

Advance Regulatory Review of California Health Care Transactions by the New Office of Health Care Affordability to Begin in 2024

November 09, 2022 | Blog | By [Lara D. Compton](#), [Kathryn F. Edgerton](#), [M. Daria Niewenhaus](#)

VIEWPOINT TOPICS

- Health Care
- Health Care Compliance, Fraud & Abuse, and Regulatory Counseling

RELATED PRACTICES

- Health Care Compliance, Fraud & Abuse, and Regulatory Counseling
- Health Care Transactions

RELATED INDUSTRIES

- Health Care
- Hospitals & Health Systems

The health omnibus trailer [SB-184](#), which created the Office of Health Care Affordability (OHCA), is set to usher in a significant change in California's health care regulatory landscape. Beginning in 2024, certain health care mergers, acquisitions, affiliations, and other arrangements that result in material changes of assets, control, or governance will be subject to advance review by OHCA.

Below we answer frequently asked questions about OHCA's responsibilities, starting with its charge to prospectively monitor and review health care transactions.

When will OHCA begin reviewing transactions?

Transactions that occur on or after April 1, 2024, are subject to advance review by OHCA, which will begin collecting transaction notices in January of 2024.

Which Health Care Entities are subject to advance transaction review?

Subject to certain exceptions discussed below, health care service plans, health insurers, hospitals, hospital systems, fully integrated delivery systems, pharmacy benefit managers, physician organizations (with greater than 25 physicians), other providers (e.g., ASCs, certain clinics, clinical labs, imaging facilities, and other health facilities), and payers (collectively, Health Care Entities) are subject to the prospective transaction review process.^[1]

Various health care providers and entities are not subject to the new transaction review process, including dentists, pharmacies, drug manufacturers, durable medical equipment suppliers, home health agencies, and emergency medical transportation. Additional providers may be exempted from review by regulation, which may take into account various factors including, but not limited to, annual gross and net revenues, patient volume, and high-cost outliers in a given service or geographic region.

However, transactions involving otherwise exempted providers will be subject to review if the provider is being acquired by, or affiliating with, an entity that is subject to prospective transaction review by OHCA.

What types of transactions are subject to OHCA review?

Generally, agreements or transactions that involve a change to ownership, operations, or governance structure that do either of the following are subject to review:

- sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of a Health Care Entity's assets to one or more entities; or
- transfer control, responsibility, or governance of a material amount of the assets or operations of the Health Care Entity to one or more entities.

OHCA's review process is intended to supplement existing market oversight responsibilities of the Attorney General (related to nonprofit facility transactions), the Department of Managed Health Care, and the Department of Insurance; therefore, certain transactions that are already subject to review by these agencies are exempt from OHCA notice and review requirements. Also exempt are transactions where a county is purchasing, acquiring, or otherwise governing or controlling an entity to ensure continued access to health care.

OHCA will promulgate regulations further detailing which transactions will be subject to advance review, including thresholds for annual gross and net revenues and market share in a given service or region.

What is the OHCA prospective transaction review timeframe and process?

Health Care Entities will be required to provide OHCA at least 90 days' prior written notice of a transaction. OHCA will decide within 60 days of receipt if it will conduct a cost and market impact review and generate a public report or grant a review waiver. Transactions may not proceed without obtaining a waiver from OHCA or completing the review process as further described below.

During the cost and market impact review process, OHCA will consider:

- changes in size or market share in a given service or geographic region;
- prices relative to other providers;
- quality, equity, access, and other factors in the public interest; and
- benefits of the transaction, including improvements in access, quality, and efficiency.

Notably, the review process will include an investigation by OHCA, which has the authority to subpoena health care entities and other relevant market participants (e.g., sponsors and investors) to submit data and documents. Once the review is complete, the parties and the public will be provided the opportunity to comment on a preliminary report issued by OHCA before a final report is generated. The new law does not specify a minimum or maximum timeframe for OHCA to review the transaction and generate a report. However, if OHCA decides to conduct a review, the transaction may not be completed until 60 days after the final report is issued. As a result, transactions will be made public prior to closing.

Additional details regarding the notice, review, and investigation processes will be established by regulation.

Could the new OHCA transaction review process create confidentiality concerns?

