From: Usaj, Suzanne <Suzanne.Usaj@wonderful.com>
Sent: Monday, October 16, 2023 5:53 PM
To: Brubaker, Megan@HCAI <Megan.Brubaker@hcai.ca.gov>
Subject: RE: Revised CMIR draft regulations- Comments requested by 10/17

Hi Megan,

Here are my comments:

- Filing exemptions for entities in a health professional shortage area (p. 4): Support limiting this to shortages specifically in mental health and primary care
- Change of control thresholds (p. 7): Support original the lower threshold of 10%.
- Confidentiality (p. 13): I express concerns around lacking clarity on how confidentiality is defined and applied and/or providing for the submitter to deem documents confidential.
  A submitter should not have the right to deem their own documentation "confidential" without supporting reasoning that does not conflict with the expressed intent of OHCA or any other government regulations. Recent Federal legislation that passed in TiC, CAA, and other bills has worked to remove the veil of secrecy around provider billing and pricing. This would mean that nothing that has been or would be deemed confidential can be simply labelled and treated as "confidential" without cross referencing against other federal and state regulations. It also is important to state that the CMIR regulations should support driving affordability not only in appropriate mergers but also in allowing for the revenue and payment rates to be considered. Understanding what contract with networks/insurers/health plans will prevail following the action (merger, acquisition, etc.) is important.
- Whether to conduct a CMIR (p. 15): Support the explicit inclusion of serial transactions, vertical and cross market mergers

Thank you for the opportunity to weigh in.

Suzanne Dezember Usaj
Sr. Director, Total Rewards

theWonderfulcompany.

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Mobile: (310) 923-8103

Suzanne.Usaj@Wonderful.com
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Via Electronic Mail to CMIR@hcai.ca.gov

October 16, 2023

Secretary Mark Ghaly, MD, MPH, Chair
Office of Health Care Affordability Board
California Health and Human Services Agency
1600 Ninth Street, Room 460
Sacramento, CA 95814

Elizabeth Landsberg, Director
Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 800
Sacramento, CA 95833

Vishaal Pegany, Deputy Director
Office of Health Care Affordability
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Megan Brubaker, Manager
Office of Health Care Affordability
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

RE: Revised Proposed Emergency Regulatory Action – Promotion of Competitive Health Care Markets; Health Care Affordability (Cost and Market Impact Review)

Dear Chair Ghaly, Director Landsberg, Deputy Director Pegany, and Ms. Brubaker:

The California Nurses Association/National Nurses United (CNA), representing more than 100,000 registered nurses (RNs) in California, appreciates the opportunity to submit written comments to the Office of Health Care Affordability (OHCA) on the revised Proposed Emergency Regulatory Action on Cost and Market Impact Review (CMIR). To reiterate, CNA strongly supports OHCA's development of CMIR regulations on an emergency basis and we urge OCHA to broadly implement its authority to review market failures or market power within California's health care sector.

Supplementing the comments CNA submitted to OHCA on August 31, 2023, CNA urges OHCA, as described in our comments below, to make a number of additions and clarifications to its revised proposed CMIR emergency rule to further strengthen the CMIR emergency rule's protections for patients and health care workers.

1. **Oppose exclusion of "health professions training programs" from the scope of CMIR rules (§ 97431(a)).**

CNA urges the deletion of the phrase "health professions training programs" from the added exclusionary language added to the definition of "affiliation" or "affiliate" in § 97431(a). This exclusionary language would inappropriately exclude affiliations between health care entity employers and alleged training programs that lock nurses or other health care workers in exploitative training repayment agreement provision (TRAP) contracts. Worker debt TRAPs, which are prevalent in the health care sector, lock workers in often unsafe or unhealthy working conditions by requiring workers to pay for alleged costs of employer-mandated training programs if they leave employment before completing a period of work with the employer. CNA

and our parent union, National Nurses United (NNU), has written extensively on this topic,[1] and the federal Consumer Financial Protection Bureau published a report on the practice in July 2023.[2] In July 2023, the California Office of the Attorney General also issued a legal alert on warning against unlawful employer-driven debt arrangements, including training-related workplace debt arrangements.[3] As NNU identified in comments to the CFPB, health care employers sometimes trap workers in training debt by requiring a new worker to sign a contract with an affiliated training program or corporation. Excluding "health professions training programs" from the scope of the CMIR rule would tacitly allow use of these exploitative workplace contracts for health care workers and put them outside of OHCA's scrutiny.

2. **Oppose deletion of management services organizations from the scope of CMIR rules (§ 97431(j)).**

As CNA described in our August 31, 2023, comments on the CMIR emergency rule, we support the inclusion of management service organizations. Likewise, we oppose the deletion of management services organizations throughout the revised draft emergency rule.

3. **The exclusion of transactions that are "typical in the day-to-day operations of the health care entity" from material change transaction notices is concerningly vague (§ 97431(k)(i)).**

The exclusionary language added to the draft emergency rule's definition of "material change transaction" in § 97431(k)(i)(1) is vague and subject to interpretation by health care entities in their own favor against notice. Specifically, CNA opposes the new inclusion of the language stating that "[t]ransactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity." This language is vague and open to a different interpretation by each regulated health care entity. The CMIR material change notice requirement should militate towards notice where OHCA can determine that a CMIR is not warranted. However, by including exclusionary language that can be cast broadly, OHCA will allow regulated health care entities to interpret OHCA regulation and make such a determination themselves rather than the Office doing so.

[1] *See* National Nurses United, "Comment from National Nurses United to the Consumer Financial Protection Bureau, Request for Information: Employer-Driven Debt," *Regulations.gov*, Docket # CFPB-2022-0038, Comment ID CFPB-2022-0038-0048 (Sep. 22, 2022), available at https://www.regulations.gov/comment/CFPB-2022-0038-0048.

[2] Consumer Financial Protection Bureau, "Consumer risks posed by employer-drive debt," Issue Spotlight (Jul. 20, 2023), available at https://www.consumerfinance.gov/data-research/research-reports/issue-spotlight-consumer-risks-posed-by-employer-driven-debt/full-report/.

[3] California Department of Justice, Office of the Attorney General, "State Law Restrictions on Employer-Driven Debt," Legal Alert, No. OAG-2023-01 (July 25, 2023), available at https://oag.ca.gov/news/press-releases/attorney-general-bonta-issues-warning-against-unlawful-employer-driven-debt.

4. **Narrowing the CMIR notice requirements for transitions in health professions shortage areas to "designated mental or primary care" excludes notice of major hospital and health facility closures in underserved areas (§ 97435(c)(5)).**

As CNA stated in our August 31, 2023, comments to OHCA on the first draft of the proposed CMIR emergency rule, we support the inclusion of material change notice requirements for health care entities located in or serving health professional shortage areas. However, the revised draft, in § 97435(b)(3), would narrow this requirement to require material change notice by entities located only in a designated mental health or primary care health professional shortage area. Narrowing the scope of § 97435(b)(3) would mean that acute care facilities in health professional shortage areas would not be required to provide notice to OHCA under the CMIR notice requirements unless the health care entity were located in a mental health or primary care shortage area. In order to track transactions that may impact access to and affordability of health care in rural and underserved areas, CNA encourages reverting back to the original language drafted for § 97435(b)(3).

