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California Finalizes SB 184 Pre-Transaction Notice Requirements for “Material Change” Health Care Transactions

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On December 18, 2023, the California Office of Administrative Law approved the emergency regulations promulgated by the Office of Health Care Affordability (OHCA) that set forth the procedural framework for (i) the pre-transaction notice required to be provided under the California Health Care Quality and Affordability Act (“SB 184”) by specified “health care entities” for certain “material change transactions” involving the provision of “health care services” in California, and (ii) the review process to be conducted by OHCA with respect to such proposed material change transactions.

The regulations revise the prior drafts of emergency regulations released by OHCA on November 28, 2023, October 9, 2023, and July 27, 2023. The regulations became effective as of December 18, 2023.

SB 184 and the implementing regulations reflect part of an increasing state trend towards enhanced regulatory scrutiny that is intended to reduce the adverse impact on competition, costs, and patient-consumers arising from, among other items, (i) an increased volume of transactions, resulting in consolidation/convergence among providers, payors/insurers, management services organizations, technology companies, and other health care businesses; (ii) increased private investment (versus traditional control by physicians and providers) and corresponding re-emergence of concern regarding potential for “corporate practice of medicine” abuses; (iii) a recognized need for greater emphasis on patient-centered care, including satisfaction, accessibility, quality, equity, health outcomes, and coordination of care; and (iv) financial/budgetary constraints, including those resulting from expansion of Medicaid populations, rising costs, staffing shortages, technology, and demographics (aging and a rise in chronic disease).

The new disclosure requirements will significantly extend the transaction timeline for many health

care transactions involving California-based operations by requiring a minimum of 90 days' advance notice to be provided to OHCA prior to the closing of a material change transaction. Thus, notice will be required to be provided by January 1, 2024, for transactions that close on or after the April 1, 2024, effective date. The 90-day minimum advance notice period may also be extended if OHCA determines that further review of the proposed transaction is required to evaluate the potential impact of a proposed transaction on costs, quality, access, or other competitive aspects.

The notice requirements are intended to promote transparency with respect to potential market developments recognized by the legislature as key drivers of escalating health care costs, including those relating to consolidation, market power, venture capital activity, high-profit margins, and other so-called market failures. The new disclosure requirements significantly expand the scope of the current regulatory and public scrutiny of health care transactions by, among other items, (i) establishing lower transaction materiality thresholds that will trigger the notice requirements; (ii) expanding the scope of entities and transactions subject to review under current law, including oversight by the California Attorney General (CAG), the California Department of Managed Health Care (DMHC), and the California Department of Insurance (DOI); and (iii) requiring the comprehensive disclosure of information to OHCA and the public.

The following discussion provides an overview of certain key procedural elements set forth in the regulations, including a description of:

- the type, size, and/or location of health care entities and transactions subject to the notice requirement;
- the comprehensive information, data, and documents required to be submitted to OHCA under the notice process; and
- the transaction review timeline, including the potential extension of the 90 days' advance notice period for the conduct of a cost and market impact review (CMIR) of the transaction.

Overview of OHCA Pre-Transaction Review Authority: SB 184 became effective as an urgency statute on June 30, 2022, adding Chapter 2.6 (commencing with Section § 127500) to Part 2 of Division 107 of the California Health and Safety Code ("H&S"). SB 184 established OHCA as an office within the California Department of Health Care Access and Information (HCAI) to, among other items, (i) monitor the impact of consolidation, market power, venture capital activity, profit margins, and other market failures on competition, prices, access, quality and equity, and (ii) promote competitive health care markets in a manner supportive of such efforts by the CAG, the DMHC, and the DOI.

SB 184 authorizes OHCA to examine mergers, acquisitions, corporate affiliations, or other transactions that entail a material change to ownership, operations, or governance structure involving specified health care entities. OHCA is charged with (i) prospectively analyzing such transactions that are likely to have significant effects, (ii) seeking input from the parties and the public, and (iii) reporting on the anticipated impacts on the health care market. Contrary to the approval authority granted to CAG, DMHC, and DOI under existing law to impose conditions or block certain health care mergers and acquisitions, the role of OHCA is limited to collecting and reporting information to the public and the other enforcement agencies.

