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OFFICE OF HEALTH CARE AFFORDABILITY
FINDING OF EMERGENCY AND NOTICE OF PROPOSED EMERGENCY REGULATIONS

PROMOTION OF COMPETITIVE HEALTH CARE MARKETS;
HEALTH CARE AFFORDABILITY;
COST AND MARKET IMPACT REVIEWS (CMIR)

SUBJECT MATTER OF PROPOSED REGULATIONS

Implementation of promotion of competitive health care markets and cost and market impact reviews pursuant to Health and Safety Code sections 127501 *et seq.* (CMIR program).

SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION

The Office of Healthcare Affordability (OHCA or Office) within the Department of Health Care Access and Information (HCAI) is statutorily required to review and evaluate consolidation, market power, and other market failures through cost and market impact reviews of mergers, acquisitions, or corporate affiliations involving health care service plans, health insurers, hospitals, physician organizations, pharmacy benefit managers, and other health care entities. (Health & Saf. Code, § 127501, subd. (c)(12).) OHCA is required to adopt emergency regulations to implement the CMIR program and the initial adoption of these regulations is statutorily deemed to be an emergency for purposes of administrative rulemaking. (Health & Saf. Code, § 127501.2, subd. (a).) This is OHCA's initial adoption of regulations to implement the CMIR program.

As directed by statute, OHCA specifically finds these emergency regulations necessary for the immediate preservation of public health and safety, and general welfare of the citizens of California. (Health & Saf. Code, § 127501.2, subd. (a)(1).)

Pursuant to Health and Safety Code section 127501.10, the Health Care Affordability Board was established (Board), and Board members were appointed in the spring of 2023. As required by statute, the Board discussed these emergency regulations at its August 22, 2023, and September 19, 2023, meetings. (Health & Saf. Code, § 127501.2, subd. (c).)

One of HCAI's core values is transparency. Therefore, OHCA posted a draft of these regulations for the public's initial review on July 31, 2023, with a 30-day period to provide comments. Additionally, OHCA held a public workshop (in-person and virtual) during this comment period on August 15, 2023. On October 9, 2023, OHCA posted text

it modified after review and consideration of the first round of comments; this comment period lasted from October 9 through 17, 2023.

Approximately 13 parties made comments at the workshop, and by the end of both comment periods, OHCA received a total of 36 letters with substantive comments from unions, physician groups, health plans, hospital systems, private equity, consumer advocacy groups, and medical, hospital, and nursing associations. OHCA provided a summary of the public comments to the Board and the Health Care Affordability Advisory Committee (AC) at their respective September 2023 meetings.

The Federal Trade Commission (FTC) and the Department of Justice released a draft update of its merger guidelines in July 2023 which describe and guide the agencies' review of mergers and acquisitions under the Clayton Act. As discussed further below, OHCA considered these guidelines in its drafting of the instant proposal. The Office also reviewed other states' legal frameworks, such as Massachusetts, Oregon, New York, Hawaii, and the laws of other California state entities. This included the Attorney General's (AG) framework for review of non-profit hospital transactions, the Department of Managed Care's (DMHC) review of health plan merger reviews, and the Department of Insurance's (CDI) insurance plan transaction reviews.

AUTHORITY AND REFERENCE

Pursuant to Health and Safety Code section 127501(c)(16), 127501.2, 127507(c)(3), 127507.2(a)(3)(A), and 127507.2(b), the Office shall adopt, amend, or repeal, in accordance with the Administrative Procedure Act, rules and regulations as may be necessary to enable it to carry out the laws relating to review of agreements or transactions under the California Health Care Quality and Affordability Act (Health and Safety Code, section 127500, *et seq.* (Act).

These regulations implement, interpret, or make specific Health and Safety Code sections 127500.2, 127500.5, 127502.5, 127507, 127507.2, and 127507.4.

INFORMATIVE DIGEST

Existing Law

Existing law requires the Office to adopt and promulgate regulations for the purpose of establishing the CMIR program. (Health & Saf. Code, § 127501, subd. (c)(16).) Specifically, Health and Safety Code section 127507.2(b) requires:

> [t]he office [to] adopt regulations for notification to affected parties for the basis of the review, factors considered in the review, requests for data and information from affected parties, the public, and other relevant market participants, and relevant timelines.

Furthermore, OHCA must adopt regulations for proposed material changes that warrant a notification, establish appropriate fees, and consider appropriate thresholds, including, but not limited to, annual gross and net revenues and market share in a given service or region. (Health & Saf. Code, § 127507, subd. (c)(3).)

Finally, OHCA *may* adopt regulations to expedite its review of notices of material change, as warranted as warranted, depending on the nature of the agreement or transaction. (Health & Saf. Code, § 127507.2, subd. (a)(3)(B).)

Because OHCA must receive written notice at least 90 days prior to parties entering into agreements or transactions that will occur on or after April 1, 2024, OHCA must adopt these emergency regulations by no later than December 31, 2023. (Health & Saf. Code, § 127507, subd. (c)(1) and (c)(2).)

General Policy Statement

The preponderance of research evidence finds the widespread consolidation of health systems, hospitals, and physicians has contributed to the high price of health care across the United States.[1],[2],[3],[4],[5] Merging entities often claim improved quality through care coordination and increased efficiency and a reduction in duplicative care, but a large and growing body of research evidence suggests these promises often go

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[1] March 2020 Report to the Congress: Medicare Payment Policy, MedPAC, (2020). Available at mar20_entirereport_sec.pdf (medpac.gov) , last accessed October 30, 2023.

[2] Furukawa MF, Kimmey L, Jones DJ, Machta RM, Guo J, Rich EC. Consolidation of providers into health systems increased substantially, 2016-18: study examines provider consolidation into vertically integrated health systems, Health Aff (Millwood) (2020) 39:1321–5.

[3] Abe Dunn and Adam Shapiro. "Do Physicians Possess Market Power?" *Journal of Law and Economics* 57, no. 1 (January 1, 2014), available at: https://chicagounbound.uchicago.edu/jle/vol57/iss1/6, last accessed October 27, 2023.

[4] Thomas Koch and Shawn W. Ulrick. "Price Effects of a Merger: Evidence from a Physicians' Market." SSRN Scholarly Paper. Rochester, NY: Social Science Research Network, August 1, 2017, available at: https://doi.org/10.2139/ssrn.3026344, last accessed October 27, 2023.

[5] Cory Capps, David Dranove, and Christopher Ody. "The Effect of Hospital Acquisitions of Physician Practices on Prices and Spending." Journal of Health Economics 59 (May 1, 2018): 139–52, available at: https://doi.org/10.1016/j.jhealeco.2018.04.001, last accessed October 27, 2023.

unrealized.[6] Federal antitrust enforcers continue to play an important role in overseeing large mergers, acquisitions, and other consolidating transactions of major health care providers, and the recent withdrawal of two antitrust policy statements related to enforcement in health care markets[7] and the proposal of new merger guidelines[8] demonstrate an ongoing desire by the federal enforcement agencies to better protect competition through more effective review of proposed mergers and conduct in health care markets. Recognizing state oversight of health care mergers can fill gaps in federal review, many state legislatures have passed laws requiring parties to file a notice with state officials and some require approval by a state entity, like the state attorney general, before a consolidating transaction can occur.[9],[10],[11] Since 2013, the Massachusetts Health Policy Commission has collected and reviews material change notices before health care providers complete a material change transaction.

In California, only a few state agencies review consolidation among health care entities. The AG has broad authority to take action based on unfair competition laws and reviews consolidation transactions among non-profit health care entities. CDI and DMHC review

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[6] Schwartz, K, Lopez, E, Rae, M, and Neuman, T. What we know about provider consolidation, KFF (2020), available at: https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation, last accessed October 27, 2023.

[7] Federal Trade Commission Withdraws Health Care Enforcement Policy Statements (July 14, 2023), available at: https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements; Justice Department Withdraws Outdated Enforcement Policy Statements (February 23, 2023), available at: https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements, last accessed October 27, 2023.

[8] FTC-DOJ Merger Guidelines (Draft for Public Comment), available at: https://www.ftc.gov/legal-library/browse/ftc-doj-merger-guidelines-draft-public-comment, last accessed October 27, 2023.

[9] Montague, AD, Gudiksen, KL, and King, JS. State action to oversee consolidation of health care providers, Milbank Memorial Fund (2021), available at: https://www.milbank.org/publications/state-action-to-oversee-consolidation-of-health-care-providers, last accessed October 27, 2023.

[10] King, JS, Chang, SM, Montague, AD, Gudiksen, KL, Gu, AY, Arnold, D, et al. Preventing anticompetitive healthcare consolidation: lessons from five states, The Source on Healthcare Price and Competition (2020), available at: https://sourceonhealthcare.org/wp-content/uploads/2020/06/PreventingAnticompetitiveHealthcareConsolidation.pdf, last accessed October 27, 2023.

[11] The Source. Merger Review, available at https://sourceonhealthcare.org/market-consolidation/merger-review/, last accessed October 26, 2023.

mergers of health insurers and health care service plans based on their respective licensing and regulatory jurisdictions. However, even with such oversight, the Legislature recognized the further need for transparency for market consolidation transactions not currently reviewed by these agencies. While these agencies have authority to impose conditions on mergers and acquisitions or block them, the primary role of the Office is to review consolidation activity and collect and report information that is informative to the public. (Health & Saf. Code, § 127507, subd. (a)(1).)

In 2022, the Act (Senate Bill (SB) 184, Chapter 47, Statutes of 2022) established OHCA within HCAI. Recognizing that health care affordability has reached a crisis point as health care costs continue to grow, OHCA's enabling statute emphasizes it is in the public interest that all Californians receive health care that is accessible, affordable, equitable, high-quality, and universal. (Health & Saf. Code, § 127500.5, subd. (a)(1).)

In enacting SB 184, the Legislature found:

> Escalating health care costs are being driven primarily by high prices and the underlying factors or market conditions that drive prices, particularly in geographic areas and sectors where there is a lack of competition due to consolidation, market power, venture capital activity, the role of profit margins, and other market failures. Consolidation through acquisitions, mergers, or corporate affiliations is pervasive across the industry and involves health care service plans, health insurers, hospitals, physician organizations, pharmacy benefit managers, and other health care entities. Further, market consolidation occurs in various forms, including horizontal, vertical, and cross industry mergers, transitions from nonprofit to for-profit status or vice versa, and any combination involving for-profit and nonprofit entities, such as a nonprofit entity merging with, acquiring, or entering into a corporate affiliation with a for-profit entity or vice versa. (Health & Saf. Code, § 127500.5, subd. (a)(4).)

OHCA has three primary responsibilities, to: (1) slow health care spending growth, (2) promote high value system performance, and (3) assess market consolidation. OHCA will collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by the Board. (Health & Saf. Code, § 127500.5, subd. (*l*).) Through its CMIR program, OHCA will analyze transactions that are likely to significantly impact on market competition, the state's ability to meet targets, or affordability for consumers and purchasers. Based on results of the review, OHCA will then coordinate with other state agencies to address consolidation as appropriate. (Health & Saf. Code, § 127507.2, subd. (d)(1).)

This rulemaking creates a new chapter within Title 22 of the California Code of Regulations (CCR), and contains regulations implementing SB 184.

This proposal will:

- Establish a section defining terms used in the regulations. (Proposed section 97431.)
- Establish a section outlining the scope of the proposed regulations. (Proposed section 97433.)
- Establish a section defining the transactions for which a filing of a notice with the Office is required. (Proposed section 97435.)
- Establish a section providing an Office email address for parties with questions about whether a notice is required. (Proposed section 97437.)
- Establish a section outlining the procedure for filing notices of material change transactions and the elements of required filings. (Proposed section 97439.)
- Establish a section outlining the requirements for requesting expedited review of material change notices. (Proposed section 97440.)
- Establish a section outlining the factors the Office will consider in deciding whether to conduct a CMIR, providing an appeals process for the Office's determination, outlining the factors the Office will consider in a CMIR, and providing the procedure for the issuance of preliminary and final reports of the Office's findings. (Proposed section 97441.)
- Establish a section clarifying the Office may also conduct a CMIR based on market power or market failures. (Proposed section 97442.)

SPECIFIC PURPOSE AND NECESSITY FOR EACH REGULATION

Section 97431. Definitions.

OHCA provides a general section on definitions for consistency and clarity. OHCA references terms such as "cost and market impact review," "fully integrated delivery system," "hospital," "payer," "physician organization," and "provider" to the statute for convenience. Standard terms such as "Department," "Director," and "Office" are non-substantive and consistent with existing HCAI regulatory structure.

Subsection (a). Affiliation.

There is a wide range of affiliations, partnerships, and other collaborative agreements among, physician organizations, hospitals, health systems, health care service plans, health insurers, and other organizations that perform functions related to the delivery of health care services. These affiliations may provide opportunities for control over multiple health care entities and consolidation that may lead to market power directly impacting competition, affordability, and access.[12]

[12] Gu and Gudiksen, Collaborative Agreements in Health Care Complexities, Uncertainties, and Considerations for Oversight (May 2023).

The definition of "affiliation" is necessary because the circumstances of an affiliation may constitute the type of material change transaction OHCA has statutory authority to review. The inclusion of "affiliate" in the definition is necessary because, in some cases, an affiliate, performing functions of a health care entity, may be considered a health care entity that is a party to a transaction and may be required to file a notice of a material change transaction. The definition of "affiliate" is also necessary because the affiliate's revenue is used for purposes of calculating total average annual California-derived revenue when a health care entity discerns whether it meets the threshold revenue requirements for reporting material change transactions.

OHCA revised its original draft definition based on the OHCA AC's and public comments to exclude education and research programs. (UC Health Letter dated August 31, 2023, in Underlying Data.) Health care entities may have affiliation agreements with education and research programs (such as teaching hospitals) which do not implicate control, and therefore, do not pose a concern with market power or consolidation. Thus, OHCA excludes such programs because it does not view those types of agreements as included in the legislative intent for review of potential impacts on market competition or market power.

Subsection (c). Culturally Competent Care.