5. **Add or amend language to ensure that series of vertical transactions are considered material change transactions under § 97435(c)(9), (10).**

Two paragraphs added to § 97435(c), listing which circumstances require filing a material change transaction notice, are written in a manner that could be interpreted to apply only to horizontal transactions. CNA urges amendments to this section to ensure that series of and repeated similar transactions include both vertical and horizontal transactions. Both paragraphs (9) and (10) of subsection (c) of § 97435 refer to transactions involving "the same or related health care services." This phrase may inadvertently limit the scope of both paragraphs (9) and (10) to horizontal mergers or acquisitions. Vertical transactions could be characterized as transactions that do not involve the same or related health care services. For example, an acute care hospital corporation could purchase a pharmacy benefits manager or acquire health care entities that provide ambulatory care services.

6. **Support additions to the factors in determining whether to conduct a CMIR (§ 97441(a)(2)).**

CNA supports the factors added to § 97441(a)(2) that can serve as a basis for OHCA's decision to conduct a CMIR, including transactions that may lessen negative labor market impact in subparagraph (D), series of similar transactions or trends toward consolidation in subparagraph (G), and transactions that entrench a dominant market position, including vertical or cross-market mergers. We also support the amendments to subparagraph (I) to clarify the inclusion of transactions between health care entities in California and out-of-state entities that "negatively impact affordability, quality, or limit access to health care services in California or undermine the financial stability or competitive effectiveness of health care in this state." As we stated in our August 31, 2023, comments to OHCA, California-based Kaiser Foundation Hospitals' announced plans to acquire several out-of-state health care systems, including Geisinger Health System in Pennsylvania, may negatively impact health care affordability, quality, and access in California. This is particularly of concern as Kaiser Foundation Hospitals

promises to investment $2 to $5 billion into Geisinger rather than investing those funds to support maintaining or improving health care services, affordability, workforce stability, or quality of care.

7. Support additions of factors considered in a CMIR (§ 97441(e)).

CNA also supports the factors added to § 97441(e) that will be examined by OHCA in a CMIR, including the examination of a transaction's effect on workers and the labor market in paragraph (5) and the examination of whether the transaction may foreclose competitors of a party to the transaction from a segment of the market or increase barriers to entry in any health care market in paragraph (6).

8. CNA reiterates our previous comments to OHCA on the CMIR emergency rule.

Finally, CNA reiterates our previous comments on the CMIR emergency rule. Our comments supported all of the following changes to the CMIR emergency rule.

- The addition of safe staffing levels and past labor practices as factors in determining whether to conduct a CMIR.
- The express inclusion of health care service reductions, closures, or shifts and an entity's past practices of health care service reductions, closures, or shifts as factors in determining whether to conduct a CMIR.
- Clarifying that a CMIR can be conducted without being tied to a transaction that was noticed as a material change.
- Further detailing the "availability and access" factor considered in a CMIR to include health care service reductions, closures, or shifts and an entity's past practices of health care service reductions, closures, or shifts.
- As a factor OHCA considers in a CMIR, adding the effect on premiums, deductibles, provider network, prior authorization, out-of-pocket costs to patients, step therapy, surprise billing, medical debt collection, and other financial and administrative barriers to care for patients.
- Requiring health care entities to report additional information on labor market impact and the health care entity's history of and anticipated post-transaction changes in staffing, prices, and location and availability of services.
- Adding provisions on public posting of CMIR reports and permitting OHCA to hold public hearings and receive verbal public comment on CMIRs.
- Lowering the material change notice patient revenue and asset thresholds.
- Using total annual revenue rather than net patient revenue in its material change notice requirements.

CNA again appreciates the opportunity to provide OHCA with additional comments on the draft CMIR emergency rules. If you have any questions, please contact Carmen Comsti at ccomsti@calnurses.org.

Sincerely,

Michelle Grisat
National Director of Health Policy
California Nurses Association/National Nurses United

From: Lucas, Carol K. <clucas@buchalter.com>
Sent: Friday, October 13, 2023 12:00 PM
To: OHCA CMIR
Subject: Comments on Revised Draft of Proposed Emergency Regulations relating to Material Change Transactions and Pre-Transaction Review

To whom it may concern:

I am a practicing health care lawyer in California and was pleased to see the revised draft of the proposed Emergency Regulation. The recent draft, however, did not address two comments that I have, one technical and one more substantive:

1. On page 9, line 14 you use the term "limited liability corporation." There is no such business entity in California (or, to my knowledge, in any other US jurisdiction). California recognizes corporations and limited liability **companies,** which is likely what you meant.
2. More substantively, please clarify what "less than 25 physicians" means. Does it mean physician owners? Physician employees? FTE physicians providing services? All physicians providing services in any capacity? An RBO, for example, could have 20 exclusive primary care physicians and dozens of contracted specialist physicians who only occasionally provide services on behalf of the organization. Some clarity on how physicians are to be counted would be helpful in trying to determine whether a notice is required to be filed.

Thank you for your consideration.

Carol Lucas

Buchalter

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October 17, 2023

VIA E-MAIL (CMIR@HCAI.CA.GOV)
Ms. Megan Brubaker
HCAI, Office of Health Care Affordability
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95814

RE: Comments on Proposed CMIR Emergency Regulations (Dated 10/9/23)

Dear Ms. Brubaker:

The California Independent Physician Practice Association ("CIPPA") submits these comments in response to the Proposed Cost and Market Impact Review Emergency Regulations dated October 9, 2023 (the "Revised Proposed Regulations").

The Revised Proposed Regulations make several improvements to the July 27, 2023 version, including: (1) striking the inclusion of "management services organizations" in sections 97431(g)(3), 97431(j), 97435(c)(5), and 97435(d)(7); (2) adding new exclusions from the definition of "material change transactions" in sections 97431(j)(1) &(2); and (3) the clarification that the transaction notice is due to the Office 90 days before the expected closing date in 97435(a). However, the Revised Proposed Regulations also add new problematic language, and several of our previously expressed concerns have not been addressed.[1] As a result, we remain concerned that certain aspects of the Revised Proposed Regulations will inhibit transactions that promote competition and make it more difficult for independent medical groups to provide services outside a hospital setting. Our specific concerns are outlined below.

I. OHCA is Including Factors for Determining the Need to Conduct Cost and Market Impact Reviews that are Unrelated to Cost, Quality, Access, or Market Conditions.