Health Care Entities Subject to SB 184's Pre-Transaction Notice Requirements. The broad range of "health care entities"[1] that are subject to the SB 184 pre-transaction notice requirements consist of (i) payers;[2] (ii) providers[3] (including physician organizations,[4] hospitals and other health facilities,[5] clinics,[6] ambulatory surgery centers or accredited outpatient settings, clinical laboratories,

and imaging facilities); (iii) fully integrated delivery systems;[7] (iv) pharmacy benefit managers;[8] and (v) parents, affiliates, subsidiaries, or other entities that act in California on behalf of a payer.[9]

- **Health Care Entities Exempt from Pre-Transaction Notice Requirements.** The following entities are exempt from the notice requirements: (i) health care service plans licensed under the Knox-Keene Health Care Service Plan Act of 1975 (which are subject to review by the DMHC); (ii) health insurers (subject to review by the DOI); (iii) nonprofit corporations (subject to review by the CAG); and (iv) counties that are purchasing, acquiring, or taking control to ensure continued access to health care services in the county. In addition, physician organizations with less than 25 physicians that are not "high-cost outlier" practices[10] are exempt from the disclosure process; provided, however, that a health care entity that enters into a transaction with such a high-cost outlier organization remains subject to the notice filing requirements under SB 184.
- **Size or Location of Health Care Entity.** Each health care entity that is a party to the material change transaction is required to submit the notice (each such party, a "submitter") if it meets one of the following thresholds:
    - a health care entity with annual California-derived 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 California-derived 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 with at least $25 million or that owns or controls California assets of at least $25 million; or
    - a health care entity located in a designated mental health or primary care health professional shortage area.[11]

Material Change Transactions That Are Subject to Pre-Transaction Notice Requirements

- **"Transactions"** subject to SB 184's pre-transaction notice requirements include a broad range of transactions consisting of mergers, acquisitions, affiliations, or agreements involving a health care entity, or the provision of health care services in California that involve a transfer of assets (sell, lease, exchange, option, encumber, convey, or dispose) or control, responsibility, or governance of the assets or operations of the health care entity in whole or in part to one or more entities.
- **"Health care services"** are services for the care, prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health (mental health or substance use disorder) condition, illness, injury, or disease, including, but not limited to, (i) acute care, diagnostic, or therapeutic inpatient hospital or outpatient services; (ii) pharmacy, retail and specialty, including any drugs or devices; (iii) performance of functions to refer, arrange, or coordinate care; (iv) equipment used, such as durable medical equipment, diagnostic, surgical devices, or infusion; and (v) technology associated with the provision of services or equipment listed above, such as telehealth, electronic health records, software, claims processing, or utilization systems.
- **"Material Change"** A transaction involving the provision of health care services is a material change transaction subject to the pre-transaction notice requirements in any of the following circumstances:

1. Fair market value is $25 million or more.
2. The transaction is more likely than not to increase the annual California-derived revenue of any health care entity that is a party to the transaction by either $10 million or 20 percent or

more of annual revenue.
3. The sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25 percent or more of the total California assets of the submitter.
4. The transfer of control, responsibility, or governance of the submitter, in whole or in part, of a material amount of the assets or operations of the health care entity to one or more entities if the transaction, directly or indirectly, results in (i) the transfer of 25 percent or more of the voting power or the governance of the management and policies, or (ii) another change of control effected through supermajority rights, veto rights, and similar provisions even if ownership shares or representation on a governing body are less than 25 percent.
5. Results in an entity contracting with payers on behalf of the consolidated or combined providers and increases the annual California-derived revenue of any providers in the transaction by either $10 million or more or 20 percent or more of annual California-derived revenue.
6. Formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation that (i) is projected to have at least $25 million in California-derived annual revenue or (ii) the operation or transfer of control of California assets related to the provision of health care services is valued at $25 million or more.
7. Part of a "roll up"[12] where the acquiring entity or its affiliates have engaged in a series of similar or related transactions to implement a strategy of buying up similar health care entities during a 10-year "look back" period. The regulations require the aggregation and disclosure of a series of transactions that (i) cumulatively meet the revenue, asset, and control thresholds set forth in the regulations, and (ii) involve either (1) the same parties or their affiliates or (2) the acquiring entity's participation in similar transactions with unrelated health care entities that provide the same or related health care services.

- **Excluded Transactions:** A "material change transaction" does *not* include (1) transactions in the usual and regular course of business that are typical in the day-to-day operations, or (2) situations in which the health care entity directly or indirectly already controls, is controlled by, or is under the common control with all other parties to the transaction, such as a corporate restructuring.
- **Pre-Filing Questions.** The regulations indicate that a health care entity may contact OHCA for guidance if the entity is unsure if a notice is required with respect to a transaction.