OHCA adapts the definition of "culturally competent care" from the Georgetown University Health Policy Institute.[13] The Health Policy Institute is a multi-disciplinary group of faculty and staff dedicated to conducting research on key issues in health policy and health services research.

Culturally competent care is also a concern for other California departments. This definition aligns with the requirements and initiatives to reduce disparities and provide culturally competent care by numerous regulatory and oversight agencies in California including but not limited to the California Department of Health Care Services, the DMHC, Covered California, and HCAI to identify and meet specific needs of the populations served. (See e.g., Health & Saf. Code, §§ 1262.5, 1367.04, & 1367.043; Cal. Code Regs., tit. 28, § 1300.67.04.)

This definition is necessary to define OHCA's weighing of factors in determining whether to conduct a CMIR in proposed section 97441(a)(2). This factor will focus on the effect of the transaction on the availability and accessibility of health care services that meet the cultural needs of diverse communities. Health and Safety Code section 127507.2(a)(1) and (a)(2) require the Office to consider access to health care in its analysis of a transaction.

[13] Cultural Competence in Health Care: Is it important for people with chronic conditions? (Health Policy Institute), available at: https://hpi.georgetown.edu/cultural/, last accessed October 27, 2023.

The Office will also consider access to culturally competent care under this factor to further legislative intent: “It is the intent of the Legislature to promote the goal of health care affordability while recognizing the need to maintain and increase the supply of trained, culturally and linguistically competent health care workers[.]” (Health & Saf. Code, § 127500.5, subd. (g); see also, § 127500.5, subd. (a)(5) [“Californians of color experience health disparities, including barriers to accessing care, receiving lower quality of care, lack of access to culturally and linguistically competent care, and experiencing worse health outcomes.”].)

Subsection (g). Health Care Entity.

This definition is necessary to define what entities are required to file notices of material change transactions pursuant to proposed section 97435. Health and Safety Code section 127500.2(k) expressly defines the term, so this definition is cross-referenced in the regulatory definition. Additionally, Health and Safety Code section 127500.5(i) provides “the intent of the Legislature [is] to increase transparency on mergers, acquisitions, and corporate affiliations involving health care service plans, health insurers, hospitals or hospital systems, physician organizations, pharmacy benefit managers, and other health care entities that may impact market competition and affordability for consumers and purchasers.” Furthermore, it is OHCA’s responsibility to “review and evaluate consolidation, market power, and other market failures through cost and market impact reviews of mergers, acquisitions, or corporate affiliations involving health care service plans, health insurers, hospitals, physician organizations, pharmacy benefit managers, and other health care entities.” (Health & Saf. Code, § 127501, subd. (c)(12).) The definition of “health care entity” includes the statutorily defined meaning and pharmacy benefit managers because these entities are referenced in sections 127500.5(i) and 127501(c)(12).

In its definition of health care entity, OHCA also includes any parents, affiliates, subsidiaries, or other entities that act as an agent in California on behalf of a payer, provider, fully integrated delivery system, or pharmacy benefit manager, and which either: (1) control, govern, or are financially responsible for the health care entity; or (2) are subject to the control, governance, or financial control of the health care entity, such as an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks; or (3) in the case of a subsidiary, a subsidiary acting on behalf of another subsidiary.

It is necessary to explicitly list these groups to address potential asset re-allocation by a health care entity that is designed to circumvent the revenue thresholds in section 97435(b). OHCA includes the second qualifiers in subsection (g)(3)(i), (ii), and (iii) for the entities in subsection (g)(3) to clarify these entities must either control, govern, or are financially responsible for the health care entity, be subject to the control, governance, or financial control of the health care entity, such as an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks, or in the case of a subsidiary, a subsidiary acting on behalf of another subsidiary.

The categories outlined in subsection (g)(3)(i), (ii), and (iii) are those that, in OHCA's view, are just as likely to pose a concern in the transactions governed by the Act as health care entities themselves. In other words, these are the entities which, when they engage in covered transactions, are just as likely in OHCA's view to affect affordability, access, and equity.

This definition also helps ensure OHCA can review material change transactions in which a health care entity uses affiliated entities that may not appear to be health care entities to complete a transaction and potentially avoid compliance with the notice filing requirements. As there was public confusion regarding whether physician organizations comprised of less than 25 physicians need to comply with filing requirements, the definition clarifies that the statutory exclusion applies, but is limited by the statute. (Health & Saf. Code, § 127500.2, subd. (p)(6).)

Subsection (h). Health Care Services.

OHCA derives the definition of health care services from established definitions in the health care industry and federal and California law. OHCA focuses on core services that could be impacted by the types of transactions regulated by the Act and these proposed regulations. This definition and the focused list of examples are necessary because OHCA defines the term transaction by reference to those impacting the provision of health care services in California and transactions requiring a notice by reference to those that impact the provision of health care services. (See e.g., proposed sections 97431(p) 97435(c)(1), (c)(7), (c)(9), (c)(10).) The definition also includes payments for services because OHCA must review material change transactions by payers. The inclusion of payments in the definition ensures that payer material change transactions are included in the circumstances requiring filing in section 97435(c).

Generally, health care services are broadly understood to include prevention, diagnosis, treatment, cure, or relief. (See e.g., 42 U.S.C. § 234(d)(2)(A) ["the diagnosis, prevention, or treatment of any human disease or impairment"]; see also, Health & Saf. Code, § 1345, subd. (b); Cal. Code Regs., tit. 28, § 1300.67.) OHCA drafted this definition to provide a non-exhaustive list of the types of health care services performed by entities subject to OHCA's statutorily mandated reviews, including health care service plans, health insurers, hospitals, physician organizations, pharmacy benefit managers, and other health care entities. In consultation with economic experts and other state entities, OHCA delineated health care services that pose concerns for affordability, access, and equity in covered transactions.

OHCA includes inpatient services in subsection (h)(1) to focus on hospitals, which is an area of consolidation or acquisition of or by other hospitals or investors.

OHCA includes outpatient services in subsection (h)(2) to include ambulatory surgery, radiology, dialysis, etc., which is another area of concern for investment and consolidation.

In furtherance of the legislative intent, OHCA includes pharmacy services in subsection (h)(3). (See e.g., Health & Saf. Code, § 127501, subd. (c)(12).)

OHCA includes the performance of functions to refer, arrange, or coordinate care services in subsection (h)(4) because physician organizations and other providers refer patients for treatment and care and health care service plans and health insurers authorize payment and sometimes assist with the coordination of referrals.

OHCA includes equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion inpatient services in subsection (h)(5) because these are all types of items and services that may be prescribed by providers for patient care and are generally covered for payment by health care service plans and health insurers.

OHCA includes technology associated with the provision of services or equipment in subsections (h)(1) through (5), such as telehealth, electronic health records, software, claims processing, or utilization systems in subsection (h)(6) because medical technology permeates health care delivery systems. With increasing use and access by patients and the federal mandates of the interoperability rules for patients to have access to their health records and take their information with them, electronic health records are included within the definition of a health care service as associated technology.[14] The now widespread use of telehealth for appointments with medical providers requires the use of technology. Health care service plans and health insurers utilize computer systems for claims processing and utilization and there is a growing trend to outsource these computer systems, along with increasing investments in these services.

Subsection (j). Material Change Transaction.

Health and Safety Code section 127507(c) requires a health care entity to provide OHCA with written notice of agreements or transactions that will occur on or after April 1, 2024, that do either of the following:

- Sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its assets to one or more entities.
- Transfer control, responsibility, or governance of a material amount of the assets or operations of the health care entity to one or more entities. (Health & Saf. Code, § 127507, subd. (c)(1)(A) & (c)(1)(B).)

OHCA is required to promulgate regulations to define material changes that warrant a notification to the Office. (Health & Saf. Code, § 127507, subd. (c)(3).)

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[14] Interoperability and Patient Access Fact Sheet, March 9, 2020, available at: https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet.

The definition of "material change transaction" is necessary to define those transactions that require the filing of a notice. The definition references section 127507 and the proposed regulation implementing the statute. The Office also enumerates transactions that are not material, such as those in the day-to-day, usual and regular course of business, and situations that amount to internal adjustments or restructurings in subsections (j)(1) and (j)(2). This is necessary to minimize the Office's burden from receiving notices of transactions that would not typically trigger health care consolidation concerns. Health care entities will determine whether their proposed transactions are typical in day-to-day, usual and regular course of business, and it will be a fact-specific inquiry for the Office to determine whether transactions proposed by a filer meet these exceptions.

This exemption follows precedent established by the AG in non-profit hospital merger reviews. The AG exempts agreements in the "usual and regular course of activities" of nonprofit corporations. (Cal. Code Regs, tit. 11, §999.5, subd. (a)(4).) The FTC also exempts transfers of goods or realty "in the ordinary course of business" as part of recent amendments. The FTC found that certain categories of transactions regarding real property assets were unlikely to violate antitrust laws and the reporting requirement for those types of transactions was an unnecessary burden.[15]

Subsection (k). Notice.

The definition of "notice" refers to notices of material change transactions set forth in proposed section 97435. As the Office uses "notice" for shorthand throughout the regulations, this definition is necessary for brevity and clarity.

Subsection (p). Transaction.

The definition of "transaction" is based on the statutory discussion of covered transactions in Health and Safety Code section 127507(a) and (c):

> (a) The office … shall promote competitive health care markets by examining mergers, acquisitions, corporate affiliations, or other transactions…
> (b) …
> (c) (1) … that do either of the following:

[15] Baer, William J, Former Director, Bureau of Competition. *Reflections on 20 Years of Merger Enforcement under the Hart-Scott-Rodino Act*, Public Statement before The Conference Board, Washington, D.C., October 29, 1996 and before The 35th Annual Corporate Counsel Institute, Northwestern University School of Law, Corporate Law Center, San Francisco, CA, October 31, 1996, available at https://www.ftc.gov/news-events/news/speeches/reflections-20-years-merger-enforcement-under-hart-scott-rodino-act, last accessed July 10, 2023.

(A) Sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its assets to one or more entities.
(B) Transfer control, responsibility, or governance of a material amount of the assets or operations of the health care entity to one or more entities.

The Office restates the statutory language in the regulation for convenience of the regulated public.

The Office considered further defining "merger" or "acquisition" or "agreement" but determined these terms are well understood in the industry. OHCA defines "affiliation" in subsection (a) for clarity. OHCA further defines a transfer of "control, responsibility, or governance" in proposed section 97435(e).

The Office also includes the language "impacting the provision of health care services in California." The definition is necessary so health care entities understand what constitutes a transaction under section 127507 and focus OHCA's inquiry on the material change transactions that pose the greatest concerns for affordability, access, and equity in this State.

Section 97433. Scope.

This section prescribes the scope of Article 1 regulations and sets the stage for requirements governing the filing of notices of material change transactions and the circumstances under which such notices will trigger a cost and market impact review. OHCA adds a scope section for consistency with the Department's other regulations and to assist users of the California Code of Regulations to find the appropriate sections.

Section 97435. Material Change Transactions.

Subsection (a)

Subsection (a) is necessary to explain the date by which entities must file a notice with the Office. Subsection (a) clarifies section 127507(c)(2)'s reference to "entering into the agreement or transaction" by defining it as the closing date of the transaction.

The definition is necessary because a transaction or agreement may have many milestones, such as signing a letter of intent, negotiating finer contract terms, entering into escrow, closing a deal, or transferring funds necessary to complete the transaction. While the statute requires at least 90 days' advance notice, the parties may submit notice of the material change transaction earlier to enable OHCA to begin and conduct its review sooner. By clarifying that notice is required at least 90 days before closing, parties can plan accordingly for the anticipated completion of their transactions.

Subsection (b). Who Must File.

Subsection (b) is necessary because it specifies who must file notice of a material change transaction.

Health and Safety Code section 127507(c)(3) requires OHCA to adopt regulations for "proposed material changes that warrant notification, establish appropriate fees, and consider appropriate thresholds, including, but not limited to, annual gross and net revenues and market share in a given service or region." Health care entities entering into transactions can determine if they must submit a notice of material change transaction by applying the proposed multi-step test, the first part of which is set forth in subsection (b). If a health care entity meets the thresholds set forth in (b)(1), (b)(2), or the geographic threshold in (b)(3), it then determines whether the transaction fits within any of the circumstances listed in subsections (c)(1) through (c)(8). For clarity, the regulation references the exemptions for filing in section 127507(d)(1) through (4).

Statutorily, only a health care entity is responsible for filing a notice. (Health & Saf. Code, § 127507, subd. (c)(1).) Because more than one health care entity may meet the listed thresholds in subsection (b), there may be more than one health care entity required to file notice of a transaction.

Under Health and Safety Code Section 127507(c)(1), a health care entity shall provide the Office with notice of agreements or transactions that either "sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its 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." Subsections (b) and (c) implement, interpret, and make specific those transactions the Office views to be material under section 127507(c)(3).

Subsection (b)(1)

In subsection (b)(1), OHCA establishes a threshold for a health care entity with an annual revenue of at least $25 million, or that owns or controls California assets of at least $25 million. This threshold would encompass, for instance, a "larger" health care entity, perhaps a hospital or health care service plan, that is contemplating a transaction with another "larger" or "smaller" entity.

This threshold is necessary to specify the size of the submitting entity for purpose of performing the multi-step test in subsections (b) and (c). In establishing this threshold, OHCA considered the thresholds established by other states, and consulted economic experts regarding the revenue and ownership of entities engaging in consolidation that pose the most concern for affordability, access, and equity.

For instance:

- Massachusetts defines one type of material change as any clinical affiliation between two or more providers or provider organizations that each had annual net patient service revenue of $25 million or more in the preceding fiscal year. (958 CMR 7.02.)
- Oregon establishes a material change transaction is subject to review under its rules if at least one party to the transaction had average annual revenue of $25 million or more in the party's three most recent fiscal years along with another party's annual revenue of $10 million or more in that party's three most recent three fiscal years. (ORS 409-070-0015(1)(a) and (1)(b)(A).)

OHCA considered alternative thresholds, what health care entities and transactions such thresholds would likely include, and the filings that would be generated for the Office's review in adopting the threshold set forth in subsection (b)(1).

