



## 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

Regulations related to promotion of competitive health care markets and cost and market impact reviews pursuant to Health and Safety Code sections 127501 *et seq.* (CMIR program), codified in the California Code of Regulations (CCR) at Title 22, Division 7, Article 1, sections 97431 *et seq.*

#### SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION

The Office of Health Care 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).) Until January 1, 2027, OHCA may adopt any necessary regulations to implement its CMIR program as emergency regulations. (Health & Saf. Code, § 127501.2, subd. (a).) As authorized by statute, OHCA 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).)

Regulations adopting OHCA's CMIR program became effective on December 18, 2024. Since the adoption of these regulations, OHCA has determined certain clarifying amendments are necessary. Among other things, this regulatory proposal will clarify the entities subject to OHCA's filing requirements for material change transactions. One of HCAI's core values is transparency. Therefore, OHCA posted a draft of these regulations for the public's review on June 5, 2024, with a 15-day period for the public to provide comments.<sup>1</sup> OHCA received 6 written comments.

---

<sup>1</sup> OHCA initially published draft revisions to the text on its website on May 14, 2024, with a 10-day period for public comment. However, before it received any public comments, it removed the draft text for further review.

Before the Office adopts any regulation, OHCA's Board must discuss the proposed regulation at one Board meeting. (Health and Saf. Code, § 127501.2, subd. (c).) The Board discussed the draft revisions at its June 26, 2024 meeting, and received oral public comments regarding the revisions at that meeting.

## **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*

OHCA's existing CMIR regulations:

- Establish a section defining terms used in the regulations. (Section 97431.)
- Establish a section outlining the scope of the proposed regulations. (Section 97433.)
- Establish a section defining the transactions for which a filing of a notice with the Office is required. (Section 97435.)
- Establish a section providing an Office email address for parties with questions about whether a notice is required. (Section 97437.)
- Establish a section outlining the procedure for filing notices of material change transactions and the elements of required filings. (Section 97439.)
- Establish a section outlining the requirements for requesting expedited review of material change notices. (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. (Section 97441.)
- Establish a section clarifying the Office may also conduct a CMIR based on market power or market failures. (Section 97442.)

## General Policy Statement

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. (f).) Through its CMIR program, OHCA will analyze transactions that are likely to significantly impact 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 the Attorney General to address consolidation as appropriate. (Health & Saf. Code, § 127507.2, subd. (d)(1).)

This rulemaking amends regulations contained in Title 22 of the CCR that implement SB 184.

This proposal will:

- Amend section 97431 to clarify terms defined for purposes of Article 1 of Chapter 11.5 of Division 7 of Title 22 of the CCR.
- Amend section 97435 to clarify, among other things: (1) health care entities who are a party or a subject of a material change transaction must file notice thereof with OHCA; (2) the threshold in subsection (b)(3) applies only to providers or fully integrated delivery system in a designated primary care health professional shortage area in California; and (3) the definition of “annual California-derived revenue” for purposes of subsection (c).
- Amend section 97438 to, among other things: (a) require health care entities to exercise and attest to the use of reasonable diligence to ascertain the information required by this section; (b) clarify the information submitters must provide in a notice of material change transaction; and (c) clarify the processes for obtaining review of confidential documents and information submitted in support of requests for expedited review of notices of material change transactions, and withdrawal of expedited review requests.
- Amend section 97439 to authorize submitters to withdraw requests for expedited review if their requests for confidentiality are denied.
- Amend section 97441 to, among other things, expand the factors considered in whether to conduct a CMIR to include the ability to meet any health care cost targets established by the Health Care Affordability Board.
- Amend section 97442 to expand the factors considered in the conducting of a CMIR to include the effect on any health care entity’s ability to meet any health care cost targets established by the Health Care Affordability Board.

## **SPECIFIC PURPOSE AND NECESSITY FOR EACH REGULATION**

### **Amend section 97431 of Division 7 of Title 22, Definitions.**

#### Subsection (a)

OHCA amends the definition of “affiliation” to add cross-references to the regulations where the term is used for clarity. It strikes “affiliate” in parentheses to avoid confusion over the definition of whether “affiliation” applies to “affiliate” in the regulations. These amendments are necessary because stakeholders have expressed confusion regarding whether the “affiliation” definition applies to incidences of “affiliate.”