In Section 97441, the Revised Proposed Regulations describe the factors the Office will use to determine if a transaction should be subject to a cost and market impact review (CMIR). Each subdivision of proposed regulation 97441 relates to cost, quality, access, or market conditions, except new subdivision (G) of subdivision (a)(2). Subdivision (G) provides:

> "If the transaction is part of a series of similar transactions by the health care entity or entities or furthers a trend toward consolidation."[2]

As such, a single transaction that is "part of a series of similar transactions" could trigger a CMIR even when the subject transaction has little or no impact on affordability, access, quality, or

[1] See Comment Letter from California Independent Physician Practice Association to M. Brubaker, HCAI, Office of Health Care Affordability (Aug. 30, 2023), *available at* https://hcai.ca.gov/wp-content/uploads/2023/10/Merged-Regs-Public-Comment.pdf.
[2] OHCA Revised Proposed Reg. § 97441(a)(2)(G).

otherwise poses a risk of market failure. As framed, a transaction being "part of a series of similar transaction"—standing alone—is sufficient to trigger a CMIR.

The Legislature gave guidance to the Office of Health Care Affordability (OHCA) on the types of transactions that should be subject to a full CMIR, directing OHCA to conduct a review "(i)f the office finds that a material change…is likely to have a significant impact on market competitions, the state's ability to meet cost targets, or costs for purchasers and consumers…"[3]

We do not believe that Revised Proposed Regulation 97441(a)(2)(G) is in line with this guidance, because it allows for a full cost and market impact review based solely on the fact that the transaction is one in a series of similar transactions and without a finding that the transaction creates a specific concern relating to cost, access, quality, equity, workforce stability, or other market failures. **As a result, OHCA should strike 97441(a)(2)(G) when it finalizes the regulations.**

II. The Revised Proposed Regulations Cover Transactions Not Related to the Provision of Health Care Services.

Revised Regulation 97431(p) expands the definition of "transaction" as follows:

> (p) "Transaction" includes mergers, acquisitions, affiliations, or agreements involving a health care entity, **or** the provision of health care services in California, that involve a transfer of assets (sell, lease, exchange, option, encumber, convey, or dispose) or control, responsibility, or governance of the assets or operations of the health care entity in whole or in part to one or more entities.[4]

Under this new language, transactions no longer need to relate to the provision of health care services to be covered by the California Health Care Quality and Affordability Act ("HCQAA"). The defined scope of the HCQAA will be a critical factor in the ability of OHCA to process submissions in a timely and efficient manner. Including transactions unrelated to health care services in the list of agreements that need to be internally reviewed for HCQAA compliance significantly expands the administrative burden placed on health care entities and could result in a deluge of notices far afield from the focus of OHCA and the HCQAA. **We request that OHCA modify 97431(p) to require that transactions be related to the provision of health care services.**

[3] Cal. Health & Saf. Code §127507.2(a)(1).
[4] OHCA Revised Proposed Reg. § 97431(p) (emphasis added).

III. New Language Included in the Revised Proposed Regulations Broadly Expands Captured Transactions.

The Revised Proposed Regulations contain significant changes to subsections 97435(c)(9) and (10), which specify circumstances that trigger the filing of a material change notice with the Office. The paragraphs now read:

> (9) 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).
>
> (10) 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).[5]

Although OHCA has the authority to define the appropriate circumstances that trigger a material change notice, we are concerned that this expanded scope may overwhelm the ability of the Office to provide timely reviews. **We would suggest that OHCA limit the look back provisions to 5 years and require the combined transactions to have a significant impact likely to drive up costs.**

IV. The Revised Proposed Regulations Continue to Expand the Circumstances that Require Filing of a Notice Beyond What Is Permitted Under the HCQAA.

As suggested by our August 30, 2023 letter, the Revised Proposed Regulations strike the contents of subdivision (5) of subsection 97435(c), but unfortunately replace it with an equally problematic new provision. Subdivision (5) now states:

> (5) 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.[6]

[5] Id. § 97435(c)(9) & (c)(10).
[6] Id. § 97435(c)(5).

Our concerns with the overly expansive nature of the emergency regulations are more thoroughly detailed in our August 30, 2023 letter,[7] but much like the original version of 97435(c)(5), this new language exceeds the authority granted by HCQAA, which limits covered transactions to the following categories:

> (A) Sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a material amount of its [i.e., the health care entity's] 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[8]

A transaction that involves an entity taking on responsibility relating to contracting with payors on behalf of consolidated or combined providers is not one that "dispose[s] of a material amount" of the provider's assets nor can it reasonably be understood as "transfer[ring] control, responsibility, or governance of a material amount of the assets or operations of the health care entity to one or more entities."[9] **Accordingly, OHCA should strike new subdivision (5) of subsection 97435(c) when it finalizes the regulations.**

V. The Revised Proposed Regulations Still Allow OHCA to Impermissibly Toll the Sixty-Day Period for Initial Review.

As explained in our August 30 letter,[10] the Legislature provided the Office with 60 days from receipt of a notice of material change to "advise the noticing health care entity of the office's determination to conduct a cost and market impact review or provide a written waiver from the review."[11] The statutory directive to OHCA is mandatory—the office "shall" take one of these two steps within 60 days. And although the Office "may adopt regulations that *expedite* these timelines, as warranted, depending on the nature of the agreement or transaction,"[12] the HCQAA does not provide OHCA with authority to extend this 60-day period.

The fact that the Office does not limit the number of times it can ask for further information, nor does it limit when during the 60-day period it can seek further information, compounds this concern. A two-month period to conduct an initial review is enough time to assess whether a transaction should be subjected to a CMIR. **We urge OHCA to strike paragraph 97441(b)(2) from the final regulations.**

For the same reason, we believe OHCA is without the authority to toll the 60-day period based on review of the transaction by other state or federal regulatory agencies or courts. Again, the

[7] See CIPPA Comment Letter, pp. 2-4 (Aug. 30, 2023), *available at* https://hcai.ca.gov/wp-content/uploads/2023/10/Merged-Regs-Public-Comment.pdf.
[8] Cal. Health & Saf. Code § 127507(c)(1)(A) & (B).
[9] Id.
[10] See CIPPA Comment Letter, pp. 10-11 (Aug. 30, 2023), *available at* https://hcai.ca.gov/wp-content/uploads/2023/10/Merged-Regs-Public-Comment.pdf.
[11] Cal. Health & Saf. Code § 127507.2(a)(3)(A).
[12] Id. § 127507.2(a)(3)(B) (emphasis added).