Subsection (b)(2)

In subsection (b)(2), OHCA establishes a threshold for a health care entity with annual revenue, as defined in subsection (d), of at least $10 million or that owns or controls California assets of at least $10 million and is a party to a transaction with any health care entity satisfying subsection (b)(1).

This threshold is necessary to specify an alternative test for the size of the contracting entities for purpose of performing the multi-step test in subsections (b) and (c).

This threshold would, for instance, encompass a "smaller" health care entity meeting the $10 million revenue threshold, such as a clinic, contemplating a transaction with a "larger" health care entity qualifying under subsection (b)(1). Under this scenario, both health care entities must file a notice. If a health care entity has revenue less than the $10 million threshold, it would not have to file a notice, but the larger entity qualifying under subsection (b)(1) would need to file.

Alternatively, if two health care entities each have revenue less than $10 million, then neither would be required to file.

In establishing this threshold, OHCA considered the thresholds established by other states, and consulted economic experts regarding the revenue and ownership of entities engaging in consolidation that pose the most concern for affordability, access, and equity.

Oregon, for example, establishes a material change transaction is subject to review under its rules if at least one party to the transaction had average annual revenue of $25 million or more in the party's three most recent fiscal years along with another party's annual revenue of $10 million or more in that party's three most recent three fiscal years. (ORS 409-070-0015(1)(a) and (1)(b)(A).)

OHCA considered alternative thresholds, what such thresholds would likely include, and the filings that would be generated for the Office's review in adopting the threshold set forth in subsection (b)(2).

Subsection (b)(3)

In subsection (b)(3), any health care entity located in a California health professional shortage area (HPSA) would meet the threshold. (42 C.F.R. § 5.1.) HPSA means any of the following which the Secretary of Health and Human Services determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility. (42 C.F.R. § 5.2.)

HPSAs are located in 38 counties of California; the 135 HPSAs collectively cover a population of 4,703,150.[16] Providers in HPSAs may be prone to acquisition, which is why OHCA adopts this threshold in subsection (b)(3). OHCA considered as an alternative listing a "medically underserved area" (MUA) instead of HPSA. However, California's statutory definition of MUA refers to the HPSA (see e.g., Health and Safety Code section 128552) whereas federal references are lifetime designations based on data from the 1980s and 1990s. As the term MUA is not as up-to-date as HPSA, OHCA has chosen the HPSA term, which is updated every few years.

Further, in choosing to use HPSA, this proposal focuses only on two of the three types, that is, primary care and mental health. This proposal does not include dental care since the Act does not include dental care as health care. This proposal establishes a test of whether a health care entity is located at an address in a California HPSA.

Determining whether a facility is located in a HPSA is as simple as entering an address in the federal web site provided in the regulatory text.[17]

If multiple parties to the transaction meet the thresholds in subsections (b)(1) through (b)(3), each party would be required to file separate notices. In Massachusetts, most filings involve two parties. In Oregon, there is a joint form for filing (both parties must be healthcare entities). While OHCA considered whether to allow joint filings, this proposal requires separate filings to ensure full transparency to the public of each entity that

[16] California Health and Human Services Agency datasets, as of July 2023, available from https://data.chhs.ca.gov/dataset/?q=hpsa, last accessed October 27, 2023.

[17] Health Resources and Services Administration, Health Workforce Data, Tools, and Dashboards, available at https://data.hrsa.gov/topics/health-workforce/health-workforce-shortage-areas?hmpgtile=hmpg-hlth-srvcs, last accessed October 26, 2023.

meets the threshold and circumstances, and strives to obtain information from the perspectives of all transacting parties for a more comprehensive analysis.

OHCA proposes to post filings online and make the public aspects searchable. Each party to the transaction will have the opportunity to describe the transaction as it affects them which will be informative for members of the public or researchers interested in health care consolidation.

Subsection (c). Circumstances Requiring Filing.

Once a health care entity who is a party to a transaction has determined that they are not exempt and meet any of the thresholds set forth in subsections (b)(1) through (b)(3), they must determine if their transaction falls within one or more of the circumstances set forth in subsections (c)(1) through (c)(8). The Office proposes eight circumstances which, if any one or more are met, require submission of a notice.

These circumstances are necessary to define materiality so health care entities can understand and comply with the requirement to submit notices of material change transactions to the Office. Section 127507 requires the Office to adopt regulations for proposed material changes that warrant a notification. (Health & Saf. Code, § 127507, subd. (c)(3).)

A wide variety of health care entities are subject to the Act so it is necessary for OHCA to define materiality for the material changes that can involve health care entities of varying types and sizes and may impact consolidation.

Subsection (c)(1)

The first circumstance applies if the proposed fair market value of the transaction is $25 million or more and the transaction concerns the provision of health care services.

In establishing this circumstance, OHCA considered the transactional thresholds established by other states, other California state entities, and consulted economic experts regarding the transactional value that poses the most concern for affordability, access, and equity.

Assembly Bill (AB) 1091 (2023) proposes to adopt a filing requirement for a material change with a value of fifteen million dollars or more. (Proposed Corporations Code section 5931.)

OHCA considered alternative characteristics for this circumstance, the transactions such circumstances would likely include, and the filings that would be generated for the Office's review in adopting this circumstance. OHCA chose a proposed market of $25 million or more and to require notice when the transaction concerns the provision of health care services because it is generally consistent with the proposed filing threshold

in AB 1091, other states' approaches, and focuses on the impacts of consolidation on affordability, access and equity for health care services in California.

Subsection (c)(2)

The second circumstance applies if the transaction is more likely than not to increase annual California-derived revenue of any health care entity that is a party to the transaction by either $10 million or more or 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation.

Normal or stabilized levels of utilization or operation refer to the implementation of the transaction, which could take a month or one or more years, but which each party to the transaction will likely have calculated as part of their due diligence in deciding to move forward with the transaction.

In establishing this circumstance, OHCA considered that transactions often transfer a material amount of assets or control in order to achieve desired returns on performance and profit. OHCA examined similar transactional thresholds established by other states, and consulted economic experts regarding the types of transactions where significant investments impact consolidation and that pose the most concern for affordability, access, and equity.

For instance:

- Massachusetts defines one type of material change as any other acquisition, merger, or affiliation (such as a corporate affiliation, contracting affiliation, or employment of health care professionals) of, by, or with another provider, providers (such as multiple health care professionals from the same provider or provider organization), or provider organization that would result in an increase in annual net patient service revenue of the provider or provider organization of ten million dollars or more, or in the provider or provider organization having a near majority of market share in a given service or region. (958 CMR 7.02, Material Change (c).)
- New York defines a "material transaction includes any of the following that occur during a single transaction or in a series of related transactions within a rolling 12-month period that result(s) in a health care entity increasing its total gross in-state revenues by $25 million or more." (New York State Public Health Law (PHL), Article 45-A, effective August 1, 2023.)

OHCA considered alternative characteristics for this circumstance, the transactions such circumstances would likely include, and the filings that would be generated for the Office's review in adopting the circumstance set forth in subsection (c)(2). The Office chose the $10 million or more or 20% more of annual California-derived revenue at normal or stabilized levels of utilization or operation because it includes transactions that in the Office's view, are most likely to impact affordability, access, and equity. It is also generally consistent with thresholds established by other states.

Subsection (c)(3)

The third circumstance applies if the transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of the submitter(s).

Health and Safety Code section 127507(c)(A) requires an examination of transactions that "sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its assets to one or more entities." Therefore, the initial focus of this circumstance is on the sale, transfer, lease, exchange, option, encumbrance, or other disposition of assets.

In establishing this circumstance, OHCA considered the transactional thresholds established by other states, and consulted economic experts regarding the transfers that pose the most concern for affordability, access, and equity.

For instance:

- In Rhode Island, since 1997, transfers of 20% or more of ownership, assets, membership interest, authority or control of a hospital in Rhode Island require approval by both the Department of Health and the Rhode Island Department of the Attorney General (RIAG) under the authority of the Hospital Conversions Act. (RI ST § 23-17.14-6.)
- In Hawaii, an "acquisition" means any acquisition by a person or persons of an ownership or controlling interest in a hospital, whether by purchase, merger, lease, gift, or otherwise, that results in a change of ownership or control of twenty per cent or greater or which results in the acquiring person or persons holding a fifty per cent or greater interest in the ownership or control of that hospital. (HI ST § 323D-71A.)

Additionally, AG regulations provide an agreement or transaction involves a "material amount of the assets or operations" if among other things, "… [t]he agreement or transaction directly affects more than 20% of the value of the health facilities or facilities that provide similar health care that are operated or controlled by the nonprofit corporation." (Cal. Code Regs., tit. 11, § 999.5, subd. (a)(2)(A).)

OHCA considered alternative characteristics for this circumstance, the transactions such circumstances would likely include, and the filings that would be generated for the Office's review in adopting the circumstance set forth in subsection (c)(3). The Office has determined that 25 percent of California assets is a material amount because it includes transactions that in the Office's view, are most likely to impact affordability, access, and equity. It is also generally consistent with thresholds established by other states and the AG.

Subsection (c)(4)

The fourth circumstance applies if the transaction involves a transfer of control, responsibility, or governance of the submitter, in whole or in part, as defined in subsection (e).

This circumstance implements Health and Safety Code section 127507(a) and (c)(1)(B) which requires the Office to promote competitive health care markets by examining mergers, acquisitions, corporate affiliations, or other transactions that transfer control, responsibility, or governance of a material amount of the assets or operations of the health care entity to one or more entities.

Similarly, AG regulations provide an agreement or transaction involves a "material amount of the assets or operations" if among other things "… [t]he agreement or transaction involves the sale, transfer, exchange, change in control or governance of, or otherwise disposes of any general acute care hospital as defined in Health and Safety Code section 1250(a)." (Cal. Code Regs., tit. 11, § 999.5, subd. (a)(2)(C).)

Subsection (c)(5)

The fifth circumstance applies if the transaction will result in an entity contracting with payers on behalf of consolidated or combined providers and is more likely than not to increase the annual California-derived revenue of any providers in the transaction by either $10 million or more or 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation.

This circumstance could include multiple physician groups, or a variety of providers in a geographic location, who transfer control to and/or authorize a management service organization (MSO) to contracting with payers on their behalf. These types of arrangements can lead to consolidation and sometimes market power.

In establishing this circumstance, OHCA considered the transactional thresholds established by other states, and consulted economic experts regarding the impact of MSO contracting on health care consolidation that impacts affordability, access, and equity.

For instance:

- Massachusetts defines a material change as any formation of a partnership, joint venture, accountable care organization, parent corporation, management services organization, or other organization created for administering contracts with carriers or third-party administrators or current or future contracting on behalf of one or more providers or provider organizations. (958 CMR 7.02, Material Change (e).)
- Oregon establishes a material change transaction is subject to review under its rules if a transaction to form a new partnership, joint venture, accountable care

organization, parent organization or management services organization between or among health care entities that will, among other things, consolidate or combine providers of essential services when contracting payment rates with payers, insurers, or coordinated care organizations. (ORS 409-070-0010(1)(e)(B).)

- New York defines a "material transaction includes any of the following that occur during a single transaction or in a series of related transactions within a rolling 12-month period that result(s) in a health care entity increasing its total gross in-state revenues by $25 million or more." (New York State Public Health Law (PHL), Article 45-A, effective August 1, 2023.)

OHCA considered alternative characteristics for this circumstance, the transactions such circumstances would likely include, and the filings that would be generated for the Office's review in adopting the circumstance set forth in subsection (c)(5). The Office also considered distinctions between the types of MSOs that are owned by providers versus MSOs who are not owned but are given control by providers to contract with payers on behalf of providers. OHCA chose to align its approach with other states' approaches.

Subsection (c)(6)

The sixth circumstance applies if the transaction involves the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health care services in California that is projected to have at least $25 million in California-derived annual revenue at normal or stabilized levels of utilization or operation, or transfer of control of California assets related to the provision of health care services valued at $25 million or more. A revenue component defines what transactions are material for purposes of this circumstance.

A transaction is defined in the regulations to include mergers, acquisitions, affiliations, or agreements impacting the provision of health care services in California, that involve a transfer of assets or transfer of control, responsibility, or governance of the assets or operations of any health care entity in whole or in part to one or more entities. (Proposed section 97431(p).) This section is necessary to encompass transactions where, for example, the character or name of the parties' businesses have changed but a transfer of assets or transfer of control, responsibility, or governance of the assets or operations of any health care entity in whole or in part to one or more entities has nonetheless taken place. This provision will clarify the transaction should still be reported even if the business is a newly formed entity.

In AB 1091, the AG proposes to adopt a filing requirement for a material change with a value of fifteen million dollars or more. (Proposed Corporations Code section 5931.)

OHCA considered alternative characteristics for this circumstance, the transactions such circumstances would likely include, and the filings that would be generated for the Office's review in adopting the circumstance set forth in subsection (c)(6). The Office

chose the “at least $25 million in California-derived annual revenue at normal or stabilized levels of utilization or operation, or a transfer of control of California assets related to the provision of health care services valued at $25 million or more” because this language includes the larger transactions that in the Office’s view, are most likely to impact affordability, access, and equity. It is also generally consistent with AB 1091’s proposed approach but increased to avoid encompassing transactions that would not necessarily pose a consolidation concern.

Subsection (c)(7)

The seventh circumstance applies if the transaction is part of a series of related transactions for the same or related health care services occurring over the past ten years involving the same health care entities or entities affiliated with the same entities. The proposed transaction and its related transactions will constitute a single transaction for purposes of determining the revenue thresholds in subsection (b) and asset and control circumstances in subsection (c).

Because, as a result of a series of transactions, there will be a material change in control or assets, the Office wants to review the transactions together. In this way, the Office will be able to examine trends (Health and Safety Code 127507(a)), and determine if the series will ultimately negatively impact the marketplace or consumers. Additionally, reviewing past incremental transactions assists OHCA in determining whether a proposed transaction is likely to have a significant impact (e.g., by looking at the impacts of previous transactions). (Health & Safety Code, § 127507.2(a)(1).) Finally, such a lookback will assist the Office in determining whether the same entity is structuring multiple transactions involving the same or related health care services and the same or affiliated entities, to fall beneath the thresholds to avoid regulatory review but slowly acquire market power, instead of engaging in a singular transaction. Because smaller transactions may not be as visible to the public as larger transactions, OHCA establishes a separate circumstance to focus on such transactions.

