OHCA approval of a transaction is not required, the notice requirement and burdensome review process could potentially delay a transaction closing by several months.

## Background

The California Health Care Quality and Affordability Act,<sup>1</sup> which was signed into law June 30, 2022, as part of Senate Bill 184, established the Office of Health Care Affordability (OHCA) within the Department of Health Care Access and Information. OHCA is responsible for collecting and analyzing data with respect to health care costs for consumers. As part of its authority, OHCA will review certain health care mergers and acquisitions in an effort to combat rising health care costs and promote competition in California among health care entities.

Under the new law, certain health care entities operating in California must notify OHCA of agreements or transactions that will be entered into on or after April 1, 2024, involving either of the following: (i) a sale, transfer, lease, exchange, option, encumbrance, conveyance, or dispose of a “material amount” of the assets of the health care entity or (ii) a transfer of control, responsibility or governance of a “material amount” of the assets or operations of the health care entity, in either case to one or more entities.<sup>2</sup> Such notice must be provided under penalty of perjury on OHCA’s website using a portal that OHCA will create for this purpose at least 90 days prior to such health care entity “entering into the agreement or transaction.”<sup>3</sup> The law applies to a broad spectrum of health care entities subject to the notice requirement, including payers, providers (e.g., physician organizations with 25 or more physicians or otherwise considered “high cost utilizers,” risk-bearing organizations, health facilities such as general acute-care hospitals and ambulatory surgical centers, clinical laboratories and imaging facilities) and fully integrated delivery systems, with limited exceptions. OHCA will make the notice of material change filed by the health care entity, including all information and documents submitted to OHCA in connection with such filing, publicly available.<sup>4</sup>

Once a notice of material change is filed, OHCA has 60 days to decide whether to (i) conduct a cost and market impact review (CMIR) of the proposed transaction or (ii) waive such review. OHCA is required to conduct a CMIR if the proposed transaction poses a risk of significant impact on market competition, the state’s ability to meet cost targets, or costs for purchasers and consumers; however, the statute does not provide standards for the CMIR. After completing the CMIR, OHCA will issue a preliminary report and allow for responses/comments by the public and parties involved in the proposed transaction; however, the statute does not provide a timeframe for such period. OHCA will issue a final public report of its findings based on responses received to its preliminary report or refer its findings to the California Attorney General for further review of any anti-competitive behavior. The proposed transaction cannot be implemented until 60 days after OHCA issues a final report unless OHCA waived a CMIR. Of note, the statute does not provide for a time period for OHCA to issue its preliminary or final report, potentially

<sup>1</sup> See, Cal. Health & Saf. §127500 et seq.

<sup>2</sup> Of note, the term “material amount” is not defined in the statute. See proposed Regulations below.

<sup>3</sup> Of note, the statute does not define what “entering into the agreement or transaction” means. So, there is uncertainty as to whether this means signing a definitive purchase agreement or closing the transaction. See proposed Regulations below.

<sup>4</sup> This includes non-public information if OHCA believes that such disclosure is in the public’s interest after taking into account privacy and trade secret and similar considerations of the parties to the transaction. See proposed Regulations below.

delaying closing a transaction by several months. Additionally, OHCA is entitled 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, but the law does not provide for a cap on such amount.

## Regulations

The statute directs OHCA to adopt regulations governing material changes, notification, fees, and appropriate health care entity thresholds including annual gross and net revenues of market share. To this end, OHCA released proposed emergency regulations<sup>5</sup> that would go into effect Jan. 1, 2024, to the public for comments by Aug. 31, 2023. Notably, the proposed regulations would:

1. Expand the type of health care entities subject to the new law to include pharmacy benefit managers, management services organizations (MSOs), any health care entity entering into a transaction with a physician organization with fewer than 25 physicians, and any entity that controls, governs, or is financially responsible for the health care entity or is subject to the control, governance, or financial control of the health care entity.
2. Set the following thresholds for health care entities who must file a notice of a transaction that constitutes a “material change”:
  - a) 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
  - b) 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 the requirement of the foregoing clause (a); or
  - c) a health care entity located in or serving at least 50% of patients who reside in a health professional shortage area.
3. Add nine circumstances that constitute a “material change” transaction, including transactions<sup>6</sup>:
  - a) with a proposed market value of \$25 million or more and concerning the provision of health care services;
  - b) that involve 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;
  - c) that are likely to increase the 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 or stabilized levels of utilization or operation;
  - d) that change the form of ownership of a health care entity, including from physician-owned to private-equity-owned and publicly held to privately held; or

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<sup>5</sup> See [Draft Proposed Emergency Regulation Text, 22 CCR 97431 et seq.](#)

<sup>6</sup> Assumes that any party to the transaction satisfies one of the requirements set forth in paragraph 2 above.

- e) that involve a change of control, responsibility or governance (defined as a transfer of 10% or more of the control, responsibility or governance of a health care entity or of full or partial voting control of the members of the governing body of a health care entity).
4. Add a requirement for the notifying party to provide a substantial amount of information to OHCA, including:
- a) detailed descriptions of the transaction and entities in the transaction;
  - b) information regarding submissions to any other state or federal agency;
  - c) information regarding any court proceedings involving the transaction;
  - d) a description of any prior transactions that involved the provision of health care services involving any of the health care entities in the proposed transaction during the preceding 10 years; and
  - e) a description of post-transaction changes to ownership, governance, operational structure, employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions and employment protections, city or county contracts relating to health care services, seismic compliance, and competition within 20 miles of any physical facility offering comparable patient services.
5. Clarify the content and documentation requirements for notice filings to include:
- a) copies of current agreements and term sheets;
  - b) contact information for individuals signing the agreement;
  - c) pro-forma post-transaction balance sheet for surviving/successor entity;
  - d) current organizational charts including parent and subsidiary organizations and similar charts for any post-transaction entities;
  - e) certified financial statements for the prior three years;
  - f) articles of incorporation or organization, bylaws, partnership agreements or other corporate governance documents, if applicable;
  - g) any Hart-Scott-Rodino (HSR) filings with the FTC;
  - h) documentation related to the mitigation of any potential adverse impacts of the transaction to the public; and
  - i) analytic support and/or documentation supporting the submitter's responses.
6. Clarify the timeline with respect to:
- a) Decision whether to conduct a CMIR: 60-day period may be tolled while other state or federal agencies or courts are reviewing the transaction or during the period when OHCA is awaiting further documentation or information requested by OHCA from the parties to the transaction.

- b) Issuance of Preliminary Report: 90 days from OHCA’s final decision to conduct a CMIR, subject to a 45-day extension if OHCA needs additional time. OHCA may toll either the 90-day period or the 45-day extension period during any period when other state or federal agencies or courts are reviewing the transaction or for any period when OHCA is awaiting documentation or information requested by OHCA from the parties to the transaction.
  - c) Public Comment Period: 10 business days after issuance of the preliminary report.
  - d) Issuance of Final Report: Within 30 days of the close of the public comment period, subject to extension by OHCA for “good cause.”
7. Define “entering into the agreement or transaction” as the date any parties’ respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived.
8. Allow notifying parties to submit requests for confidential treatment of portions of a notice and any related information and documents submitted to OHCA; otherwise, all such information would be treated as a public record. Such requests for confidentiality may be granted at OHCA’s discretion.

Interested parties had an opportunity to submit public comment through Aug. 31, 2023. Accordingly, the proposed regulations are subject to change.

California follows states like New York, Washington, and Oregon, which have similarly enacted new laws to provide greater oversight of certain health care transactions.

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