Legislature provided OHCA with the discretion to "expedite" the 60-day period, not extend it. **As such, OHCA should strike paragraph 97441(b)(3) from the final regulations.**

VI. OHCA Should Include a More Robust Pre-Filing Inquiry Process in the Final Regulations.

CIPPA appreciates OHCA's decision to include a process for expedited review but has concerns about how narrow the process is constructed. Revised Proposed Regulation 97440(b) sets forth the conditions for when expedited review is allowed. Those circumstances are:

> (b) A submitter shall demonstrate that either of the conditions in subsections (b)(1) or (2) exist to obtain expedited review:
>
> > (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.[13]

Although these circumstances certainly warrant an expedited review process, they do not include situations where the transactions promote competition, preserve access to health care services, and are not likely to materially impact the cost of health care services. These transactions should also be granted expedited review to relieve pressure on the Office and increase efficiency. **CIPPA requests that the Office add to 97440(b) a third set of conditions that will enable submitting health care entities to obtain expedited review for transactions that do not consolidate health care entities, preserve access to care, and are unlikely to materially impact the cost of health care services.**

VII. Summary of Requests for Action

To summarize, CIPPA asks that OHCA take the following actions as it finalizes the emergency regulations that will govern the Material Change Transaction Review Process:

- Strike 97441(a)(2)(G);
- Reinsert language to 97431(p) that requires transactions be related to the provision of health care services to trigger the notice obligation;
- With respect to 97435(c)(9) and (10), which define two of the circumstances triggering the notice obligation, limit the look back provisions to 5 years and require the combined transactions to have a significant impact likely to drive up costs;
- Strike new paragraph (5) of subsection 97435(c);

[13] OHCA Revised Proposed Reg. § 97440(b)(1) & (b)(2).

- Strike paragraphs 97441(b)(2) and 97441(b)(3) that permit OCHA to toll the 60-day review period; and

- Add to subsection 97440(b) a third set of conditions that will enable submitting health care entities to obtain expedited review for transactions that do not consolidate health care entities, preserve access to care, and are unlikely to materially impact the cost of health care services.

We look forward to continuing to work with OHCA as it refines the Revised Proposed Regulations. Please reach out to CIPPA's government affairs advocates, Jon Ross ((916) 448-2162; jross@ka-pow.com) or John Doherty ((916) 207-7852; jd@jd-lawgroup.com), if we can be of further help.

Sincerely,

Ed Cohen, M.D.
President & Chairman of the Board

Glenn Littenberg, M.D.
Chair, Health Policy

cc: All Health Care Affordability Board Members
Dr. Mark Ghaly, CHHS Secretary
Elizabeth A. Landsberg, HCAI Director
Vishaal Pegany, OHCA Deputy Director
Sheila Tatayon, OHCA Assistant Deputy Director
Richard Figueroa, Deputy Cabinet Secretary
Angela Pontes, Deputy Legislative Secretary

HLB HOOPER LUNDY BOOKMAN

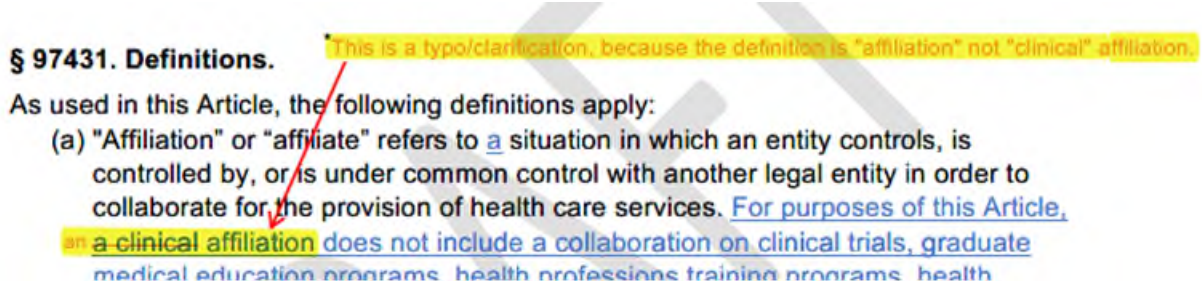
MEMORANDUM

CONFIDENTIAL

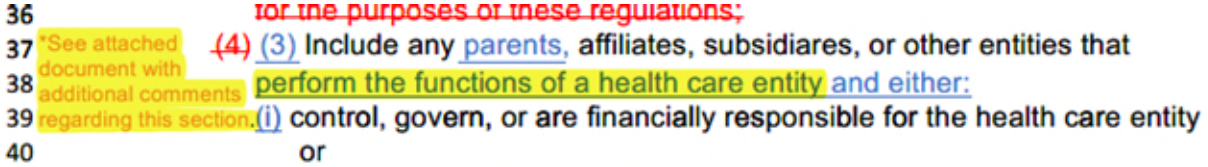
TO:	HCAI - OHCA	**FILE NO:**	99999.999
FROM:	Hooper, Lundy & Bookman		
DATE:	October 17, 2023		
RE:	Comments to OHCA Revised Proposed California Code of Regulations Regarding Material Change Transactions and Pre-Transaction Review (the "Proposed Regulations")		

We are providing comments to the Proposed Regulations for your review and consideration. The comments are described below and reflected on the attached PDF (highlighted in yellow).

1. **Section 97431(a) (Page 1 of 18)**: We believe the reference to "clinical affiliation" should just be "affiliation."



2. **Section 97431(g)(3) (Page 1 of 18)**: What does the phrase, "perform the functions of a health care entity" mean? Especially when read together with the language added in subsection (ii) below. Is this an intent to roll in MSO's even though they were deleted elsewhere?



(ii) ~~that~~ 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; and

3. **Section 97431(g)(4) (Page 2 of 18):** How are the number of physicians to be calculated when there are some part-time physicians? On a full time equivalent (FTE) basis? For example, if there are 6 physicians who practice with a group – 2 of whom are full time and 4 of whom work half-time, would that equate to 4 (FTE) physicians for purposes of the Proposed Regulations, or 6 physicians?

~~(5)~~ (4) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in 127500.2(p)(6) of the Code. ~~For purposes of these regulations, any~~ Any health care entity entering into a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435. Still unclear whether this is 25 Full Time Equivalents?

4. Section 97435(j) (Page 2 of 18): Typo correction and clarification request as shown below/attached:

~~services and support.~~

(k) (j) "Material change transaction," as used in section ~~12507~~127507(c)(1) of the Code, shall mean a transaction (as defined in this section), which meets the requirements of section 97435(c). ~~;~~ provided, however, "Material change transaction" does not include:

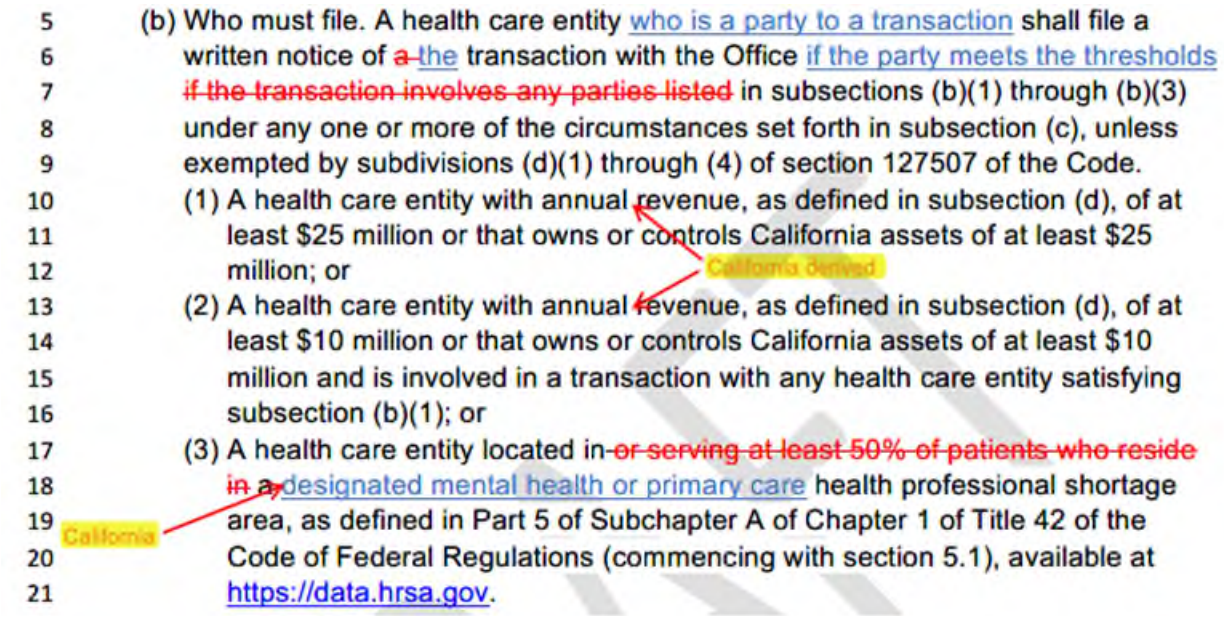
Typo

to clarify that (1) & (2) are carve-outs if they otherwise roll in something from (c) below.

(1) Transactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity.

(2) Situations in which the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under

5. Section 97435 (Page 4 of 18): OHCA added "California" qualifiers in some places, but not others. Was that intentional? We are proposing to add "California" qualifiers in the three places noted in our mark-up.



(b) Who must file. A health care entity who is a party to a transaction shall file a written notice of ~~a~~ the transaction with the Office if the party meets the thresholds ~~if the transaction involves any parties listed~~ in subsections (b)(1) through (b)(3) under any one or more of the circumstances set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the Code.

(1) A health care entity with annual revenue, as defined in subsection (d), of at least $25 million or that owns or controls California assets of at least $25 million; or

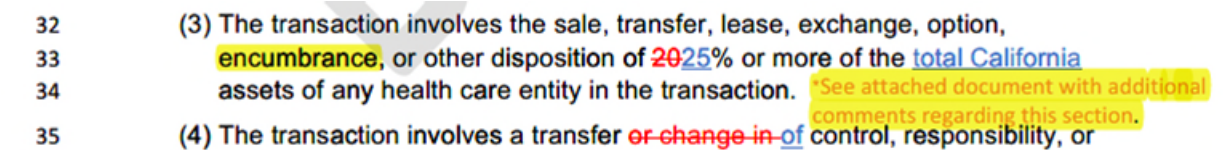
California derived

(2) 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 involved in a transaction with any health care entity satisfying subsection (b)(1); or

(3) A health care entity located in ~~or serving at least 50% of patients who reside in a~~ designated mental health or primary care health professional shortage area, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section 5.1), available at https://data.hrsa.gov.

California

6. Section 97435(c)(3) (Page 4 of 18): We are troubled by the continued inclusion of "encumbrance" in the definition of a material change transaction. We believe it is an overreach to include encumbrances since giving a lien or security interest does not transfer control over assets or operations at the time the security interest is given, and it is typical for security interests to be in the form of an "all asset" lien (hence exceeding your proposed 25% threshold). If you are going to include encumbrances, then we suggest that the regulations carve out traditional financing transactions with institutional lenders as well as tax exempt financing (such as through HUD or tax-exempt bond financing). Even if encumbrance is deleted entirely from the definition, the office should still get notice of a "material transaction" if and when the secured party attempts to foreclose on its interest and take control of the assets (assuming the threshold is triggered at that time).

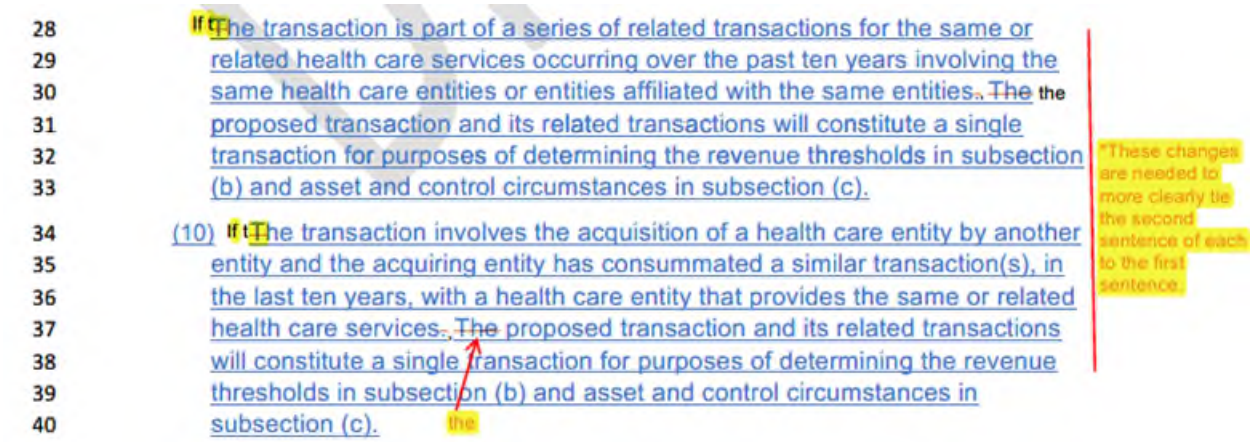


(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of ~~20~~25% or more of the total California assets of any health care entity in the transaction.

*See attached document with additional comments regarding this section.

(4) The transaction involves a transfer ~~or change in~~ of control, responsibility, or

7. **Section 97435(c)(9) and (10) (Page 5 of 18)**: Clarification request as shown below/attached:



8. **Section 97439(d)(4) (Page 13 of 18)**: RE: Confidentiality Request: If OHCA denies a confidentiality request, the submitter should have the ability to withdraw its notice (so as to maintain confidentiality).

9.. **Section 97440 (Page 14 of 18)**: RE: Request for Expedited Review: Please include a timeframe for the office to respond to an expedited review request, so that the submitter has a date certain for when it will learn if it is going to obtain an expedited review. We also note that there are extremely limited circumstances under which a submitter can request an expedited review (basically severe financial distress or reduction in critical health care services). However, there may be other legitimate circumstances that could merit an expedited review but are not necessarily anticipated. Could you include a discretionary catch all that would give the office the ability to consider and grant expedited review on some other grounds (for example if it determines doing so is “in the best interests of the public.”