As the FTC has noted with respect to its own merger guidelines:

> Informed by recent enforcement experience, the proposed guidelines also address serial acquisitions. A variety of sectors have seen firms consolidate markets through roll-up strategies that rely on a series of smaller acquisitions. The proposed draft clarifies that enforcers may evaluate an overall pattern of serial acquisitions or examine it as part of an industry trend.[18]

[18] Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding FTC-DOJ Proposed Merger Guidelines Commission File No. P234000 (July 19, 2023.)

OHCA utilizes a ten-year lookback because this is consistent with the FTC's recent proposed guidelines.

The FTC is proposing changes to their filing form that includes the 10-year lookback: the Commission proposes extending the time frame to report on prior acquisitions from five to ten years because the current five-year requirement for prior acquisitions is often insufficient to meaningfully identify patterns of serial acquisitions or a trend toward concentration or vertical integration. The FTC "believes ten years would once again provide for a better framework to allow the Agencies to engage in a more detailed consideration of how numerous past acquisitions, including those in related sectors, affect the competitive landscape of the current transaction under review."

Subsection (c)(8)

The eighth circumstance applies if the transaction involves the acquisition of a health care entity by another entity and the acquiring entity has consummated a similar transaction(s), in the last ten years, with a health care entity that provides the same or related health care services. The proposed transaction and its related transactions will constitute a single transaction for purposes of determining the revenue thresholds in subsection (b) and asset and control circumstances in subsection (c).

This circumstance differs from circumstance (c)(7) in that it focuses on the acquisition of one health care entity by another health care entity, and the acquiring entity has consummated similar transactions in the last ten years with unrelated health care entities that provide the same or related health care services.

This scenario envisions what the FTC refers to as a "roll-up"[19] and entails a series of transactions in which actors make investments in similar small health care entities.

> Many of today's behemoth systems — such as Northwell Health in New York, Sutter in California, and the University of Pittsburgh Medical Center in Pennsylvania — grew often by buying one small hospital, physician practice, or surgery center at a time, below the threshold where they would attract federal regulators' scrutiny or merit use of their limited resources.[20]

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[19] See, e.g., *FTC v U.S. Anesthesia Partners* complaint, filed in federal district court on September 21, 2023, at https://www.ftc.gov/system/files/ftc_gov/pdf/2010031usapcomplaintpublic.pdf, last accessed October 27, 2023.

[20] Elisabeth Rosenthal, KFF Health News. *Your Exorbitant Medical Bill, Brought to You by the Latest Hospital Merger*, August 11, 2023,

The acquiring entities may engage in a series of similar or related transactions in which they are buying up similar health care entities, thereby monopolizing the market, and driving up prices for consumers. In a recent example in Texas:

> The FTC's complaint, filed in federal district court, alleges that USAP and Welsh Carson, which created USAP, engaged in a three-part strategy to consolidate and monopolize the anesthesiology market in Texas. First, they executed a roll-up scheme, systematically buying up nearly every large anesthesia practice in Texas to create a single dominant provider with the power to demand higher prices. Second, USAP and Welsh Carson further drove up anesthesia prices through price-setting agreements with remaining independent practices. Third, USAP sidelined a significant competitor by striking a deal to keep it out of USAP's territory.[21]

By having a lookback provision that allows the Office to review the current proposed transaction in a context with other transactions over the prior ten years, the Office can review trends, to determine if monopolistic behavior is occurring. OHCA selected a ten-year lookback here for the same reasons it did in circumstance (c)(7).

Subsection (d). Revenue.

This subsection is necessary so health care entities can ascertain whether they have to file notice of a material change transaction.

In order to determine if a health care entity falls within the revenue and asset thresholds set forth in subsection (b), OHCA defines "revenue" in subsection (d). In subsections (d)(1) through (d)(5), if a health care entity (here, either a health care service plan, health insurer, hospital, long-term care facility, or risk-bearing organization) is already reporting revenue, the Office designates a definition of revenue that relies upon information the health care entity already submits to a regulatory agency. This provides these entities an easy means of computing revenue for purposes of the regulation.

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https://kffhealthnews.org/news/article/hospital-mergers-exorbitant-medical-bills-ballad-health/, last accessed October 27, 2023.

[21] FTC Challenges Private Equity Firm's Scheme to Suppress Competition in Anesthesiology Practices Across Texas, Press Release dated September 21, 2023, available at https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-challenges-private-equity-firms-scheme-suppress-competition-anesthesiology-practices-across?utm_source=govdelivery, last accessed October 11, 2023.

In subsection (d)(6), OHCA defines revenue for other provider or provider organizations, as net revenue, which includes the total revenue received for patient care, as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed, including the elements set forth in subsection (d)(6)(A) through (d)(6)(D). The definition requires net revenue to be determined when it was generated or occurred (as opposed to booked, accrued, or taxed) because it is a better reflection of the submitter's financial status as the time of filing. Revenue can be booked, accrued, or taxed months or even years after it was generated or occurred. Each of these categories denote revenue which provider and provider organizations customarily receive.

In subsection (d)(7), OHCA defines revenue for pharmacy benefit managers all payments and revenue received from health care entities to provide pharmacy benefit management services as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed. This is a proper description of revenue based on the entity's type of service. The definition requires net revenue to be determined when it was generated or occurred (as opposed to booked, accrued, or taxed) because it is a better reflection of the submitter's financial status as the time of filing. Revenue can be booked, accrued, or taxed months or even years after it was generated or occurred.

OHCA narrowed revenue to mean California-derived revenue, since some health care entities are national (or even international) in scope, and OHCA is focused impacts within the state. OHCA chose the total average of the three most recent fiscal years to account for external factors impacting the entity, such as a global pandemic or recession. Requiring the revenue to be counted as it was "generated or occurred" rather than "when booked, accrued, or taxed" prevents some income-reporting avoidance strategies.

Subsection (e). Control, Responsibility, or Governance.

The Office is required to review transactions in which a transfer of control, responsibility, or governance occurs. (Health & Saf. Code, § 127507, subd. (c)(1)(B).) Therefore, it is necessary to define what transfers are material for the purposes of establishing when a notice is required to be filed. The definition is necessary because the Office focuses on such transfers in subsection (c)(4) which reviews whether the transaction involves a transfer of control, responsibility, or governance and subsection (c)(6) which reviews whether a transfer of control of California assets related to the provision of health care services valued at $25 million or more.

This proposal lists three scenarios where transactions would yield material changes in control, responsibility, or governance. In the first scenario, voting power is altered materially by adding or substituting members of a governing body or by an arrangement. In the second, supermajority and veto rights are implicated. The third scenario focuses not on voting rights but on governance, which could occur by one party taking over the governance of the management of another party. In scenarios (1) and (3), 25% is used as the tipping point for materiality. The Office originally considered setting these limits at ten percent, but adopts language with a higher limit.

OHCA considered comments from stakeholders that change of control must be more than 50% percent of voting power because of the definitions of "control" in the California Corporations Code section 160(b). However, the Act requires health care entities to provide notice of transactions that "transfer control, responsibility, or governance of a material amount of the assets or operations of a health care entity." (Health & Saf. Code, § 127507, subd. (c)(1)(B).). The Corporations Code also defines "control" as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a corporation." By tasking OHCA with establishing regulations that warrant notification and consider appropriate thresholds, the Legislature mandated OHCA define what constitutes a material transfer of control, responsibility, or governance. If one-quarter of an operation is being affected, OHCA has determined there is a material transfer of control that could affect affordability, access, and equity.

OHCA recognizes there are situations where less than 25% of voting or governance power exist when ownership share or representatives may be vested with supermajority or veto rights. Veto rights is a term commonly understood to equate to control of decisions and directions of a health care entity. Corporations use supermajority voting for corporate actions that may significantly impact the future of the company. Certain owners or officers may have super voting status because they control a majority or near majority of the shares of a corporation, meaning their votes carry greater weight allowing them to control the supermajority voting needed for corporate decisions and direction.[22]

This subsection was also informed by AG regulations regarding language for adding or substituting members or transferring voting control. (Cal. Code Regs., tit. 11, subd. (a)(3) ["For purposes of section 999.5 of these regulations, an agreement or transaction will "transfer control, responsibility, or governance" if: (A) There is a substitution of a new corporate member or members that transfers the control of, responsibility for, or governance of the nonprofit corporation; or (B) There is a substitution of one or more members of the governing body, or any arrangement, written or oral, that would transfer voting control of the members of the governing body."].)

Additionally, in deciding to include scenarios involving supermajority voting and super voting status, OHCA consulted with consolidation experts on the use of supermajority voting structures by corporations and how they can impact decisions on mergers and acquisitions.

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[22] Super Voting: Everything You Need to Know, available at: https://www.upcounsel.com/super-voting, last accessed October 27, 2023; Supermajority Voting Provision, available at: https://corporatefinanceinstitute.com/resources/equities/supermajority-voting-provision/, last accessed October 27, 2023.

Section 97437. Pre-Filing Questions.

As a new program, the Office understands heath care entities may have questions regarding whether they must file a notice pursuant to these regulations. Therefore, the Office has set up an email account to which entities may direct inquiries. While not a regulatory directive, placement of this information in this Article will assist those trying to comply with the law.

Section 97439. Filing of Notices of Material Change Transactions.

Subsection (a).

Subsection (a) is necessary to establish the manner of submission of material change notices to OHCA. The Office will make a data portal available online, and this subsection provides the method for establishing an account to log in and create a submission.

The subsection requires the input of a first and last name, valid email account, display name and password, and entry of a system-generated code. A submitter may be a law firm or other management company that is not the submitting health care entity itself, so the Office needs contact information for a single point of contact for communication about the notice and the Office's review. Therefore, a submitter needs to provide an email address for a monitored account. Since the contact individual is providing information for Office use, that information is deemed non-public, as it will not further the transparency of the notice posting. The Office requires a document or section/page citation where narrative responses are allowed in the notice to facilitate clear responses and save time wasted sifting or scrolling through pages of documents to verify the response.

Finally, subsection (a) requires the submitter to submit information under penalty of perjury. Certification under penalty of perjury is necessary to ensure that the submission contains truthful, factual representations made in good faith. (See e.g., *In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 [judicial explanation for the use of certifications under penalty of perjury: "The whole point of permitting a declaration under penalty of perjury, in lieu of a sworn statement, is to help ensure that declarations contain a truthful factual representation and are made in good faith."].) Accordingly, the certification under penalty of perjury in the notice is necessary to ensure the submission of truthful and accurate information.

In addition, the certification under penalty of perjury helps ensure the reliability of the statements to the Office (since certifying under penalty of perjury can have a deterrent effect on those who may be considering not providing true, accurate or complete information), and provides the Office with the option of referring the matter to law enforcement in the event such information is not true, complete or accurate. (*In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 ["The oath or declaration must be in such form that criminal sanctions of perjury might apply where material facts

so declared to be true, are in fact not true or are not known to be true, holding modified by *Laborde v. Aronson* (2001) 92 Cal.App.4th 459].)

Subsection (b). Form and Contents of Public Notice.

Subsection (b) requires a submitter to indicate which thresholds and circumstances in section 97435 they meet and provide the listed information to the Office. The subsection also states the information in the notice will be publicly posted on the Office's website. This fulfills the Office's mandate for public transparency and effectuates the Office's role of collecting and providing information informative to the public. This approach also follows the practice of posting in other states and in California. (*See*, for example, the Attorney General website at https://oag.ca.gov/charities/nonprofithosp or Massachusetts Health Policy Commission website at https://www.mass.gov/info-details/transaction-list-material-change-notices.)

The Office requires general information about the transaction and entities in the transaction, including the following information regarding the submitter:

- Business Name
- Business Website
- Business Mailing Address

This information enables the Office to determine what businesses are involved in the transaction, review the businesses' websites for information about the business, if necessary, and determine the geographic area in which the business operates.

- Description of organization, including, but not limited to, business lines or segments, ownership type (corporation, partnership, limited liability corporation, etc.), governance and operational structure (including ownership of or by a health care entity).
    - For health care providers or fully integrated delivery systems, include a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity or patients served in California (e.g., number of licensed beds, number of patients per county in the last year).
    - For health care service plans, health insurers, risk-bearing organizations, or fully integrated delivery systems, include number of enrollees per county in the last year.

OHCA seeks a description of the submitter's business organization to determine the kind of health care entity they are and what services they provide. This facilitates the Office's analysis of potential impacts of the transaction on the health care market and consumers. Information about the organization's ownership type facilitates the Office's understanding of the governance and control of the entity and helps the Office identify related entities. Understanding the governance and operational structure helps the

Office determine whether there are material shifts in governance and operations as a result of the transaction, and facilitates an analysis of any anticompetitive impacts.

For health care providers or fully integrated delivery systems, the Office asks for a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity or patients served in California (e.g., number of licensed beds, number of patients per county in the last year), so it can analyze impacts on patients, health care services, and staff in the geographic areas served by the health care entities. This information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and may warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed section 97441(f).

For health care service plans, health insurers, risk-bearing organizations, or fully integrated delivery systems, the Office asks for the number of enrollees per county in the last year so it can determine whether there are any impacts on patients and health care services in the geographic areas served by the health care entities. Again, this information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- Federal Tax ID # and tax status as for-profit or non-profit

OHCA asks for this information because it helps the Office keep track of the health care entity and any separate but related entities. Requiring the federal tax ID # assists with researching the submitter when there are multiple similar names. Understanding the for-profit status of the entity helps the Office understand the business goals and operation of the entity, and additionally determine whether, if the entity is a hospital, it is subject to AG review.

- California health care licenses issued by regulatory agencies such as the Department of Managed Health Care, Department of Insurance, Department of Public Health, or state and local business licenses related to the provision of health care services, or registration(s) with the Secretary of State held by the submitter, if any, and identification of any other states where health care-related licenses are held and license type. For purposes of this subsection, provide the health care license type and numbers only for those facilities, services, and professions involved in the transaction. Individual professional licenses are not required.