Yes, the new process could create concerns regarding confidentiality. Generally, information submitted to OHCA by the parties to the transaction may become public as part of the reporting process. While OHCA must keep confidential all nonpublic information and documents (Confidential Information) that were not required as part of the notice to OHCA of the transaction or from the parties to the transaction as part of the review process (e.g., information that was produced by non-parties in response to a subpoena), there are two significant exceptions. First, Confidential Information may be disclosed to the Attorney General without the consent of the source of the information. Second, OHCA may, after providing the source of the information with an opportunity to object, include Confidential Information in a preliminary report or final report if it believes that disclosure should be made in the public interest after taking into account any privacy, trade secret, or anticompetitive considerations. As a result, there is no guarantee that any information provided to OHCA will remain confidential.

However, all nonpublic information and documents obtained during the prospective transaction review process is not subject to disclosure under the California Public Records Act or any similar local law requiring the disclosure of public records.

What are the costs involved?

Regulations will establish filing fees. Additionally, OHCA may contract with experts and consultants to assist in reviewing transactions and is entitled to reimbursement by the Health Care Entity, subject to review, for all actual, reasonable, and direct costs (including administrative costs) incurred.

When are regulations expected?

OHCA may promulgate regulations on an emergency basis. According to this [timeline](#), the regulations process will begin between January and June of 2023, and the first regulatory priority appears to be data collection. However, based on current timelines, we expect regulations for the prospective transaction review process to be adopted in advance of notice collection, which begins in January of 2024. The public comment period for emergency regulations is five calendar days beginning on the day that the Office of Administrative Law (OAL) posts the notice of the pending emergency action on its website. Mintz is monitoring the rulemaking process and is well positioned to assist in submitting comments to the OAL once the emergency regulations are posted.

Can OHCA block a transaction?

No, but OHCA may refer the transaction to the Attorney General for further review of unfair methods of competition, anticompetitive behavior, or anticompetitive effects.

Do other states conduct similar prospective reviews of transactions?

California joins Connecticut, Delaware, Massachusetts, Nevada, New Jersey, Oregon, Rhode Island, and Washington as states that have implemented measures towards health care cost containment and market oversight. It appears that the California Assembly drew heavily from the Massachusetts model in

developing the California model. In 2012, Massachusetts established the Massachusetts Health Policy Commission (HPC), an independent state agency with the authority to limit unnecessary growth in health spending. Since its establishment, the HPC has received approximately 150 notices of transactions and other “material changes” requiring notice to the HPC. The HPC has opted to undertake a cost and market impact review of nine transactions and has posted six final reports. It is unclear whether California will take a similar approach to Massachusetts in determining which transactions warrant a cost and market impact review.

What steps should a Health Care Entity take if it contemplates entering into a transaction subject to advance review by OHCA?

Strategic planning efforts should now include the OHCA transaction notice requirements to assure technical compliance and to allow sufficient time to complete the transaction review and reporting process if necessary. In Mintz’s experience with similar review in other states, such as the Massachusetts HPC “notice of material change” process, parties to the subject transaction and their counsel should aim to work cooperatively with OHCA to complete the process in an efficient manner.

[1] “Fully integrated delivery system,” “physician organization,” “provider,” and “payer” are all defined by statute.

Authors

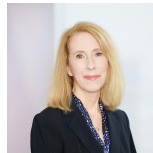


Lara Compton

Kathryn F. Edgerton, Member

Katie Edgerton Professional Headshot Mintz

Kathryn F. Edgerton is a Member at Mintz and a Certified Information Privacy Professional (CIPP-US) who advises hospitals and other health-related organizations on a broad range of transactional, regulatory, and strategic issues. Her clients include physician organizations, long-term and behavioral health providers, telemedicine providers, home health providers, and medical spas.



M. Daria Niewenhous, Member Emerita

More Viewpoints

California Passes New Law Requiring Physicians and their Employers to Notify Patients about the Open Payments Database

October 11, 2022 | Blog | By Lara Compton, Rachel Yount

[Read more](#)

California Health Care Legislative Update

June 15, 2021 | Blog | By Lara Compton

[Read more](#)

California Attorney General Probes Bias in Health Care Algorithms