COMMENTS - HOOPER, LUNDY & BOOKMAN 10/17/23

Title 22, California Code of Regulations
Division 7. Health Planning and Facility Construction

Chapter 11.5. Promotion of Competitive Health Care Markets; Health Care Affordability
Article 1. Material Change Transactions and Pre-Transaction Review.

Note to reader: This is a revised draft, based on the original draft dated 7/27/23. Deletions are shown in ~~strikeout~~; additions are show in underline.

If you would like to comment on this draft, send your comments to CMIR@HCAI.CA.GOV by 5 p.m. on Tuesday, October 17, 2023.

§ 97431. Definitions.

*This is a typo/clarification, because the definition is "affiliation" not "clinical" affiliation.

As used in this Article, the following definitions apply:

(a) "Affiliation" or "affiliate" refers to a situation in which an entity controls, is controlled by, or is under common control with another legal entity in order to collaborate for the provision of health care services. For purposes of this Article, an ~~a clinical~~ affiliation does not include a collaboration on clinical trials, graduate medical education programs, health professions training programs, health sciences training programs, or other education and research programs.

(b) "Cost and market impact review" shall mean the review conducted by the Office pursuant to section 127507.2 of the Health and Safety Code ("the Code").

(c) "Culturally competent care" means the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients.

(d) "Department" shall mean the Department of Health Care Access and Information.

(e) "Director" shall mean the director of the Department of Health Care Access and Information.

(f) "Fully integrated delivery system" shall have the meaning set forth in section 127500.2(h) of the Code.

(g) "Health care entity" shall:

(1) Have the meaning set forth in section 127500.2(k) of the Code;

(2) Include pharmacy benefit managers as set forth in sections 127501(c)(12) and 127507(a) of the Code;

~~(3) Include a management services organization, which qualifies as a "payer" for the purposes of these regulations;~~

*See attached document with additional comments regarding this section.

~~(4)~~ (3) Include any parents, affiliates, subsidiares, or other entities that perform the functions of a health care entity and either:

(i) control, govern, or are financially responsible for the health care entity or

(ii) ~~that~~ 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; and

~~(5)~~ (4) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in 127500.2(p)(6) of the Code. ~~For purposes of these regulations, any~~ Any health care entity entering into a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435.

*Still unclear whether this is 25 Full Time Equivalents?

(h) "Health care services," for purposes of this Article, are services for the care, prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health (mental health or substance use disorder) condition, illness, injury, or disease, including but not limited to:

(1) Acute care, diagnostic, or therapeutic inpatient hospital services;
(2) Acute care, diagnostic, or therapeutic outpatient services;
(3) Pharmacy, retail and specialty, including any drugs or devices;
(4) Performance of functions to refer, arrange, or coordinate care;
(5) Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and
(6) Technology associated with the provision of services or equipment in paragraphs (1) through (5) above, such as telehealth, electronic health records, software, claims processing, or utilization systems.

(i) "Hospital" shall mean any facility that is required to be licensed under subdivision (a), (b), or (f) of section 1250 of the Code, except a facility operated by the Department of State Hospitals or the Department of Corrections and Rehabilitation.

~~(j) "Management services organization" means an entity that provides administrative or management services for a health care entity, not including the direct provision of health care services. Administrative or management services include, but are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.~~

(k) (j) "Material change transaction," as used in section ~~12507~~(c)(1) of the Code, shall mean a transaction (as defined in this section), which meets the requirements of section 97435(c). ~~; provided, however,~~ "Material change transaction" does not include:

127507

*Typo

to clarify that (1) & (2) are carve-outs if they otherwise roll in something from (c) below.

(1) Transactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity.

(2) Situations in which the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under

common control with, all other parties to the transaction, such as a corporate restructuring.

~~(l)~~ (k) "Notice" shall refer to the notice of a material change transaction as set forth in section 97435.

~~(m)~~ (l) "Office" shall mean the Office of Health Care Affordability established by section 127501 of the Code.

~~(n)~~ (m) "Payer" shall have the meaning set forth in section 127500.2(o) of the Code.

~~(o)~~ (n) "Physician organization" shall have the meaning set forth in section 127500.2(p) of the Code.

~~(p)~~ (o) "Provider" shall have the meaning set forth in section 127500.2(q) of the Code.

~~(q)~~ (p) "Transaction" includes mergers, acquisitions, affiliations, or ~~other~~ agreements involving a health care entity, or the provision of health care services in California, that involve a ~~change~~ transfer of assets (sell, ~~transfer,~~ lease, exchange, option, encumber, convey, or dispose) or ~~entail a change, directly or indirectly, to ownership, operations, or governance structure involving any health care entity.~~ control, responsibility, or governance of the assets or operations of the health care entity in whole or in part to one or more entities.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Sections 127500.2, 127507, and 127507.2, Health and Safety Code.

§ 97433. Scope.

Sections 97435 through 97441 govern the procedure for filing notices of material change transactions and the Office's criteria and procedure for review of material change transactions and cost and market impact reviews, if deemed necessary.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Sections 127500.5,127507, and 127507.2, Health and Safety Code.

§ 97435. Material Change Transactions.

(a) A health care entity (hereinafter referred to as a "submitter") who meets the criteria of subsection (b) shall provide the Office with notice of a transaction at least 90 days before the closing date of the transaction, for those transactions expected to close on or after April 1, 2024.

~~Effective January 1, 2024, pursuant to section 127507 of the Code, a health care entity who meets any threshold in subsection (b) (hereinafter referred to as a "submitter") shall provide the Office with at least 90 days' advance notice of transactions that will be entered into on or after April 1, 2024.~~

For purposes of section 127507(c)(2) of the Code, the phrase "entering into the

agreement or transaction" refers to the closing date. ~~any parties' respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived.~~

(b) Who must file. A health care entity who is a party to a transaction shall file a written notice of ~~a~~ the transaction with the Office if the party meets the thresholds ~~if the transaction involves any parties listed~~ in subsections (b)(1) through (b)(3) under any one or more of the circumstances set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the Code.

(1) A health care entity with annual revenue, as defined in subsection (d), of at least $25 million or that owns or controls California assets of at least $25 million; or

California derived

(2) A health care entity with annual ~~r~~evenue, as defined in subsection (d), of at least $10 million or that owns or controls California assets of at least $10 million and is involved in a transaction with any health care entity satisfying subsection (b)(1); or

(3) A health care entity located in ~~or serving at least 50% of patients who reside in~~ a designated mental health or primary care health professional shortage area, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section 5.1), available at https://data.hrsa.gov.

California

(c) Circumstances requiring filing. A transaction is a material change transaction pursuant to section 127507(c)(1) of the Code if any of the ~~following~~ circumstances in paragraphs (1) through (10) below exist~~:~~.

(1) The proposed fair market value of the transaction is $25 million or more and the transaction concerns the provision of health care services.

(2) 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 ~~at least~~ $10 million or more or 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation.

(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of ~~20~~25% or more of the total California assets of any health care entity in the transaction.

*See attached document with additional comments regarding this section.