OHCA asks for this information so it understands where health care entities are licensed to operate. Knowing what California health care licenses are held impacts whether the transaction may be reviewed by CDI or DMHC. Knowing whether there are any other licenses held in other states is useful in multi-state transactions and in determining whether complaints have been made about an entity. This proposal further narrows the license type or number for only those facilities, services, and professions involved in the transaction. This also helps OHCA evaluate where there may be impacts from a proposed transaction.

- Contact person, title, e-mail address, and mailing address for public inquiries.

OHCA asks for this information so it can communicate with health care entities during its review of the proposed transaction and subpoena information if necessary. (Health & Saf. Code, § 127507.2, subd. (a)(4).)

- Primary languages used by submitter when providing services to the public as well as the threshold languages used when providing services to Medi-Cal beneficiaries, as determined by the Department of Health Care Services;

The Office is required to improve equity of health care for Californians. (Health & Saf. Code, § 127500.5, subd. (b).) OHCA asks about primary languages of the submitter when providing services to the public because this helps the Office evaluate whether and to what extent there may be impacts on different non-English speaking populations. If, for instance, the transaction was to eliminate the health care entity from the market or certain of its services, this could impact equity and access. A threshold language is a language identified on the Medi-Cal Eligibility Data System (MEDS) as the primary language of 3,000 beneficiaries, or five percent of the beneficiary population, whichever is lower, in an identified geographic area. OHCA asks for this information for the same reason as it asks about primary languages.

- Description of all other parties to the transaction and if any other health care entities will be submitting a notice. For each party to the transaction, describe, to the extent the submitter has access to the information, the following:
    - The entity's business (including business lines or segments);
    - Ownership type (corporation, partnership, limited liability company, etc.), including 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;
    - Governance and operational structure (including ownership of or by a health care entity);

OHCA asks for information regarding other parties to the transaction so it obtains a comprehensive view of the transaction for analysis purposes under proposed sections 97441(a)(2) and 97441(f). OHCA asks about other potential submitters for compliance

purposes so it can ensure all appropriate parties to the transaction are filing a notice. The Office needs to know whether to expect a separate filing in order to review the entirety of the transaction. Normally, all the requested information should be available to the submitting health care entity as part of the mutual covenants in a transaction, but the Office has included a provision exempting any information for which the submitter does not have access.

OHCA asks for the information specified above for the same reasons as it asks for the information about the submitter. OHCA incorporates the above-provided reasons herein by reference. Additionally, OHCA asks for information about 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, so it can develop a comprehensive analysis of impacts on any entities that are related to the health care entities to the transaction.

- Annual revenues for prior three years;

OHCA asks for annual revenues for the prior three years for the other submitters because this helps the Office verify which thresholds the transaction meets in proposed section 97435(b). Specifically, proposed section 97435(d) defines revenue by references to the most recent three years.

- Current county or counties of operation;

OHCA asks for the current county or counties of operation of other entities to the transaction so it can analyze impacts on patients, health care services, and staffing in the geographic areas served by other entities. This assists the public in ascertaining regional impacts from the proposed transaction. There are 58 counties in California, and most counties are considered well-known segmented areas of the state. County lines are easily discernable in most general maps in circulation so are easily distinguishable by the public. While some metropolitan areas cross county boundaries (for instance, the greater Los Angeles area includes multiple counties, or the greater Sacramento area overlaps Sacramento, Placer, Yolo, and El Dorado counties), county lines provide certain distinctions for service areas based upon city or county local government agreements.

The Office considered using zip codes as an indicator of geographic boundaries. However, there are approximately 1700 zip codes used in California, with some zip codes covering only a single block, so at this time, OHCA concluded requiring zip code information in a filing may be too burdensome for a submitter.

County information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- If a health care provider is a party to the transaction, include a summary description of provider type(s), physical address of facilities owned, operated, or leased where patient services are provided, service lines, number of staff, capacity, and patients served in California (e.g., number of licensed beds, number of patients, quantity of services provided in the prior year);

For health care providers who are parties to the transaction, the Office asks for this information so it can analyze impacts on patients, health care services, and staffing in the geographic areas served by the health care provider. This information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- Primary and threshold languages, as determined by the Department of Health Care Services, used;

OHCA asks about primary and threshold languages of other entities to the transaction for the same reason as it asks for the information about the submitter. OHCA incorporates those reasons here.

- If a payer is a party to the transaction, include a description of the county(ies) where coverage is sold, counties in which they are licensed to operate by the Department of Managed Health Care and/or the Department of Insurance, and the number of enrollees residing in the California county in the year preceding the transaction; and
- For all health care entities that are parties to the transaction, include a description of the business addresses, if known, of any new entity(ies) that will be formed as a result of the transaction.

For payers, the Office asks for a description of the county(ies) where coverage is sold, counties in which they are licensed to operate by the Department of Managed Health Care and/or the Department of Insurance, and the number of enrollees residing in the California county in the year preceding the transaction because this helps the Office review potential impacts on patients and health care services in the geographic areas served by the payer. This information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

For all health care entities, the Office asks for a description of the business addresses, if known, of any new entity(ies) that will be formed as a result of the transaction so it can review information related to post-transaction impacts. Again, this information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- Proposed or anticipated date of transaction closure;

OHCA requests the proposed or anticipated date of transaction closure because section 127507(c)(2) requires at least 90 days' notice of a transaction to be filed with the Office. Parties may file earlier.

- Description of transaction, which shall include the following:
  - The goals of the transaction;
  - A summary of terms of the transaction;
  - A statement of why the transaction is necessary or desirable;
  - General public impact or benefits of the transaction, including quality and equity measures and impacts;
  - Narrative description of the expected competitive impacts of the transaction; and
  - Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public.

OHCA asks for a narrative description of the transaction so it can evaluate whether, from the submitter's point of view, the transaction will have procompetitive or anticompetitive impacts. This information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- The submission date and nature of any applications, forms, notices, or other materials submitted or required regarding the proposed transaction to any other state or federal agency, such as, but not limited to, the Federal Trade Commission or the United States Department of Justice.

OHCA asks for information regarding the date and nature of any applications, forms, notices, or other materials submitted or required regarding the proposed transaction to any other state or federal agency, such as, but not limited to, the Federal Trade Commission or the United States Department of Justice. This information assists the Office in understanding timelines necessary for the transaction to occur and any possible conditions that may be imposed. Additionally, it allows OHCA to gather what representations the submitter has made to other agencies regarding the other transaction. The Office may also choose to toll the 60-day period during any time period in which review by another state, federal regulatory agency, or court may directly impact the Office's determination. (Proposed section 97441(b)(3).)

- Whether the proposed transaction has been the subject of any court proceeding and, if so, the:
  - Name of the court;
  - Case number; and
  - Names of the parties

OHCA asks for information related to whether the transaction has been the subject of any court proceeding so it can determine whether any third parties have challenged the transaction, and the grounds thereon. The Office may also choose to toll the 60-day period during any time period in which review by another state, federal regulatory agency, or court may directly impact the Office's determination. (Proposed section 97441(b)(3).)

- A description of current services provided by the health care entity and expected post-transaction impacts on health care services, which shall include, if applicable:
  - Counties where services are performed;
  - Levels and type of health care services offered, such as the full range of reproductive health care and sexual health care services, specialized services for LGBTQ+ populations, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services;
  - Summary of the number and type of patients served, including but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category;
  - Community needs assessments, charity care, and community benefit programs; and
  - Medi-Cal and Medicare.

OHCA requires the submitter to describe current services and expected post-transaction impacts on health care services. Points of service may be opened or closed, levels of services changed, or served population demographics narrowed or expanded. This list was influenced, in part, by the Primary Care Clinic Data Modernization Act, Senate Bill 779 (2023) (*see* Underlying Data for Bill Analysis) and by the AG's requirements in the non-profit context. (Cal. Code Regs., tit. 11, § 999.5, subd. (d)(5).)

OHCA asks for impact information based on attributes of the patients to determine whether the transaction adversely impacts certain groups, as the Office is required to improve equity of health care for Californians. (Health & Saf. Code, § 127500.5, subd. (b).)

OHCA asks for information regarding community needs assessments, charity care, and community benefit program, and Medi-Cal and Medicare because this information is maintained by the health care entities and helps OHCA evaluate post-transaction impacts on populations and communities affected by the transaction.

- If this transaction is a merger or acquisition, description of any other prior mergers or acquisitions that satisfy all of the following:
  - Involved the same or related health care services; and
  - Involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and
  - Were closed in the last ten years.

OHCA asks for additional information if the transaction is a merger or acquisition. It asks for this information because proposed circumstance (c)(7) triggers a required filing if transaction is part of a series of related transactions for the same or related health care services occurring over the past ten years involving the same health care entities or entities affiliated with the same entities. OHCA considers the proposed transaction and its related transactions to be a single transaction for purposes of determining the revenue thresholds in subsection (b) and asset and control circumstances in subsection (c). This question is necessary to gather information for OHCA's determination.

- Description of potential post-transaction changes to:
  - Ownership, governance, or operational structure.
  - Employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections.
  - City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties.
  - Seismic compliance with the Alfred E. Alquist Hospital Facilities Seismic Safety Act of 1983, as amended by the California Hospital Facilities Seismic Safety Act (Health & Saf. Code, §§ 129675-130070).
  - Competition within 20 miles of any physical facility offering comparable patient services.

OHCA requires submitters to provide a description of post-transaction changes in five categories denoting important access issues. As noted in the Bill Analysis for SB 779 regarding subsection (b)(10)(A)'s focus on labor issues:

> Clinic workforce shortage. According to a 2016 report by National Association of Community Health Centers, workforce challenges are one of the primary barriers to health center patient growth. If all health center clinical vacancies were filled today, health centers could serve two million more patients. At that time, prior to COVID-19's impact on the health care workforce, 95% of health centers had at least one clinical vacancy, and were averaging a vacancy rate for clinical positions of 13%. The number one challenge in recruitment and retention named was the ability to offer competitive salaries. According to the Kaiser Family Foundation, California has 643 areas with a Health

Professional Shortage Area designation for primary care, meaning one-third of Californians live in an area with a primary care provider shortage.

This information is relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

OHCA requests information regarding employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections to determine if the transaction may negatively impact workers or the labor market. (Proposed section 97441(a)(2)(D).)

OHCA requests information about city or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties to determine whether there will be any adverse impacts on populations affected by such contracts. (Proposed section 97441(a)(2)(A) & (a)(2)(D)(F).)

OHCA requests information about seismic compliance to determine whether there are any public safety issues posed by transaction. (Proposed section 97441(a)(2)(E).) This provision also mirrors language from the AG. (Cal. Code Regs. tit. 11, § 999.5, subd. (d)(5)(j).)

OHCA requests information regarding competition within 20 miles of any physical facility offering comparable patient services because the lack of competition can impact health care access and costs for patients if they suddenly must travel large distances to access providers as a result of a transaction.

- Description of the nature, scope, and dates of any pending or planned material changes, as used in section 97435(b), occurring between the submitter and any other entity, within the 12 months following the date of the notice.

OHCA requests a prospective look for any follow-up material change transactions in the forthcoming year. This will assist the Office in reviewing the transaction in context and in ensuring transactions have been characterized correctly in the submission.

Subsection (c). Documents to be Submitted with Notice.

While the submission of the preceding elements of the notice will provide a high-level summary of the proposed transaction and parties involved, a review of the supporting documents is important in determining whether a CMIR is needed. During public outreach, the Office received requests that documents required to be submitted not be submitted twice and have tried to accommodate that reasonable request.

The documents requested in subsection in (c)(1) will be a segregable set of documents and submitters may desire they be kept confidential. Except for documents submitted pursuant to subsection (c)(1) (which asks for the submitter's submission to the FTC pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR)), OHCA allows submitters to reference the page number or section of that submission in response to another subsection. This will save the parties the administrative burden of submitting the same document again and will reduce the volume of filings.

OHCA requests parties upload documents in machine readable format to ensure compliance with the Americans with Disabilities Act. This will assist OHCA in posting compliant documents to its website to the extent the documents are not confidential.

In this subsection, OHCA requests:

- <u>If the submitter has filed notice of the transaction with the Federal Trade Commission pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and 16 C.F.R. Parts 801-803, a copy of the Premerger Notification and Report Form and any attachments thereto;</u>

The HSR established the federal premerger notification program, which requires certain businesses planning mergers and acquisitions to notify the antitrust agencies before consummating the transaction. The current premerger filing threshold is for deals valued at more than $111.4 million. The law also mandates a waiting period of 30 days to afford the antitrust agencies time to determine if the deal violates the antitrust laws, including Section 7 of the Clayton Act, which prohibits mergers that may substantially lessen competition or tend to create a monopoly.

To the extent submitters have also had to file notice of their transaction with the FTC, OHCA asks for this filing in this subsection to review the representations made to the FTC with the transaction. The Office may also choose to toll the 60-day period during any time period in which review by another state, federal regulatory agency, or court may directly impact the Office's determination. (Proposed section 97441(b)(3).)

- <u>Copies of all current agreement(s) and term sheets (with accompanying appendices and exhibits) governing or related to the proposed material change (e.g., definitive agreements, affiliation agreements, stock purchase agreements);</u>

OHCA asks for this information because such documents establish the identities of the parties to the transaction, the terms of the transaction, the conditions of the transaction, the closing date of the transaction, and other relevant information about the financial circumstances of the transaction. This information could be relevant in determining whether any of the factors in proposed section 97441(a)(2) exist and warrant doing a CMIR. Additionally, such information is relevant in performing a CMIR in accordance with the factors in proposed 97441(f).

- Documentation sufficient to show the valuation of transaction;

OHCA requests this information because one of the circumstances triggering the requirement to file reviews the proposed fair market value of the transaction. (Proposed section 97435(c)(1).)

- Contact information for any individuals signing or responsible for the transaction or side or related agreements;

OHCA requests this contact information because the Office has statutory authority to subpoena information, if needed. The contact information provides the Office the necessary names for any necessary subpoenas, and a person to contact if any other information is needed after reviewing the submission.