Notice Process

- **Content of Notice.** The regulations require the submitters to provide a broad range of information in the notice, including the following:
    - General information regarding the submitting entity and description of all other entities involved in the transaction
    - Description of the transaction, including (i) goals; (ii) summary of terms; (iii) statement as to why the transaction is necessary or desirable; (iv) public impact or benefits, including quality and equity measures and impacts; (v) competitive impacts; and (v) actions or activities to mitigate any potential adverse impacts of the transaction
    - Materials provided to other state or federal agencies reviewing the transaction, such as the Federal Trade Commission or Department of Justice, and information regarding any court proceedings relating to the transaction
    - Description of current services and expected post-transaction impact on health care services
    - Description of prior merger and acquisition transactions that satisfy all of the following: (i) involved the same or related health care services; (ii) involved at least one of the

entities or their parents, subsidiaries, predecessors, or successors; and (iii) closed in the last 10 years
    - Description of potential post-transaction changes to (i) ownership, governance, or operational structure; (ii) employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections; (iii) city or county contracts; (iv) compliance with seismic requirements; and (v) competition offering comparable services within 20 miles of any facility offering comparable patient services
    - Description of the nature, scope, and dates of any pending or planned material changes within the 12 months following the date of the notice
    - Other supporting documents, including definitive agreements, valuation, contact information, a pro-forma post-transaction balance sheet for any surviving or successor entity, an organizational chart for the post-acquisition transaction, patients/enrollees by zip code, audited or “certified” financial statements for the prior three years, governing documents (articles of incorporation, bylaws, partnership agreement), documentation relating to the mitigation of any potential adverse impacts of the transaction on the public, and analytic or other documentational support for submitter’s responses
- **Filing Process; Public Record; Confidentiality.** The notice of the material change transaction must be filed via the OHCA portal. The notice will be posted on the OHCA website and available for public inspection.

  The information in the notice will be treated as a public record unless the submitter designates the documents or information as confidential and OHCA authorizes such confidential treatment. The submitter is required to document the grounds for confidential treatment, the time period during which such information is required to be confidential, and a statement that the confidentiality of the information has been maintained by the submitter. OHCA will not disclose any nonpublic information that is determined to be confidential to any other person or entity other than the CAG.

Cost and Market Impact Review. If OHCA finds that data or a material change is likely to have a risk of a significant impact on (i) market competition, (ii) the state’s ability to meet cost targets, or (iii) costs for purchasers and consumers, OHCA will conduct a CMIR. The CMIR will examine factors relating to a health care entity’s business and its relative market position, including, but not limited to, changes in size and market share in a given service or geographic region; prices for services compared to other providers for the same services; quality, equity, cost, and access; or any other factors OHCA determines to be in the public interest.

OHCA will notify the submitter within 45 days of the filing of a complete notice if it determines that it will *not* conduct a CMIR. OHCA must notify the submitter within 60 days following the submission of a complete notice if OHCA determines that it will conduct a CMIR.

- **Focus of CMIR.** The CMIR will include an examination of factors relating to a health care entity’s business and its relative market position, including, but not limited to:
    - Availability, accessibility, or quality of health care services
    - Lessening of competition
    - Ability to meet any health care cost targets established by the Health Care Affordability Board
    - Competition for workers and impact on the labor market
    - Foreclosure of competitors or barriers to entry in any health care market

    - Whether the parties to the transaction have been parties to any other transactions in the past 10 years that have been below the thresholds required under the regulations
    - Consumer concerns including, but not limited to, access, care, quality, equity, affordability, or coverage
    - Any other factors OHCA determines to be in the public interest
- **Compelled Disclosure.** OHCA may use subpoenas to compel health care entities and other relevant market participants to submit data and documents to support its investigation.
- **Reimbursement of Costs.** OHCA is entitled to reimbursement from the health care entity for all actual, reasonable, and direct costs incurred in reviewing, evaluating, and making the CMIR determination, including administrative costs.