#### Subsection (j)

OHCA deletes “as used in section 127507(c)(1) of the Code” after “Material change transaction” as this is error. That term is not used in Health and Safety Code section 127507(c)(1), so OHCA deletes the parenthetical qualifier for clarity.

### Subsection (j)(2)

OCHA deletes “other” in subsection (j)(2) because, as set forth herein, OHCA is amending its regulations to clarify a health care entity need not be a party to a transaction to be required to file a notice of material change transaction. As presently worded, the term “other” suggests the health care entity is a party to transaction. OHCA amends subsection (j)(2) to align this subsection with these other amendments.

### Subsection (p)

OCHA adds “including a” to better align the regulation with statute. Section 127507(c)(1) requires written notice of transactions that “[s]ell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its assets to one or more entities.” As “transfer” is a type of disposition in section 127507(c)(1), the addition will clarify “transfer” as used in this subsection does not foreclose other types of dispositions. (*Groman v. Comm. of Internal Revenue* (1937) 302 U.S. 82 [a definition that uses term “includes” is nonexclusive].)

## **Amend section 97435 of Division 7 of Title 22, Material Change Transactions.**

### Subsection (a)

OHCA relocates “(hereinafter referred to as a “submitter”)” from subsection (a) to subsection (b) of this regulation, replaces “who” with “that,” and deletes “for those transactions expected to close on or after April 1, 2024.”

OHCA relocates the first phrase to be more proximately located to the thresholds in subsection (b). OHCA replaces “who” with “that” for grammatical correctness. OHCA deletes the final phrase of the first sentence since April 1, 2024 has now passed. Accordingly, the phrase is no longer necessary.

### Subsection (b)

OHCA makes the following amendments to subsection (b):

1. Adds “, or a subject of.”
2. Adds “material change.”
3. Deletes “party.”
4. Adds “health care entity (hereinafter referred to as a “submitter”).”
5. Adds “Being a subject of a transaction means the transaction will result in the transfer, as used in section 97431(p), of a health care entity’s assets, control, responsibility, governance, or operations, in whole or in part to one or more entities.”

These amendments are necessary to align section 97435(b) with Health and Safety Code section 127507.

Presently, subsection (b) requires health care entities who are parties to the transaction to file a notice with OHCA if they meet one or more thresholds in subsection (b) and the transaction meets one more circumstances in subsection (c).

OHCA has received multiple inquiries from potential submitters asking whether their transactions meet section 97435(b). Specifically, they have questioned whether notice is required for transactions in which non-health care entities (e.g. holding companies or parent owners of the health care entity) transfer assets or control of a health care entity even though the health care entity is not a party to the transaction. Alternatively, they have asserted a notice is not required because no health care entities are actual parties to the transaction.

Health and Safety Code section 127507(c) prescribes the transactions subject to OHCA's jurisdiction:

(c)(1) A health care entity shall provide the office with written notice of agreements or transactions that will occur on or after April 1, 2024, that do either of the following:

(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.

Significantly, section 127507(c)(1) does not limit submitters to those who are parties to a transaction. Rather, the statute examines only whether a “*transaction*” entails the actions in section (c)(1)(A) and (c)(1)(B), without regard to an entity’s role in the transaction (e.g. a buyer or seller, or a party). Accordingly, OHCA amends the requirement a health care entity must be a party to the transaction and expands the regulation to apply to health care entities who are either parties to the transaction or a subject of the transaction. OHCA defines “being a subject of a transaction” to address those situations wherein the transaction transfers, as used in section 97431(p), a health care entity’s assets, control, responsibility, governance, or operations, in whole or in part. This amendment will align the regulation with section 127507(c)(1)(A) and (c)(1)(B).

OHCA makes other necessary amendments for clarity, including relocating the reference to a health care entity as a submitter and inserts “material change” before “transaction” to align the phrase with the definition in section 97431(j).