- If applicable, any *pro forma* post-transaction balance sheet for any surviving or successor entity;

OHCA requests any *pro forma* post-transaction balance sheet, if applicable, for any surviving or successor entity because it provides information about forecasted future financial performance for the transaction. The information can be useful in evaluating the outcome of the transaction and the impact on the financial condition of the submitter. Both the outcome and the financial condition of the submitter is helpful in reviewing both potential positive and negative impacts on the delivery of health care services and potential changes to market conditions

The Knox-Keene Act of the DMHC also requires submission of projected balance sheets when evaluating the financial condition of applicants for health care service plan licenses or modifications to licenses. (Cal. Code Regs., tit. 28, § 1300.51, subd. (c).)

This provision also mirrors language requesting such a sheet in the AG's regulations. (Cal. Code Regs., tit. 11, § 999.5, subd. (d)(11)(H).)

- A current organizational chart of the organization of any entity party to the transaction, including charts of any parent and subsidiary organization(s) and proposed organizational chart(s) for any post-acquisition or transaction;

OHCA requests this information so it can view any shifts of control, governance, or ownership post-transaction. Such information will assist OHCA's evaluation of transactions falling within circumstance (c)(4) in proposed section 97435, and assist in evaluating any impacts from the transaction resulting from such shifts. Changes in personnel are also required to be reported by DMHC for plan transaction reviews (Health and Safety Code section 1300.52.2) and to the AG in the non-profit context. (Cal. Code Regs., tit. 11, § 999.5, subd. (d)(11)(F).)

- Existing documentation identifying the number of patients per zip code or enrollees per zip code in the last year.

OHCA asks for this documentation to support OHCA's requests for such data in proposed section 97439(b)(1)(D)(i) and (b)(1)(D)(ii) and (b)(3)(F) and (b)(3(H).

- Certified financial statements for the prior three years and any documentation related to the liabilities, debts, assets, balance sheets, statements of income and expenses, any accompanying footnotes, and revenue of all entities that are parties to the transaction. Certified financial statements mean audited financial reports, or if a health care entity does not routinely prepare audited financial reports, a comprehensive financial statement. The comprehensive financial statement shall include details regarding annual costs, annual receipt, realized capital gains and losses, and accumulated surplus and accumulated reserves using the standard accounting method routinely used by the health care entity and must be supported by sworn written declarations by the chief financial officer, chief executive officer or other officer who has financial management and oversight responsibility, certifying the comprehensive financial statement is complete, true, and correct in all material matters to the best of their knowledge, and that the health care entity does not routinely prepare audited financial reports, or the most recent audited financial report is not available. For California-derived revenue requirements (as used in this Article), the certification under this paragraph requires that revenue be calculated as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed;

OHCA requests certified financial statements for the prior three years and any documentation related to the liabilities, debts, assets, balance sheets, statements of income and expenses, any accompanying footnotes, and revenue of all entities that are parties to the transaction in subsection (c)(8). OHCA expanded this section after public outreach to clarify acceptable statements for smaller health care entities who may not receive audits. This requirement is consistent with Health and Safety Code section 127501.4(i)(2)'s collection requirements. The information is necessary to verify the revenue thresholds listed in section 97435(d) and to view parties' financial condition before and after a transaction.

- Articles of organization or incorporation, bylaws, partnership agreements, or other corporate governance documents of all entities that are parties to the transaction, including any proposed updates that occur as a result of the transaction;

OHCA requests this information because these documents reflect the ownership, control, and governance of the parties to a transaction both before and after the transaction. OHCA requests this information so it can view any shifts of control,

governance, or ownership post-transaction. Such information will assist OHCA's evaluation of transactions falling within circumstance (c)(4) in proposed section 97435, and assist in evaluating any impacts from the transaction resulting from such shifts.

- Any documentation related to the mitigation of any potential adverse impacts of the transaction on the public; and

OHCA asks for this information to support the submitter's narrative response in response to proposed section 97439(b)(5)(F). This helps the office balance the positive and negative aspects of a transaction.

- Any analytic support for and/or documents supporting the submitter's responses to the narrative answers provided.

OHCA seeks this information to support and verify any narrative responses provided by the submitter in its submission.

Subsection (d). Confidentiality of Documents Submitted with Notice.

The Office understands that some of the documentation it requires to review a transaction may be confidential for various reasons. The Office's electronic submission system will accept two versions of documents - public and non-public (confidential with redactions and an unredacted version). The system is capable of securely storing the non-redacted confidential version and limiting access to designated Office staff. The Act requires OHCA to post the notice, including all information and materials submitted to the office for review with regard to the material change, if the Office determines a CMIR is warranted. (Health & Saf. Code, 127507, subd. (c)(2).)

This subsection will provide, consistent with the Act, that information provided to the Office by the submitter shall be treated as a public record unless the submitter designates documents or information as confidential when submitting through the Office portal system and the Office accepts the confidential designation in accordance with subsections (d)(1) through (d)(3).

Subsection (d)(1) requires submitters to file two versions of any document for which confidentiality is requested. The Office will maintain confidentiality pending its determination of confidentiality. This provision is necessary so the Office protects the document from disclosure while it decides whether the request should be granted. A redacted version is necessary so the Office can post the public aspects of the records. The Office will not protect as confidential documents that are publicly available as this indicates the submitter did not treat the document as confidential in other contexts.

OHCA establishes that specified categories of documents are automatically confidential in subsection (d)(2). OHCA recognizes the industry typically views these types of documents as sensitive or confidential. Therefore, to avoid administrative burden for both the Office and submitters, OHCA has deemed them automatically confidential

under this regulation when marked confidential. Section 127507.2(c)(2) provides that "[n]otwithstanding any other law, all nonpublic information and documents obtained under this article shall not be required to be disclosed pursuant to the California Public Records Act … or any similar local law requiring the disclosure of public records."

OHCA recognizes four categories of confidentiality in subsection (d)(3)(i) through (iv). Submitters are required to articulate in their request for confidentiality whether any of these bases apply to their request.

Category one is premised on the type of confidentiality afforded to trade secrets under California law at Civil Code section 3426.1. This statute recognizes such status when information derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. This subsection requires the release of the covered information be damaging or prejudicial to the business concern to be entitled to confidentiality under OHCA regulations.

Category two bases confidentiality on whether another state or federal agency deems the filed document confidential and, if so, for what period of time. Such confidentiality may have been premised on the FTC deeming documents confidential during HSR review. OHCA wants to consistently afford confidentiality when another entity has deemed documents confidential and for the same period of time. This will avoid breaching confidentiality when another entity has granted it.

Category three bases confidentiality on whether the information is confidential based on statute or other law. Here, submitters can raise any other legal basis for confidentiality beyond the protection afforded by reliance on section 3426.1. This is necessary so parties can establish any other legally appropriate basis for confidentiality.

Category four is a catch-all provision in which submitters can make any other argument that deeming the documents confidential serves the public interest. This category is necessary so submitters can make confidentiality arguments when there is no statute or other law requiring confidentiality but keeping the documents confidential would serve the public interest.

OHCA will notify a submitter whether their request for confidentiality has been granted, and will mark the information as confidential. This will provide notice to OHCA staff of which documents they must maintain as confidential and separate from the public file. The Office clarifies here that confidentiality does not extend to the AG because section 127507.2(c)(1) provides OHCA "shall keep confidential all nonpublic information and documents obtained under this article that were not required with the notice of material change or from the parties to the transaction, and shall not disclose the confidential information or documents to any person, other than the Attorney General...." (Emphasis added; see also, § 127507.2, subd. (d)(1) ["The office may refer its findings, including the totality of documents gathered and data analysis performed, to the Attorney General

for further review of any unfair methods of competition, anticompetitive behavior, or anticompetitive effects."].)

Subsection (e). Notification of Changes.

The Office recognizes a proposed transaction may be altered due to unforeseen circumstances or external factors. This proposal requires notification of a change within five business days, chosen as a reasonable timeframe, and – if the change is material – may require a re-submittal of the material change notice. This determination will be highly fact-specific, but will be predicated on the materiality of the change for the Office's review. In other words, if the change is highly material, it is more likely to be deemed a basis for requiring re-submittal of notice to the Office.

Subsection (f). Withdrawal of Notice.

There is a myriad of reasons why a transaction may fall through or be cancelled. Having filed a notice of a proposed transaction does not require parties to complete the transaction, so this proposal includes a necessary method for cancelling a submission. The Office anticipates handling this request for withdrawal through its account established in the Office's electronic portal.

However, the regulation provides the Office is entitled to collect costs incurred in connection with the Office's review up until the first business day after the withdrawal notice is received, pursuant to section 127507.4. Health and Safety Code section 127507.4(b)(2) entitles OHCA to reimbursement from health care entities for all "actual, reasonable, and direct costs incurred in reviewing, evaluating, and making the determination referred to in Section 127507.2, including administrative costs."

This right to reimbursement is similar to the AG recovering costs for non-profit reviews, pursuant to 11 CCR 999.5(j). The Office considered adding a filing fee to submissions, which is required by Oregon and the FTC, as well as by DMHC in reviewing material modifications, but the Office has chosen at this time not to impose any fees for filing.

Section 97440. Request for Expedited Review.

The Office may but it is not required to adopt regulations to expedite its review of notices of material change, as warranted, depending on the nature of the agreement or transaction. (Health & Saf. Code, § 127507.2, subd. (a)(3)(A) and (a)(3)(B).)

In the Office's first comment period and workshop, a number of stakeholders requested an avenue for requesting expedited review of a transaction – for instance, when a

hospital is threatened by or even in the midst of bankruptcy.[23] This regulation will establish a right to submit a request for expedited review based on:

(1) Severe financial distress of one or more of the parties to the transaction; or
(2) Any significant reduction in the provision of critical health care services within a geographic region or regions.

"Severe financial distress" shall be shown by a grave risk of immediate business failure and the demonstration of a substantial likelihood any party to the transaction (or an entity affected by the transaction) will have to file for bankruptcy under Chapter 11 of the Bankruptcy Act (11 U.S.C. Sec. 1101 *et seq.)* absent the expedited review and that the transaction is necessary to ensure continued health care access in the relevant markets.

This regulation is necessary to shorten the Office's 60-day initial review of a transaction if a submitter can make the showing required by the regulation. The Office requires the request to be made concurrently with the filing of the notice so the Office is made immediately aware of the request and can act on it timely. To enable its full and timely consideration of the request, the Office requires a detailed explanation with any documentation to substantiate the necessity of expedited review, with a specification of what date the submitter requests the Office complete its review of the request.

As with the documents submitted with notice, the Office understands a submitter may believe that some documents are confidential, and the process to request confidentiality will be the same as for the notice filing.

Section 97441. Cost and Market Impact Reviews.

Subsection (a). Whether to Conduct a Cost and Market Impact Review

Health and Safety Code section 127507(c)(3) requires OHCA to adopt regulations that consider appropriate thresholds that warrant a notice of material change transactions and section 127507.2(b) requires regulations that outline the basis for a CMIR review. If the Office finds a material change transaction is likely to have a risk of a significant impact on market competitions, the state's ability to meet cost targets, or costs for purchasers and consumers, it is required to conduct a CMIR. (Health & Saf. Code, § 127507.2 subd. (a)(1).) This proposal is necessary to implement and make specific this legislative mandate.

The factors for determining whether to conduct a CMIR in this proposal are consistent with the requirements as set forth in section 127507.2(a). In its review, the Office must

[23] McDermott Will & Emery, California Publishes Draft Regulations on Filing Requirement for Healthcare Entity Transactions, August 15, 2023, https://www.jdsupra.com/legalnews/california-publishes-draft-regulations-5198645/, last accessed October 11, 2023.

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, access, or any other factors the office determines to be in the public interest. The Office must also consider the benefits of the material change to consumers of health care services, where those benefits could not be achieved without that transaction, including, but not limited to, increased access to health care services, higher quality, and more efficient health care services where consumers of health care services benefit directly from those efficiencies. (§ 127507.2, subd. (a)(2).)

The Office may base its decision to conduct a CMIR on any one or more of the following factors.

Subsection (a)(2)(A)

The first factor (a)(2)(A) reviews whether the transaction may result in a negative impact on the availability or accessibility of health care services, including the health care entity's ability to offer culturally competent care.

This factor is necessary because Health and Safety Code section 127507.2(a)(1) and (a)(2) require the Office to consider access to health care in its analysis of a transaction. The Office will also consider access to culturally competent care (as defined in section 97431(c) of this proposal) under this factor to further legislative intent. "It is the intent of the Legislature to promote the goal of health care affordability while recognizing the need to maintain and increase the supply of trained, culturally and linguistically competent health care workers[.]" (Health & Saf. Code, § 127500.5, subd. (g); see also, § 127500.5, subd. (a)(5) ["Californians of color experience health disparities, including barriers to accessing care, receiving lower quality of care, lack of access to culturally and linguistically competent care, and experiencing worse health outcomes."].)

Subsection (a)(2)(B)

Factor (a)(2)(B) reviews whether the transaction may result in a negative impact on costs for payers, purchasers, or consumers, including the ability to meet any health care cost targets established by the Health Care Affordability Board.

The Board is charged with establishing a statewide health care cost target for per capita total health care spending. (Health & Saf. Code, § 127501, subd. (c)(2).) The Office must conduct a CMIR if it finds that a material change is likely to have a risk of the state's ability to meet cost targets. (Health & Saf. Code, § 127507.2, subd. (a)(1).) Accordingly, this factor is necessary to authorize the Office to consider the effects of the transaction on an entity's ability meet such targets in deciding whether to conduct a CMIR.

Subsection (a)(2)(C)

Factor (a)(2)(C) reviews whether the transaction may lessen competition or tend to create a monopoly in any geographic service areas impacted by the transaction.

Health and Safety Code section 127507.2(a)(1) requires the Office to conduct a CMIR if it finds a material change noticed is likely to have a risk of a significant impact on market competitions. As reflected in the Act's legislative findings, rising health care costs are crippling California families. (Health & Saf. Code, § 127500.5, subd. (a)(3).) "Escalating health care costs are being driven primarily by high prices and the underlying factors or market conditions that drive prices, particularly in geographic areas and sectors where there is a lack of competition due to consolidation, market power, venture capital activity, the role of profit margins, and other market failures." (*Id*., § 127500.5, subd. (a)(4).)