Review Timeline

- **Advance Notice Period.**
    - The relevant parties to the material change transaction are required to provide a minimum of 90 days' advance written notice for a transaction that will close on or after April 1, 2024.
    - The 90-day notice period does not commence until the notice is deemed complete by OHCA. The notice is deemed to be complete on the date when all of the required information has been submitted by all parties required to submit notice.
    - OHCA must be notified within five business days if the transaction is amended, altered, or canceled. In connection with such change, OHCA may require the transaction to be "re-noticed," and the notice period may be restarted as of the date of complete re-notice.
- **Initiation of CMIR.**
    - OHCA may toll the 45- or 60-day period based on agreement by the submitter, or during any period that (i) OHCA is waiting on parties to provide additional information, or (ii) the transaction is under review by other state or federal regulatory agencies or courts.
    - Within 10 business days of the date of OHCA's determination that a CMIR is required, the submitters may appeal such determination.
    - Within five business days of OHCA's receipt of an appeal (which may be extended for an additional five business days if additional review time is needed by OHCA), OHCA will issue a determination that either upholds the original determination to require a CMIR or grant the appeal and waive the CMIR. The determination by OHCA is final.
- **CMIR Conduct.** OHCA is required to complete the CMIR within 90 days of its final decision to conduct a CMIR.
    - OHCA may extend the 90-day CMIR period for one additional 30-day period.
    - OHCA may also toll the 90-day period while it is waiting for additional information *or* if the transaction is under review by other state or federal regulatory agencies or courts.
- **Preliminary Report.** Upon completion of the CMIR, OHCA shall make factual findings and issue a preliminary report of its findings. Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report.
- **Final Report.** OHCA will issue a final report of its findings within 15 days of the close of the comment period unless OHCA extends the period subject to a showing of good cause.
- **Additional Statutory Waiting Period.** An agreement or transaction for which a cost and market impact review proceeds may not be implemented until 60 days after OHCA issues a final report.
- **Referral to CAG.** Although OHCA does not retain authority to approve the transaction, OHCA

may refer its findings, including the totality of documents gathered and data analysis performed, to the CAG for further review of any unfair methods of competition, anti-competitive behavior, or anticompetitive effects. SB 184 does not limit the authority of the CAG to maintain a competitive market and prosecute state and federal antitrust and unfair competition. Thus, the review period may be extended by further review of the transaction by the CAG.

- **Request for Expedited Review.** An expedited review process may be granted by OHCA in limited circumstances. To obtain expedited review, a submitter must demonstrate that the failure to promptly close will (i) eliminate continued access to health care services and result in "severe financial distress" in the form of immediate business failure and bankruptcy for a party or (ii) result in a significant reduction in the provision of critical health services in a geographic region.

For further information relating to the timeline for OHCA's review process, please refer to related materials available here.

Key Takeaways. The broad reach, complexity, and extended review period set forth under SB 184 will require parties to health care transactions in California to incorporate SB 184 planning into the early stages of the transaction development phase. Certain key factors to be addressed by the parties may include the following:

- **Planning and Administration.** The parties to a proposed transaction will need to develop and implement processes to (i) evaluate the potential application of SB 184 to the proposed transaction; (ii) ensure compliance with the notice requirements; (iii) provide for the timely collection, compilation, and submission of notice materials; and (iv) properly administer the notice process, including communications with OHCA and other stakeholders. Such focus will also require an evaluation as to *whether*:
    - the proposed transaction is subject to SB 184's notice framework as a "material change transaction" by specified "health care entities" involving the provision of "health care services" in California;
    - the transaction can avoid the potential application of SB 184 by closing prior to April 1, 2024;
    - the potential impact of the transaction on the availability, accessibility, quality, and costs of health care services and other competitive considerations that will be evaluated by OHCA in determining whether the transaction will be subject to an extended review period required for the conduct of a CMIR; and
    - the transaction may be eligible for expedited review from OHCA due to severe financial distress or the reduction in the provision of critical health care services that would result if the transaction does not close until after the completion of the review period.
- **Aggregation of Prior Transactions: Disclosure of Prior Acquisitions Involving the Same Parties or the Same or Related Health Care Services.** The broad disclosure obligations under the regulations require an acquiring entity to carefully identify and report prior transactions that occurred in the past 10 years (i) involving the same parties (or their affiliates) or (ii) where the acquiring entity has acquired a health care entity that provides the same or related health care services. Such prior transactions must be aggregated and treated as part of a single transaction for purposes of determining whether notice is required. Thus, an entity that has participated in other transactions over the past 10 years must identify and describe prior acquisitions involving the same parties or the same or related health care services. The aggregation requirements will call for extensive review of prior transaction history and may

require disclosure with respect to individual transactions that are beneath the general materiality thresholds but which, in the aggregate, may trigger the filing.