(4) The transaction involves a transfer ~~or change in~~ of control, responsibility, or governance of the submitter, in whole or in part, as defined in subsection (e).

(5) ~~The terms of the transaction contemplate an entity negotiating or administering contracts with payers on behalf of one or more providers and the transaction involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, management services organization, or~~

~~other organization.~~
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.

(6) The transaction involves the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health 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 ~~have~~ transfer control of California assets related to the provision of health care services valued at $25 million or more.

(7) The transaction involves a health care entity joining, merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services where any health care entity has at least $10 million in annual California-derived revenue as defined in subsection (d).
~~For purposes of this subsection, a clinical affiliation does not include a collaboration on clinical trials or graduate medical education programs.~~

(8) The transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to change from a physician-owned to private equity-owned and publicly held to a privately held form of ownership.

(9) ~~A health care entity that is a party to the transaction has consummated any transaction regarding provision of health care services in California with another party to the transaction within ten years prior to the current transaction.~~
If t~~T~~he 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~~ 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).

(10) If t~~T~~he 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).

the

*These changes are needed to more clearly tie the second sentence of each to the first sentence.

(d) Revenue. For purposes of subsection (b) of this section, "revenue" means the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years, as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed, as follows:

(1) For health care service plans, revenue as reported to the Department of Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).

(2) For health insurers, revenue as reported to the Department of Insurance pursuant to Insurance Code section 931.

(3) For hospitals, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Hospitals," incorporated by reference in 22 CCR 97018.

(4) For long-term care facilities, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Long-Term Care Facilities," incorporated by reference in 22 CCR 97019.

(5) For risk-bearing organizations required to register and report to the DMHC, revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.

(6) For other providers or provider organizations, net patient revenue, which includes the total revenue received for patient care, including:

(A) Prior year third-party settlements;

(B) Revenue received (inclusive of withholds, refunds, insurance services, capitation, and co-payments) from a health care entity or other payer to provide health care services, for all providers represented by the provider or provider organization in contracting with payers, for all providers represented by the provider or provider organization in contracting with payers;

(C) Fee for service revenue; or

(D) Revenue from shared risk and all incentive programs.

~~(7)~~ For pharmacy benefit managers ~~management services organizations~~, all payments and revenue received from health care entities to provide ~~administrative or management~~ pharmacy benefit management services. ~~Administrative or management services include, but are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.~~

(e) Control, responsibility, or governance. For purposes of this section, a transaction will directly or indirectly transfer ~~or change~~ control, responsibility, or governance in whole or in part of a material amount of the assets or operations of a health care entity to one or more entities if:

(1) ~~There is a substitution or addition of a new corporate member or members that transfers more than 10% of the voting power control of, responsibility for, or governance of a health care entity; or~~
The transaction would result in the transfer of 25% or more of the voting power of the members of the governing body of a health care entity, such as by adding one or more members, substituting one or more members, or through any other type of arrangement, written or oral; or

(2)~~There is a substitution of one or more members of the governing body of a health care entity, or any arrangement, written or oral, that would transfer full or partial voting control of the members of the governing body of a health care entity; or~~
The transaction would vest voting rights significant enough to constitute a change in control such as supermajority rights, veto rights, and similar provisions even if ownership shares or representation on a governing body are less than 25%; or

(3) The transaction would result in the transfer of ~~more than 10~~25% or more of the administrative or operational control or governance of the management and policies of at least one health care entity that is a party to the transaction.

~~(f) A transaction is not a material change transaction if the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under common control with, all other parties to the transaction, such as a corporate restructuring.~~

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Section 127500.2, 127507, Health and Safety Code.

§ 97437. Pre-Filing Questions.

Health care entities that are unsure if they must file a notice under this Article may contact the Office at CMIR@hcai.ca.gov.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Section 127507, Health and Safety Code.

§ 97439. Filing of Notices of Material Change Transactions.

(a) A notice of material change transaction pursuant to section 127507 of the Code required to be filed under this section ("notice") shall be made under penalty of perjury using the portal on the Office's website at www.hcai.ca.gov/login. A health care entity or its agent filing in the portal shall create a portal account by inputting a first and last name, valid email account, display name, and password, and submit a system-generated verification code. Alternatively, the health care entity or agency may use an existing media account from Microsoft or Google to access the portal. In making any narrative statements in response to subsection (b), if any documents support the assertion, the health care entity making the assertion shall, pursuant to subsections (c) and (d), provide and cite the document, including the section or page number of the document.

(b) Form and Contents of Public Notice. A health care entity submitting a notice ("submitter") shall indicate which threshold(s) and circumstance(s) are met, pursuant to section 97435(b) and (c), respectively, and provide the following information to the Office for public posting on the Office's website:

(1) General information about the transaction and entities in the transaction, including the following information regarding the submitter:

(A) Business Name

(B) Business Website

(C) Business Mailing Address

(D) 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).

(i) 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) ~~including zip code and county~~, and capacity or patients served in California (e.g., number of licensed beds, number of patients per ~~patient zip code~~ county in the last year~~, quantity/type of services provided annually~~).

(ii) For health care service plans, health insurers, ~~and~~ risk-bearing organizations, or fully integrated delivery systems, include number of enrollees per ~~patient zip code~~ county in the last year.

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

(F) California health care licenses held by the submitter, if any, and identification of any other states where health care-related licenses are held and~~,~~ license type~~, and numbers~~. For purposes of this subsection, provide the health care license type and numbers only for those facilities, services, and professions involved in the transaction.

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

~~(2) County(ies) in California currently served by submitter~~

~~(3) Other states currently served by submitter~~

~~(4)~~ (2) Primary languages used by submitter ~~and all other health care entities in the transaction~~ when providing services to the public ~~and~~ as well as the threshold languages used when providing services to Medi-Cal beneficiaries, as determined by the Department of Health Care Services;

~~(5)~~ (3) Description of all other entities involved in transaction and if any other health care entities will be submitting a notice. For each entity involved in the transaction, describe, to the extent the submitter has access to the information, the following:

(A) The entity's business (including business lines or segments);

(B) Ownership type (corporation, partnership, limited liability corporation, 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;

(C) Governance and operational structure (including ownership of or by a health care entity);

(D) Annual revenues for prior three years;

(E) Current county or counties ~~geographic areas (including zip code and county)~~ of operation;

(F) If a health care provider is involved in the transaction, include a summary description of ~~each~~ provider type(s), physical address of facilities owned, operated, or leased where patient services are provided, service lines, number of staff, ~~zip codes and county(ies) served~~, capacity, and patients served in California (e.g., number of licensed beds, number of patients, quantity of services provided ~~annually~~ in the prior year) ~~, and number of patient visits by county and zip code in the year preceding the transaction~~;

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

~~(G)~~ (H) If a payer, ~~describe~~ 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 ~~and zip code~~ in the year preceding the transaction; and

~~(H)~~ (I) For all health care entities, include a description of the business addresses, if known, of any new entity(ies) that will be formed as a result of the transaction.