Economists in the health care industry also attribute rising health care costs to increasing monopolization of health care markets, especially among hospitals, for instance.[24] When hospitals buy out their competitors, the effect is almost always higher prices, and can even reach 20 percent. Hospital consolidation also often leads to reduced access and quality of care. By 2017, approximately two-thirds of hospitals in the U.S. had been subsumed by a chain. Such mergers also reduce the efficiency of local health care markets.

Accordingly, this factor is necessary to focus on those transactions tending to create a monopoly because of the market effects outlined above.

Subsection (a)(2)(D)

Factor (a)(2)(D) reviews whether the transaction may lessen competition for workers or may negatively impact the labor market.

Under FTC Guideline 11, "When a Merger Involves Competing Buyers, the Agencies Examine Whether It May Substantially Lessen Competition for Workers or Other Sellers," the FTC will consider whether workers face a risk that the merger may substantially lessen competition for their labor. Where a merger between employers may substantially lessen competition for workers, that reduction in labor market competition may lower wages or slow wage growth, worsen benefits or working conditions, or result in other degradations of workplace quality.[25]

As such impacts on the labor market may affect quality and affordability of care, OHCA focuses on this factor in determining whether to conduct a CMIR.

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[24] Anti-Monopoly Basics, Hospitals and Monopoly, https://www.openmarketsinstitute.org/learn/hospitals-monopoly, last accessed October 27, 2023.

[25] Merger Guidelines, U.S. Department of Justice and the Federal Trade Commission.

Subsection (a)(2)(E)

Factor (a)(2)(E) reviews whether the transaction directly affects a general acute care or specialty hospital.

This factor is necessary because a transaction directly affecting hospitals can have substantial impacts on access to care, especially since proximity to a patient population is especially important for hospitals.

Subsection (a)(2)(F)

Factor (a)(2)(F) reviews whether the transaction may negatively impact the quality of care. Section 127507.2(a)(1) and (a)(2) require the Office to consider quality of care in its analysis of a transaction. Legislative intent also makes this interest paramount - it is "in the public interest that all Californians receive health care that is accessible, affordable, equitable, high-quality, and universal." (Health & Saf. Code, § 127500.5, subd. (a)(1).)

Given the Act's emphasis on quality of care, OHCA focuses on this factor in determining whether to conduct a CMIR.

Subsection (a)(2)(G)

Factor (a)(2)(G) reviews whether the transaction is part of a series of similar transactions by the health care entity or entities or that furthers a trend toward consolidation.

This factor is necessary to focus on "roll-ups" or serial transactions, or on trends toward consolidation in determining whether to conduct a CMIR. The Office is authorized to monitor cost trends (§ 127507, subd. (a)) and analyze changes in size and market share in a given service or geographic region in a CMIR. (Health & Saf. Code, § 127507.2, subd. (a)(1).) Reviewing past incremental transactions assists the Office in determining whether a proposed transaction is likely to have a significant impact (e.g. by looking at the impacts of previous transactions).

Subsection (a)(2)(H)

Factor (a)(2)(H) reviews whether the transaction may entrench or extend a dominant market position of any health care entity in the transaction, including extending market power into related markets through vertical or cross-market mergers.

This factor mirrors the FTC's guidelines which provide that mergers should not entrench or extent a dominant position. (Draft FTC-DOJ Merger Guidelines for Public Comment (2023).) This factor will entail an assessment of the magnitude of the lessening of competition that may arise from entrenching a dominant position based on the degree of dominance already held and the extent to which it would be entrenched by a merger.

This factor is necessary to focus the Office on whether the transaction may entrench or extend a dominant market position of any health care entity in the transaction in determining whether to conduct a CMIR.

Subsection (a)(2)(I)

Factor (a)(2)(I) reviews whether the transaction between a health care entity located in this state and an out-of-state entity may negatively impact affordability, quality, or limit access to health care services in California, or undermine the financial stability or competitive effectiveness of a health care entity located in this state.

This factor focuses on transactions between a health care entity located in this state and an out-of-state entity. Stakeholders have maintained that deals that are effectuated in an out-of-state location may still negatively impact in-state services, particularly if, for instance, premiums are raised in-state or California assets are committed to fund a transaction. DMHC, after review and approval of three mergers (CVS-Aetna, Cigna-Express Scripts, Optum-DaVita), each of which involved out-of-state indirect parent companies of the regulated health care service plans, imposed the condition on all three mergers that the health care service plans not increase premiums due to the acquisition and keep premiums at a minimum.

Accordingly, OHCA proposes to review whether a transaction affects in-state health care markets.

Subsection (b). Timing of Review of Notice.

OHCA provides that a notice will be deemed complete when it receives all of the information required by the regulations. OHCA adopts this provision so it has all of the information it needs to review a material change notice from all submitters when its review period commences. This provides an efficient ordered process for the Office so it is not tracking filings for the same transaction on different time tracks.

Section 127507.2(a)(3)(A) requires the Office to either advise the submitter of the Office's determination to conduct a CMIR or provide a written waiver from a review within 60 days of receipt of the notice. Section 127507.2(a)(3)(B) allows the Office to expedite this timeline, "as warranted, depending on the nature of the agreement or transaction." Accordingly, OHCA is adopting a two-tiered timeline for this initial 60-day review based on whether the transaction warrants a CMIR as the "nature of the agreement or transaction" is decisive of whether the Office will conduct a CMIR.

OHCA provides in regulation that, if it determines it will not conduct a cost and market impact review, OHCA will notify the submitter(s) of this determination within 45 days of the filing of a complete notice. A shortened period is possible here because OHCA will not have to provide a detailed statement of reasons for declining to conduct a CMIR. This will facilitate parties being able to proceed with the transactions sooner when a CMIR is deemed unnecessary. If OHCA determines it will conduct a CMIR, it will notify

the submitter(s) of that determination within 60 days of the filing of a complete notice. OHCA provides itself with the entirety of the statutorily allowed review period when it determines it will conduct a CMIR because it will take Office staff additional time to prepare a statement of its reasoning for its determination.

Subsection (c)

OHCA includes tolling provisions in subsections (c)(1) through (c)(5) to establish those circumstances in which the review period may permissibly deviate from the 45 or 60 day time periods established in subsection (b).[26]

First, OHCA permits tolling if it and the submitter agree to do so in writing. Parties may wish to postpone review while it tends to transactional matters, or review by other entities, for instance. OHCA requires it be memorialized in writing for a written record of the agreement.

Second, OHCA permits tolling while OHCA has requested additional information necessary to complete its review and it is waiting for such information. This provision encourages parties to provide complete information and recognizes that OHCA's review is hampered during any time period in which it lacks complete information about a transaction.

Third, OHCA permits tolling during any time period in which review of the transaction by another state, federal regulatory agency, or court may directly impact the Office's determination. This provision recognizes other agencies' review of the same transaction could affect the Office's action on a transaction. For instance, if the FTC concludes that a transaction is anticompetitive, OHCA would want to consider such findings in deciding whether to conduct a CMIR.

Fourth, if the transaction changes during the review, the Office wants to avoid reviewing a moving target and may need to halt review while new information is provided.

Fifth, this subsection references the Office's process for granting expedited review pursuant to proposed section 97440. That process is discussed *supra*.

Subsection (d). Request for Review of Determination to Conduct a Cost and Market Impact Review.

This subsection affords due process to parties who may disagree with OHCA's determination to conduct a CMIR. OHCA requires submitters to submit a request for a review of a determination to conduct a CMIR within 10 business days of the date it is determined. OHCA believes 10 days is sufficient for all submitters to convene and prepare a request. The Office anticipates this time will run parallel with Office work in

[26] Other state agencies toll time periods by regulation when they are awaiting receipt of information. (See e.g. Cal. Code Regs., tit. 2, § 1183.18, subd. (a)(3).)

determining what further information is needed to conduct the CMIR, so should not delay the ultimate review timeline set forth in subsection (d).

The Office requires the request to be in writing on behalf of and consolidated with all requesting submitters so it is clear which submitters are making the request and the office can efficiently consider a singular combined request. The request is submitted to the Director to provide submitters with an avenue for review by an individual who did not participate in making the determination to conduct a CMIR. The subsection requires the request be made in full detail and contain reasons why the submitter(s) assert a CMIR is not warranted so the Director can efficiently review the request.

The subsection provides OHCA will deny the request if it is unsupported by specific facts to inform submitters that specific reasons for the request for review are necessary.

The subsection explains the Director will either grant or deny the request for review within 5 business days of receipt. OHCA believes it can timely act upon such requests within 5 business days but allows itself the ability to extend this period by 5 days if that is necessary.

OHCA provides the Director's determination is final for clarity so parties are aware of when their right to challenge the decision in superior court accrues.

OHCA considered allowing each submitter to request a separate review with notice to all other submitters, but this proposal opts to require a consolidated written request in order to efficiently and properly evaluate the collective response to a proposed CMIR.

Subsection (e). Timeline for Completion of Cost and Market Impact Review.

The Act does not prescribe a timeline for the completion of a CMIR. However, stakeholders have posed concerns about how long their proposed transactions could be put on hold while a review is conducted. The Office has chosen to clarify the timeframes expected to provide more certainty.

This subsection provides the Office shall complete a cost and market impact review within 90 days of the final decision by the Office to conduct a CMIR, subject to subsections (e)(1) through (3). OHCA chose 90 days for completion based on consultation with economic experts and other jurisdictions regarding their experience and knowledge of the necessary time for reviews.

Subsection (e)(1) gives the Office flexibility by permitting it to extend the 90-day period by 30 days if it needs additional time to complete review. OHCA chose 30 days for completion based on consultation with economic experts and other jurisdictions regarding the typical necessary time for reviews. OHCA's decision to use a 90-day review period with a potential 30-day extension was also informed by the AG's approach which uses the same review timeframes. (Corps. Code, § 5915 [however, the AG uses a 45-day extension].)

OHCA includes tolling provisions in subsections (e)(2) and (e)(3) to provide it with additional time to review the transaction if it is hampered by the provision of incomplete information about the transaction or other state or federal regulatory agencies or courts are reviewing the subject transaction, respectively. These provisions recognize that events outside OHCA's control may hinder it completing review within the specified time period and facilitate it having complete information.

Subsection (f). Factors Considered in a Cost and Market Impact Review.

Subsection (f) establishes the factors the Office will examine in a CMIR. The list is non-exclusive so OHCA can consider any additional factors OHCA deems to be in the public interest.

Section 127507.2 provides the parameters for a CMIR. This section requires the Office 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, access, or any other factors the office determines to be in the public interest." (Health & Saf. Code, § 127507.2, subd. (a)(1).) "In conducting the review, the office shall consider the benefits of the material change to consumers of health care services, where those benefits could not be achieved without that transaction, including, but not limited to, increased access to health care services, higher quality, and more efficient health care services where consumers of health care services benefit directly from those efficiencies." (Health & Saf. Code, § 127507.2, subd. (a)(2).)

The following factors are necessary to implement, interpret, and make specific section 127507.2(a)(1) and (a)(2).

Subsection (f)(1)

This factor reviews effect on the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care.

This factor examines the same impacts of proposed section 97441(a)(2)(A) ["If the transaction may result in a negative impact on the availability or accessibility of health care services, including the health care entity's ability to offer culturally competent care."].) OHCA incorporates the statement of necessity it provides for that factor here.

Subsection (f)(2)

This factor reviews the effect on the quality of health care services to any of the communities affected by the transaction.

This factor examines the same impacts of proposed section 97441(a)(2)(F) ["If the transaction may negatively impact the quality of care], but is narrowed with respect to affected communities. OHCA incorporates the statement of necessity it provided for that factor here.

Subsection (f)(3)

This factor reviews the effect of lessening competition or tending to create a monopoly which could result in raising prices, reducing quality or equity, restricting access, or innovating less.

This factor examines the same impacts of proposed section 97441(a)(2)(C) ["If the transaction may lessen competition or tend to create a monopoly in any geographic service areas impacted by the transaction."].) This factor more specifically reviews the results of the effect of lessening competition or the creation of a monopoly. OHCA incorporates the statement of necessity it provided for that factor here.

Section 127507.2 highlights the Office's focus on prices, quality, equity, and access. (Health & Saf. Code, § 127507.2 subd. (a)(1).) The Act also highlights the promotion of innovation in health care. (Health & Saf. Code, §§ 127501.11, subd. (c)(10), 127504, subd (b)(3), 127505, subds. (a)(2) & (a)(4)(G).) Accordingly, this factor incorporates these statutory focuses.

Subsection (f)(4)

This factor reviews the effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board.

This factor examines the same impacts of proposed section 97441(a)(2)(B) ["If the transaction may result in a negative impact on costs for payers, purchasers, or consumers, including the ability to meet any health care cost targets established by the Health Care Affordability Board."].) OHCA incorporates the statement of necessity it provided for that factor here.

Subsection (f)(5)

This factor reviews the effect on competition for workers and the impact on the labor market.

This factor examines the same impacts of proposed section 97441(a)(2)(D) ["If the transaction may lessen competition for workers or may negatively impact the labor market."].) OHCA incorporates the statement of necessity it provided for that factor here.

Subsection (f)(6)

This factor reviews whether the transaction may foreclose competitors of any party to the transaction from a segment of the market or otherwise increase barriers to entry in any health care market.

As FTC guidelines recognize, a merger can raise barriers to entry by limiting independent sources of supply so that a new entrant would need to invest not only in entering the relevant market, but also in the related market, sometimes referred to as two-stage entry. A merger that increases barriers to entry, including by requiring rivals to incur additional entry costs, can entrench a dominant position. As barriers to entry can increase costs, this is relevant to section 127507.2(a)(1)'s focus on health care costs.

Subsection (f)(7)

This factor reviews whether the parties to the transaction have been parties to any other transactions in the past ten years that have been below the thresholds set forth in section 97435(b).

This factor focuses on whether the parties have engaged in transactions below the thresholds in the last ten years for the reasons set forth in the statement of necessity provided for section 97435(c)(9), which OHCA incorporates here.