### Subsection (b)(1)

OHCA replaces the period with a semi-colon in subsection (b)(1) for grammatical consistency.

### Subsection (b)(2)

OHCA adds “, or a subject of,” and “, or any entity that owns or controls a health care entity,” to subsection (b)(2).

Subsection (b)(2) provides one of three thresholds health care entities may potentially satisfy for purposes of filing a notice of material change transaction. As explained above, OHCA adds language to clarify a health care entity may be either a party to the transaction or a subject of the transaction to be required to file a notice with OHCA. This amendment will align the regulation with the language of section 127507(c)(1)(A) and (c)(1)(B). For clarity, OHCA adds a colon and paragraphs “(A)” and “(B)” to list the types of entities involved in the transaction.

OHCA amends the threshold in new paragraph (B) to include transactions with any entity that owns or controls a health care entity because transacting parties in the health care marketplace may own health care entities whose assets are being transferred or otherwise disposed of. In accordance with section 127507(c)(1), a health care entity must file the notice if the transaction meets statutory requirements. This language will ensure OHCA receives notice of transactions structured in this manner. This amendment is consistent with section 127507(c)(1)(A) and (c)(1)(B) which merely requires a transaction constitute one of the circumstances in those subdivisions to require a notice be filed with OHCA.

### Subsection (b)(3)

OHCA adds “A provider or fully integrated delivery system that is a party to, or a subject of, the transaction and provides health care services” and deletes “A health care entity located” in subsection (b)(3). As defined by these regulations and Health and Safety Code section 127500.2(k), “health care entity” includes payers. Because OHCA is focused on health care shortage areas wherein there are shortages of health care providers, not payer shortages, OHCA refines this section to expressly refer only to providers and fully integrated delivery systems.

Fully integrated delivery system means a system that includes a physician organization, a health facility or health system, and a nonprofit health care service plan that provides health care services to enrollees in a specific geographic region of the state through an affiliate hospital system and an exclusive contract between the nonprofit health care service plan and a single physician organization in each geographic region to provide those medical services. Providers include physician organizations and various types of health facilities, such as hospitals, clinics, ambulatory surgical centers or accredited outpatient settings. (Health & Saf. Code, § 127500.2, subds. (h) & (q).)

### Subsection (c)

OHCA amends subsection (c) to define the term “annual California-derived revenue” for purposes of subsection (c). Because subsection (d) defines revenue for purposes of subsection (b) (the thresholds), stakeholders have expressed confusion regarding the meaning of “revenue” as that term is used in subsection (c). Accordingly, this amendment is necessary to clarify “annual California-derived revenue” means revenue derived from the provision of health care services in California.

“Health care services” are specially defined in section 97431(h) of the regulations. As the term “transaction” is defined as “mergers, acquisitions, affiliations, and agreements impacting the provision of health care services in California,” it is necessary to define revenue triggering a notice filing by reference to that derived from the provision of health care services. (Cal. Code Regs., tit. 22, § 97431, subd. (p).)

### Subsections (c)(2) and (c)(5)

OHCA amends these subsections to require health care entities who are a party to or a subject of the transaction to file a notice with OHCA. This amendment will align the regulation with the language of section 127507(c)(1)(A) and (c)(1)(B).

OHCA adds a comma after “transaction” in subsection (c)(2) and deletes “in” in subsection (c)(5) for clarity and grammatical correctness.

### Subsection (c)(6)

OHCA relocates “annual” in subsection (c) to before “California-derived” for consistency with how these terms are ordered in other subsections.

### Subsections (c)(7) and (c)(8)

OHCA adds cross-references to subsections (c)(3), (c)(4), and (c)(6) to clarify the asset and control circumstances to which it refers by its reference to subsection (c). This amendment is necessary because stakeholders have expressed confusion about which subsections OHCA is referring to in these sections.

OHCA changes “last” to “past” in subsection (c)(8) for consistency with subsection (c)(7). As OHCA intends this language in both subsections to mean the same thing, it is necessary to use the same term for clarity.