- **Coordination with OHCA.** The parties need to coordinate and cooperate with respect to the development of a communication and outreach plan with OHCA, including through the potential use of the pre-filing information request process set forth under the regulations that authorize outreach by the parties to OHCA with respect to questions relating to the application of the filing requirements to a transaction.
- **Information Exchange/Sharing.** Although each submitter is responsible for the submission of a separate notice, the parties to the transaction will need to coordinate and cooperate with each other and their legal advisors with respect to the parties' exchange of pre-transaction information, to the extent permitted by law, to ensure an accurate and consistent description of the transaction among all parties subject to the notice requirement.
- **Preservation of Confidentiality.** In order to safeguard proprietary information and limit the public disclosure of confidential information, the submitter should work closely with its legal advisors to ensure that the appropriate portions of the notice are designated as confidential and that the justification for such confidentiality is documented in accordance with the requirements set forth in the regulations.

FOOTNOTES

[1] See 22 California Code of Regulations (hereinafter "22 CCR") § 97431(g), H&S § 127500.2(k).

[2] "Payers" is broadly defined to include (i) health care service plans as defined in the Knox-Keene Health Care Service Plan Act of 1975 or a Medi-Cal managed care plan; (ii) a health insurer licensed to provide health insurance or specialized behavioral health-only policies; (iii) a publicly funded health care program, including Medi-Cal and Medicare; (iv) a third-party administrator; or (v) any other public or private entity, other than an individual, that pays for or arranges for the purchase of health care services on behalf of employees, dependents, or retirees.

[3] See 22 CCR § 97431(o); H&S § 127500.2 (q).

[4] See 22 CCR § 97431(m) and H&S § 127500.2(p)). "Physician Organizations" consist of (1) a physician organization that files consolidated financial statements or contracts exclusively with a health care service plan; (2) a risk-bearing organization; (3) a restricted health care service plan or a limited health care service plan; (4) a medical foundation; (5) a medical group practice, a professional medical corporation, a medical partnership, or any other lawfully organized group of physicians that delivers, furnishes, or otherwise arranges for or provides health care services and is comprised of 25 or more physicians; and (6) an organization of fewer than 25 physicians that is a high-cost outlier whose costs for services are substantially higher compared to the statewide average.

[5] The list of health facilities subject to the notice requirements is set forth at H&S § 1250, including intermediate care and nursing facilities and hospices.

[6] "Clinics" consist of a clinic conducted as an outpatient department of a hospital, a medical foundation, a primary care clinic (community clinic free clinic), and a specialty clinic (surgical, chronic dialysis, and rehabilitation clinics).

[7] Fully integrated delivery system" means a system that includes a physician organization, health facility, or health system, and a "nonprofit health care service plan" that provides health care services to enrollees in a specific geographic region of the state through an affiliate hospital system

and an exclusive contract between the nonprofit health care service plan and a single physician organization in each geographic region to provide those medical services.

[8] See 22 CCR § 97431(g)(2); H&S § 127501(c)(12) and § 127507(a).

[9] See, e.g., 22 CCR § 97431(g)(3) (“health care entity” includes any ”parents, affiliates, or subsidiaries that act in California on behalf of a payer and (A) control, govern or are financially responsible for the health care entity, or are subject to control, governance or financial control by the health care entity, or (B) . . . a subsidiary acting on behalf of another subsidiary.”

[10] HCAI will establish health care cost targets for various health care sectors, including targets by geographic region, payer (by line of business), and individual health care entities. Under such standards, a physician organization will be deemed by HCAI to be a “high-cost outlier” if the costs for services provided by the practice are substantially higher compared to the statewide average for such services, as identified by HCAI through data sources that include, but are not limited to, data from state and federal agencies, other relevant supplemental data, such as financial data on providers that is submitted to state agencies, or other data reported to HCAI. HCAI’s collection of data on total health care expenditures from payers is scheduled to commence in 2024, with the target setting and enforcement efforts to begin in subsequent years. See HCAI website for additional information relating to OCHA’s authority relating health care cost targets (accessed at https://hcai.ca.gov/get-the-facts-about-the-office-of-health-care-affordability/).

[11] As defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the *Code of Federal Regulations* (commencing with section 5.1), *available at* https://data.hrsa.gov.

[12] See, e.g., Finding of Emergency And Notice Of Proposed Emergency Regulations, OHCA, November 28, 2023, p. 22 (accessed at https://hcai.ca.gov/wp-content/uploads/2023/11/CMIR-Finding-of-Emergency-Final.pdf).

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