Subsection (f)(8)

This factor reviews where there have been consumer concerns including, but not limited to, complaints or other allegations against any health care entity that is a party to the transaction related to access, care, quality, equity, affordability, or coverage.

OHCA includes this factor because consumer complaints can be highly relevant in pointing out the ill effects of market power and consolidation. OHCA focuses on the subjects from the statute in outlining the types of complaints it will review under this factor. (Health & Safety Code, § 127500.5, subds. (a)(1) & (a)(11).)

Subsection (f)(9)

This factor reviews any other factors the Office determines to be in the public interest.

OHCA includes a catch-all to allow it to consider any other factor it finds relevant in reviewing the transaction. This factor is necessary to provide the Office with flexibility in its review and the catch-all is permitted by section 127507.2(a)(1). (Health & Saf. Code, § 127507.2, subd. (a)(1) ["any other factors the office determines to be in the public interest."].)

Subsection (g). Preliminary Report of Findings.

Section 127507.2(a) provides that upon completion of the cost and market impact review, OHCA must make factual findings and issue a preliminary report of its findings. After allowing for the affected parties and the public to respond in writing to the findings in the preliminary report, the office shall issue its final report. (Health & Saf. Code, § 127507.2, subd. (a)(5).)

OHCA restates this statutory provision in subsection (g)(1) of the regulation for convenience of the regulated public.

OHCA assigns a 10-business day window for receipt of comments as it believes this affords the public adequate time for a review of the report and preparation of comments. Commenting on a preliminary report is optional.

Subsection (h). Final Report of Findings.

The Act does not require a particular lapse of time frame between the issuance of preliminary and final reports. The Office has chosen to issue its final report within 15 days after the close of the comment period in subsection (g)(2) of the regulation. If it receives few or no comments, then the Office may issue a final report sooner. If, however, the Office receives a great volume of comments, or the comments raise additional issues OHCA did not consider in its preliminary report, the Office may need to extend this time period. It defines good cause for this extension by reference to a preponderance of the evidence there is a factual basis and substantial reason for the extension because this is a well understood legal standard and it provides assurance to the public such an extension will be well-founded.

Section 97442. Market Power or Market Failure Determinations.

Health and Safety Code section 127507.2 provides "[t]he office also may conduct cost and market impact reviews on any health care entity based on a determination by the director under subdivision (g) of Section 127502.5, or in association with agreements or transactions referred to the office by a reviewing authority listed in paragraphs (1) to (4), inclusive, of subdivision (d) of Section 127507." (Health & Saf. Code, § 127507.2, subd. (a)(1).)

Section 127502.5(g) provides "[i]f data indicate adverse impacts on cost, access, quality, equity, or workforce stability from consolidation, market power, or other market failures, the director may, at any point, require that a cost and market impact review be performed on a health care entity, consistent with Section 127507.2."

This regulation is necessary to incorporate the Director's right to conduct a CMIR on a health care entity based on section 127502.5(g) based on adverse effects from market power or other market failures. As this right exists independent from the Office's conducting a CMIR for the reasons set forth in regulation, this regulation clarifies the

Office has other legal bases for conducting a CMIR.

ANTICIPATED BENEFITS OF THE PROPOSAL

These proposed emergency regulations effectuate the Legislature's directive to analyze transactions that are likely to significantly impact on market competition, the state's ability to meet targets, or affordability for consumers and purchasers. HCAI's statutory mandate is to provide transparency to the public regarding proposed health care transactions. If, after review, HCAI determines that the proposed transaction may reduce market competition or increase health care costs, HCAI will refer the matter to the AG, who may pursue legal remedies to block a transaction or impose conditions to mitigate any negative aspects on the public. (Health and Saf. Code, § 127500.5, subd. (o)(3).)

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENT(S) RELIED UPON:

Other State and Federal Laws and Regulations:

Federal Trade Commission (FTC)

- FTC-DOJ Merger Guidelines (Draft for Public Comment), available at: https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf, last accessed October 27, 2023.
- Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a.

Federal Statutes

- 42 U.S.C. § 234

Federal Regulations

- 42 C.F.R. § 5.1
- 42 C.F.R. § 5.2

Federal (Other)

- Interoperability and Patient Access Fact Sheet, March 9, 2020, available at: https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet, last accessed October 27, 2023.

Hawaii

- Hawaii Statutes, § 323D-71.

Massachusetts

- Massachusetts Gen Laws c. 6D, § 13
- 958 CMR 7.00 et seq.

Oregon

- Oregon Revised Statute 415.500 et seq.
- Oregon Administrative Rules 409-070-0000 through 0085

New York

- New York State Department of Health, Required Reporting of Material Transactions, available at https://health.ny.gov/facilities/material_transactions/#:~:text=New%20York%20State%20Public%20Health%20Law%20%28PHL%29%2C%20Article,days%20prior%20to%20the%20closing%20of%20the%20transaction, last accessed October 30, 2023.

Rhode Island

- Rhode Island Statutes § 23-17.14-6.

Legislation/Bill Analysis:

- Assembly Bill 1091, as introduced February 15, 2023.
- Senate Bill 779, Primary Care Clinic Data Modernization Act, Senate Committee of Health Analysis of March 30, 2023.

Cases:

- *FTC v U.S. Anesthesia Partners* complaint, filed in federal district court on September 21, 2023, at https://www.ftc.gov/system/files/ftc_gov/pdf/2010031usapcomplaintpublic.pdf, last accessed October 26, 2023.

Federal Policy Statements:

- Federal Trade Commission Withdraws Health Care Enforcement Policy (July 14, 2023), available at https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements, accessed October 26, 2023.
- US Department of Justice, Justice Department Withdraws Outdated Enforcement Policy Statements, available at https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements, last accessed October 26, 2023.

- Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding FTC-DOJ Proposed Merger Guidelines Commission File No. P234000 (July 19, 2023.) available at https://www.ftc.gov/system/files/ftc_gov/pdf/p234000_chair_statement_re_draft_merger_guidelines.pdf, last accessed October 30, 2023.

Reports/Articles/Other Resources:

- Abelson and Sanger-Katz, *Who Employs Your Doctor? Increasingly, a Private Equity Firm* (July 10, 2023), available at: https://www.nytimes.com/2023/07/10/upshot/private-equity-doctors-offices.html, last accessed October 27, 2023.
- Baer, William J, Former Director, Bureau of Competition. *Reflections on 20 Years of Merger Enforcement under the Hart-Scott-Rodino Act*, Public Statement before The Conference Board, Washington, D.C., October 29, 1996 and before The 35th Annual Corporate Counsel Institute, Northwestern University School of Law, Corporate Law Center, San Francisco, CA, October 31, 1996, available at https://www.ftc.gov/news-events/news/speeches/reflections-20-years-merger-enforcement-under-hart-scott-rodino-act, last accessed October 26, 2023.
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- Schwartz, K, Lopez, E, Rae, M, and Neuman, T. What we know about provider consolidation (2020), available at: https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation, last accessed October 26, 2023.
- The Source. Merger Review, available at https://sourceonhealthcare.org/market-consolidation/merger-review/, last accessed October 26, 2023.

- Super Voting: Everything You Need to Know, available at: https://www.upcounsel.com/super-voting, last accessed October 30, 2023,
- Supermajority Voting Provision, available at: https://corporatefinanceinstitute.com/resources/equities/supermajority-voting-provision/, last accessed October 30, 2023.

Public meetings:

- June 20, 2023 Board Meeting, Relevant Presentation Slides, Minutes
- June 21, 2023 Advisory Committee Meeting – Relevant Slides, Minutes
- August 15, 2023 OHCA Workshop Transcript on Draft Proposed Regulatory Text.
- August 22, 2023 Board Meeting – Relevant Presentation Slides, Minutes. (Recording at https://www.youtube.com/watch?v=RfjLfqeiErk)
- September 18, 2023 Advisory Committee Meeting – Relevant Presentation Slides
- September 19, 2023 Board Meeting – Relevant Presentation Slides, Minutes (Recording at https://www.youtube.com/watch?v=JvZuPjMearE)

General written comments received and considered

- March 2023 document from Health Access California, California Consumer Goals & Guiding Principles for the Office of Health Care Affordability
- May 16, 2023 letter from the California Independent Physician Practice Association
- May 17, 2023 letter from the American Investment Council
- July 20, 2023 letter from Health Access California
- July 26, 2023 letter from the American Investment Council
- August 14, 2023 letter from the California Hospital Association

Written comments received and considered concerning July 31, 2023 draft proposal

- August 30, 2023 letter from the California Physician Practice Association
- August 30, 2023 letter from California Health Center Partners of Southern California
- August 30, 2023 email from California Long-Term Care Ombudsman Association
- August 30, 2023 letter from ATA Action
- August 31, 2023 letter from California Chamber of Commerce
- August 31, 2023 letter from America's Physician Groups
- August 31, 2023 letter from California Ambulatory Surgery Association
- August 31, 2023 letter from California Association of Health Facilities
- August 31, 2023 letter from California Orthopaedic Association
- August 31, 2023 letter from the American Investment Council
- August 31, 2023 letter from California Nurses Association
- August 31, 2023 letter from Ropes & Gray LLP
- August 31, 2023 letter and sign-on letter from Health Access CA

- August 31, 2023 letter from UC Health
- August 31, 2023 letter from California Hospital Association
- August 31, 2023 letter from Sutter Health
- August 31, 2023 email and letter from California Association of Health Plans and the Association of California Life and Health Insurance Companies
- August 31, 2023 letter from Purchaser Business Group on Health

- August 31, 2023 letter from California Medical Association
- September 1, 2023 letter from CFT

Written comments received and considered concerning attached October 9, 2023 draft proposal:

- October 16, 2023 email from Suzanne Usaj, The Wonderful Company
- October 16, 2023 letter from California Nurses Association
- October 13, 2023 email from Carol Lucas, Buchalter
- October 17, 2023 letter from the California Independent Physician Practice Association
- October 17, 2023 letter from Hooper, Lundy & Bookman
- October 17, 2023 letter and worksheet from California Association of Health Plans and the Association of California Life and Health Insurance Companies
- October 17, 2023 letter from Kaiser Permanente
- October 17, 2023 letter from APG
- October 17, 2023 letter from California Hospital Association
- October 17, 2023 letter from Health Access
- October 17, 2023 letter from California Ambulatory Surgery Association
- October 17, 2023 letter from Sutter Health
- October 17, 2023 letter from California Medical Association
- October 17, 2023 letter from American Investment Council
- October 17, 2023 letter from Purchaser Business Group on Health
- October 17, 2023 email from Joan Allen, SEIU

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

During the process of developing this regulation, HCAI conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Pursuant to existing California law (Corp. Code sections 5914 *et seq*.), the AG has the authority to review nonprofit hospital transactions in the state based on criteria that includes whether the merger will serve the public interest and its potential effects on the availability or accessibility of health care services to the affected community. These regulations clarify that the nonprofit hospital transactions which the AG reviews are exempt from notice, pursuant to Health and Safety Code 127507(d)(4).

Pursuant to existing California law (Insurance Code sections 1091 *et seq*.), the CDI regulates and reviews certain health insurance transactions. These regulations clarify that the health insurer transactions which the Insurance Commissioner reviews are exempt from notice, pursuant to Health and Safety Code 127507(d).

Pursuant to existing California law (Health and Safety Code sections 1340 *et seq*.), the DMHC regulates and reviews certain heath care service plan transactions for cost impact or market consolidation. These regulations clarify that the plan transactions which the DMHC reviews are exempt from notice, pursuant to Health and Safety Code 127507(d).

Any of the three agencies above (AG, CDI, and the DMHC) may refer a proposed transaction to the Office for review (Health and Safety Code section 127507(e)), in which case the balance of these regulations will apply to the referred transaction and entities involved.

LOCAL MANDATE

No local mandate is imposed on a local agency or school district that requires reimbursement pursuant to Government Code section 17500 *et seq*.

DISCLOSURES REGARDING THE PROPOSED ACTION:

FISCAL IMPACT ESTIMATES

Cost or savings to any local agency or school district requiring reimbursement pursuant to Government Code section 17500 *et seq*.: None.

These regulations clarify that the transactions in which a county is purchasing, acquiring, or taking control, responsibility, or governance of an entity to ensure continued access to health care are exempt from notice, pursuant to Health and Safety Code section 127507(d)(3).

Cost or savings to any state agency:

Because the Act allows the DMHC, CDI, and the AG to refer transactions to the Office for a CMIR, the Office may provide some savings to these agencies. (Health and Saf. Code, § 127507, subd. (e) and § 127507.2, subd. (a)(1).) Such savings are, however, the direct result of the statutory authorization and not the result of these regulations.

The Act authorizes the Office to refer its findings regarding a transaction to the AG for further review of any unfair methods of competition, anticompetitive behavior, or anticompetitive effects. (Health and Saf. Code, § 127507.2, subd. (d)(1).) Referrals to the AG may increase the workload of the AG, but any increase is a direct result of statutory authorization and not the result of these regulations.

The authorizing legislation contained an appropriation for OHCA's CMIR program, including staffing, contracting resource allocation for IT software, services and infrastructure, and consulting contracts for expert services needed to support OHCA's reviews of transactions. Therefore, although there will be reviewing staff, an electronic portal for receipt and collection of material change notices and supporting documentation, and funding for contracts for expert services, all of which are intended to support the work described in regulation, the costs are attributable directly to the legislation.

With respect to the costs for experts to support the CMIR program, the Act specifically provides that OHCA may "[c]ontract with experts or consultants to assist in reviewing a proposed agreement or transaction." (Health & Saf. Code, § 127507.4, subd. (b).) OHCA is entitled to reimbursement from the health care entity subject to review for all actual, reasonable, and direct costs incurred in reviewing, evaluating, and making the determination for CMIRs, including administrative costs. (Health and Saf. Code, § 127507.2, subd. (b)(1).) Health care entities subject to review must promptly pay the Office, upon request, for all of these costs. (*Ibid*.) These costs are a direct result of statutory authorization and not the result of these regulations, and accordingly, have no ultimate fiscal effect on the Office.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other nondiscretionary cost or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.