### Subsection (d)

OHCA adds “of this regulation only” to subsection (d) to clarify the definitions are solely for the purpose of this subsection. This amendment is necessary because stakeholder have expressed confusion about whether this definition applies to the use of “revenue” in subsection (c).



## **Amend section 97438 of Division 7 of Title 22, Filing of Notices of Material Change Transactions.**

### Subsection (a)

OHCA amends subsection (a) to add a requirement a submitter must attest it used reasonable diligence to ascertain the information required by this section. This amendment is necessary to ensure a submitter exercises reasonable diligence to obtain the information required by the regulations. An attestation encourages submitters to proactively gather responsive information and alleviates the administrative burden on OHCA to conduct its own investigation to gather information. Parties can learn this information through due diligence they conduct when deciding to enter into transactions and reasonable diligence based on the revised regulation.

OHCA adds a dash between “e” and “mail” for consistency with other uses of the term in the regulations.

### Subsection (b)(1)(F)

OHCA amends this subsection to request license or registration numbers in addition to the other information required by this subsection. Presently, the subsection only requests health care license numbers. The amendment is necessary to require numbers for the other license or registration types for consistency and will alleviate the administrative burden of OHCA having to obtain this information.

### Subsection (b)(3)

OHCA amends this subsection to delete “other” for the same reasons as set forth with respect to section 97431(j)(2) and adds a requirement for submitters to exercise reasonable diligence to obtain information required by the subsection. OHCA incorporates by reference the rationale it provided in subsection (a). It is necessary to delete “to the extent the submitter has access to the information,” to replace it with a clearer affirmative obligation to ascertain responsive information.

### Subsections (b)(3)(F) and (b)(3)(H)

OHCA adds “fully integrated delivery system” (FIDS) to both subsections because FIDS include physician organizations which are a type of provider under the Act, and includes aspects of a health care service plan, a type of payer. (Health & Saf. Code, § 127500.2, subds. (h), (o)(1), & (q).) This amendment is necessary to elicit information regarding FIDS in this subsection.

OHCA adds “or the subject of” to both subsections for the reasons set forth with respect to section 97435(b).

#### Subsection (b)(3)(I)

OHCA replaces the period with a semi-colon for consistency with other subsections of the regulation.

#### Subsection (b)(10)(A)

OHCA amends subsection (b)(10)(A) to add “submitter and” for the same reasons as set forth in section 97435(b). As a health care entity is not required to be a party to a transaction to be required to file a notice, OHCA adds “submitter” to clarify a healthcare entity needs not have party status.

#### Subsection (b)(10)(D)

OHCA adds “the submitter is” to this subsection to clarify who must be a provider for the subsection to apply. It adds “or a fully integrated delivery system” for the same reasons as set forth in its rationale for amendments to subsections (b)(3)(F) and (b)(3)(H)

#### Subsection (c)(4)

OHCA amends this subsection to add “, including names, addresses, telephone numbers, and e-mail addresses.” This amendment is necessary to clarify the items of contact information OHCA seeks. This amendment will provide OHCA with more specific information in the event it needs to contact individuals signing or responsible for the transaction or side or related agreements.

#### Subsection (c)(7)

OHCA amends this subsection to add “of any payer, provider, or a fully integrated delivery system, as applicable, that is a subject of the transaction.” This amendment is necessary to clarify the entities from whom OHCA seeks information regarding the number of patients or enrollees per county. This will enable entities to more easily ascertain the sources from whom they must obtain information.

#### Subsection (d)(1)

OHCA amends this subsection to add “or a submitter requesting expedited review pursuant to section 97439.” This amendment is necessary because stakeholders have expressed confusion about what process they must follow to obtain confidentiality for documents or information they submit to obtain expedited review. This amendment will clarify they must utilize the same process as they must follow with notice filings in general.

#### Subsection (d)(3)

OHCA amends this subsection to add “a request for expedited review[.]” OHCA incorporates by reference the rationale it provided with respect to section 97438(d)(1).

