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Healthcare Alert

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Proposed amendments to OHCA regulations capture broader set of transactions

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Proposed CMIR amendments require OHCA's approval if a health care entity is the "subject of" a transaction.

What's the impact?

- Parties to a material change transaction will be required to obtain approval from California's Office of Health Care Affordability if a health care entity is the "subject of" the transaction.
- The proposed language appears to broaden the scope of entities required to obtain OHCA's approval, and addresses confidential treatment requests and attestation requirements.

Following the passage of the Health Care Quality and Affordability Act, California's Office of Health Care Affordability (OHCA) issued final regulations in December 2023 that govern notice and approval requirements for health care entities (HCEs) seeking to undergo "material change transactions." In May 2024, OHCA proposed modifications to the existing regulations, which, among other changes, appear to expand the scope of transactions subject to OHCA's approval process.

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Proposed modifications and implications

HEALTH CARE ENTITIES THAT ARE A SUBJECT OF A TRANSACTION

Under the existing law, an HCE that is a "***party*** to" the transaction and meets certain thresholds is required to obtain approval from OHCA prior to entering into a "material change transaction." OHCA's proposed regulations expand this by requiring approval if an HCE is the "***subject*** of" a transaction. An HCE is the "subject of" a transaction if the transaction "concerns [the] HCE's assets, control, responsibility, governance, or operations, in whole or in part."

Additionally, the modifications expand on one of the existing revenue thresholds that an HCE must meet to qualify as a "submitter." Under existing regulations, an HCE that has annual revenue or controls assets of at least $10 million ***and*** enters into a transaction with another HCE that has annual revenue or controls assets of at least $25 million qualifies as a submitter. The proposed regulations identify that the second prong of this threshold will be met if the transaction is with an HCE ***or*** "any entity that owns or controls an HCE" that has annual revenue or controls assets of at least $25 million.

The proposed language appears to broaden the scope of entities required to obtain OHCA's approval because it means that even if an HCE is not a direct party to a transaction, a transaction may still be reportable. Whether a party must file a material change notice and obtain OHCA's consent for a transaction is a fact-specific analysis. Thus, even if an HCE is the "subject of" a transaction, an HCE must meet certain revenue or location-based thresholds, **and** the transaction must qualify as a "material change transaction"—this is consistent with the current analysis required to determine if OHCA's consent is required under the existing regulations. OHCA acknowledged during its monthly Health Care Affordability Board Meeting on June 26, 2024, that this revision would expand the scope of transactions subject to OHCA's approval process.

REQUESTS FOR CONFIDENTIAL TREATMENT

The proposed modifications also address the process related to confidentiality requests made by submitters. The current regulations provide that a submitter may request confidential treatment of certain qualifying materials submitted as part of the notice, which OHCA may grant in its sole discretion. The existing framework does not address the process in the event OHCA denies these requests; the proposed regulations, however, prescribe that a submitter may withdraw any information submitted for confidential treatment that was later denied.

Notwithstanding the proposed withdrawal right, if the information is considered to be a critical part of the filing, it begs the question of whether the notice will still be deemed complete by OHCA if the information is subsequently withdrawn by the submitter. It follows, from a practical standpoint, that transacting parties requiring OHCA's approval may be compelled to include and

disclose certain confidential or proprietary information in the OHCA notice in the event a confidentiality request is denied.

ATTESTATION REQUIREMENTS

The proposed regulations require HCEs to include an attestation that the HCE used reasonable diligence to gather and provide information as part of the notice, which is not required by the current regulations. Given the substantial nature of information produced as part of the notice, an attestation to that effect appears to present minimal implications for submitters. Further, these attestations are typical of similar regulatory filings to government agencies. That said, it raises questions of scope of liability for submitters, and underscores the significance OHCA impresses upon submitters to provide complete and comprehensive filings.

CLARIFICATIONS TO DEFINED TERMS

In addition, the proposed regulations amend certain terminology and defined terms.

Specifically, the qualification that requires an HCE to be located in a health professional shortage area (HPSA), OHCA replaces the term "health care entity" to "provider or fully integrated delivery systems." This means that this threshold does not apply to payors (or parents, affiliates, and subsidiaries that act on behalf of payors and control an HCE) or to pharmacy benefits managers. Although this appears to narrow the HCEs subject to this threshold, the change does not have a meaningful impact on the threshold itself, and rather serves to clarify that the threshold is only applicable to brick-and-mortar health care providers, which would be a reasonable interpretation under the existing regulations. OHCA also clarifies that "annual California-derived revenue" means "revenue from the provision of health care services in California." This clarifies that the revenue thresholds used in the regulations are based on revenue generated by health care services in California, so may serve to narrow this calculation for companies that have broader operations.

Next steps for OHCA

OHCA recently discussed the proposed revisions during its monthly Health Care Affordability Board Meeting on June 26, 2024, and seeks to make these revisions effective in early September. For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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