#### Subsection (d)(4)

OHCA amends this subsection to add “If a request for confidentiality is denied, a submitter may submit a request through the portal to withdraw any information or documents for which it requested confidentiality in its submission.” This amendment is necessary to provide an avenue for submitters to withdraw information for which OHCA denies confidentiality. There is no current mechanism for the withdrawal of information or documents for which confidentiality is denied. This will alleviate any concern commercially sensitive information will be posted publicly if confidentiality is denied.

### **Amend section 97439 of Division 7 of Title 22, Request for Expedited Review of Notices of Material Change Transaction.**

#### Subsection (c)

OHCA amends this subsection to add “A submitter may submit a request through the portal to withdraw a request to expedite review if its request for confidentiality is denied in any part.” This amendment is necessary to provide an avenue for submitters to withdraw their request for expedited review if their request for confidentiality is denied in any part. For instance, if a submitter withdraws documents or information pursuant to 97438(d)(4), this may undermine the factual showing needed to obtain expedited review from OHCA. This amendment is necessary to allow a party to withdraw the request for expedited review in this instance.

### **Amend section 97441 of Division 7 of Title 22, Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Review.**

#### Subsection (a)(1)(B)

OHCA amends this subsection to add “, including the ability to meet any health care cost targets established by the Health Care Affordability Board, as set forth at 22 CCR 97447.” At the April 24, 2024, meeting of the Health Care Affordability Board, the Board approved a statewide health care spending target of 3 percent. The spending target will be phased in over time, initially starting at 3.5 percent for 2025 and 2026, the target will be lowered to 3.2 percent for 2027 and 2028 before ultimately reaching 3 percent for 2029. This Board-established spending target is codified in regulation at Title 22, section 97447.

OHCA received comments questioning OHCA’s inclusion of this factor since spending targets are not enforceable until 2026. (Health & Saf. Code, § 127502, subd. (f)(1); see also, Cal. Code Regs., tit. 22, § 97447.) However, beginning in 2025, health care

entities are required to begin annual reporting on health care spending and OHCA is required by statute to conduct a CMIR if it finds 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 amendment is necessary now to enable OHCA to consider whether a transaction may negatively impact the ability to meet any health care cost targets established by the Health Care Affordability Board. To the extent a transaction impacts compliance with spending targets, this factor would weigh in favor of conducting a CMIR on a transaction.

#### Subsection (b)(1)(C)

OHCA amends this subsection to delete “sent to the Director, with a copy to the Office” and add “submitted through the Office’s portal.” This amendment is necessary to update the means by which appeals are submitted to OHCA. As OHCA intends to use its portal for parties’ submission of information and appeals, this amendment aligns the regulation with this intent.

### **Amend section 97442 of Division 7 of Title 22, Cost and Market Impact Review Timeline and Factors; Preliminary and Final Reports.**

#### Subsection (b)(4) through (b)(9)

OHCA amends subsection (b)(4) to add a factor relating to a health care entity’s ability to meet any health care cost targets established by the Health Care Affordability Board. This amendment is necessary for the same reasons as set forth with respect to amendments to section 97441(a)(1)(B).

OHCA renumbers subsections (b)(4) through (b)(8) to accommodate this amendment.

### **ANTICIPATED BENEFITS OF THE PROPOSAL**

These proposed emergency regulations effectuate the Legislature’s directive to analyze transactions that are likely to significantly impact 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. These clarifying amendments will ensure OHCA receives complete information and notice of all transactions that likely implicate anticompetitive affordability, access, and quality concerns.

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

### Public meetings:

- June 26, 2024 Board Meeting, Relevant Presentation Slides, Minutes

### Written comments received and considered:

- Letter from John Saran, Holland and Knight LLP, June 19, 2024
- Letter from Henry Tuttle, Health Center Partners, June 20, 2024
- Letter from Janice Rocco, California Medical Association, June 20, 2024
- Letter from Ben Johnson, California Hospital Association, June 20, 2024
- Letter from Anette Millers, California Association of Health Plans, June 20, 2024
- Letter from William Barcellona, America's Physician Groups, June 20, 2024

## 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 these regulations are neither inconsistent nor incompatible with existing state regulations.

## 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.

**Cost or savings to any state agency:**

OHCA does not anticipate any additional cost or savings from this proposal beyond those it initially reported.

**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.