~~(6)~~ (4) Proposed or anticipated date of transaction closure;

~~(7)~~ (5) Description of transaction, which shall include the following:

(A) The goals of the transaction;

(B) A summary of terms of the transaction;
(C) A statement of why the transaction is necessary or desirable;
(D) General public impact or benefits of the transaction, including quality and equity measures and impacts;
(E) Narrative description of the expected competitive impacts of the transaction; and
(F) Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public.

~~(8)~~ (6) 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.

~~(9)~~ (7) Whether the proposed transaction has been the subject of any court proceeding and, if so, the:
(i) Name of the court;
(ii) Case number; and
(iii) Names of the parties

~~(10)~~ (8) 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:
(A) ~~Physical addresses~~Counties where services are performed;
(B) Levels and type of health care services offered, ~~including~~ 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;
(C) Summary of the n~~N~~umber and type of patients served, including but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category;
(D) Community needs assessments, charity care, and community benefit programs; and
~~(E) Charity care;~~
~~(F) Community benefit programs; and~~
~~(G)~~ (E) Medi-Cal and Medicare.

~~(11)~~ (9) If this transaction is a merger or acquisition, d~~D~~escription of any other prior ~~transactions~~ mergers or acquisitions that satisfy all of the following:
(A) ~~Affected or involved the provision of health care services~~ Involved the same or related health care services;
(B) ~~Involved any of the health care entities in the proposed transaction;~~ Involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and
(C) ~~Occurred~~ Were closed in the last ten years.

~~(12)~~ (10) Description of potential post-transaction changes to:

(A) Ownership, governance, or operational structure.

(B) Employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections.

(C) City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties.

(D) 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).

(E) Competition within 20 miles of any physical facility offering comparable patient services.

(2) 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.

(c) Documents to Be Submitted with Notice.

Except for documents submitted pursuant to subsection (c)(1), if a submitter is submitting a document in response to either subsections (b) or (c), a submitter may reference the page number or section of that submission in response to another subsection. Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable:

(1) 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;

~~(1)~~ (2) 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);

(3) Documentation related to valuation of transaction;

~~(2)~~ (4) Contact information for any individuals signing or responsible for the transaction or side or related agreements;

~~(3)~~ (5) If applicable, any *pro forma* post-transaction balance sheet for any surviving or successor entity;

~~(4)~~ (6) 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;

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

~~(5)~~ (8) 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;

~~(6)~~ (9) 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;

~~(7) 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;~~

~~(8)~~ (10) Any documentation related to the mitigation of any potential adverse impacts of the transaction on the public; and

~~(9)~~ (11) Any analytic support for and/or documents supporting the submitter's responses to the narrative answers provided.

(d) Confidentiality of Documents Submitted with Notice.

All of the 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 designation in accordance with paragraphs (1) through (3) below.

(1) A submitter of a notice pursuant to this section may designate portions of a notice and any documents or information thereafter submitted by the submitter in support of the notice as confidential. The submitter shall file two versions of the notice. One shall be marked as "Confidential" and shall contain the full unredacted version of the notice or supporting materials and shall be maintained as such by the Office and Department. The second

version of the notice shall be marked as "Public" and shall contain a redacted version of the notice or supporting materials (from which the confidential portions have been removed or redacted) and may be made available to the public by the Office.

(2) Marked-confidential versions of stock purchase agreement(s), ~~financial documents,~~compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office.

(3) A submitter claiming confidentiality in respect of portions of a notice, or any documents not specified above thereafter submitted in support of the notice, shall include a ~~redaction log~~ justification that provides a reasonably detailed statement of the grounds enumerated in (i) through (iv) of this paragraph, below, on which confidentiality is claimed, ~~and~~ a statement of the specific time for which confidential treatment of the information is necessary, and a statement that the information has been confidentially maintained by the entity. ~~Bases~~ A request for confidentiality shall state whether any of the following applies ~~include~~:

~~(1)~~ (i) Whether the information is proprietary or of a confidential business nature, including trade secrets (as defined in California Civil Code section 3426.1(d)), ~~and has been confidentially maintained by the entity~~ and whether the release ~~of which~~ would be damaging or prejudicial to the business concern;

(i) Whether another state or federal agency deems the filed document confidential and, if so, for what period of time;

(ii) ~~(2) the information is such that the public interest is served in withholding the information; or (3)~~ Whether the information is confidential based on statute or other law; or

(iii) Whether the information is such that the public interest is served in withholding the information.

~~(3)~~ (4) If a request for confidential treatment is granted or denied, the submitter will be notified in writing. If a request for confidential treatment is granted, the information will be marked "Confidential'' and kept separate from the public file. With the exception of the Attorney General as provided in section 127502.5(c)(4) of the Code, the Office and the Department shall keep confidential all nonpublic information and documents designated as confidential pursuant to this section.

*See attached document with additional comments regarding this section.

(e) Notification of Changes. A submitter shall notify the Office within five business days if the transaction is amended, altered, or cancelled. The Office may require a submitter to re-notice any material changes in accordance with the procedures set forth in section 97435.

(f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by submitting a written request at any time after submission of the notice and until the Office issues its final report, as described in section 97441. The Office will

remain entitled to collect any costs incurred in connection with any reviews up until the first business day after the withdrawal notice is received, pursuant to 127507.4 of the Code.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127507, 127507.2, and 127507.4, Health and Safety Code.

§ 97440. Request for Expedited Review. *See attached document with additional comments regarding this section.

(a) A submitter may request the Office expedite its review of a notice of a material change transaction by providing the Office, concurrently with the submission required by section 97435:

(1) A detailed explanation of the conditions necessitating expedited review;

(2) Any documentation substantiating the necessity of expedited review; and

(3) The date by which the submitter requests the Office complete its review.

(b) A submitter shall demonstrate that either of the conditions in subsections (b)(1) or (2) exist to obtain expedited review:

(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.

(3) As used in subsection (b)(1), "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 waiver and the transaction is necessary to ensure continued health care access in the relevant markets.

(c) A submitter may request information to be held confidential in accordance with section 97439(d).

(d) The Office will grant or deny the request based on whether the submitter has sufficiently demonstrated conditions for expedited review exist and the transaction is immediately required to mitigate such conditions.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127507.2Health and Safety Code.

§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Reviews; Findings.

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

(1) In determining whether to conduct a cost and market impact review based on ~~a market failure or market power or~~ the Office's finding a noticed material change 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, the Office will consider the factors set forth in subsection (a)(2).

(2) The Office ~~may~~ shall base its decision to conduct a cost and market impact review on any one or more of the following factors:

(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.

(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.

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

(D) If the transaction may lessen competition for workers or may negatively impact the labor market.

~~(D)~~ (E) If the transaction directly affects a general acute care or specialty hospital.

~~(E)~~ (F) If the transaction may negatively impact the quality of care.

(G) If the transaction is part of a series of similar transactions by the health care entity or entities or furthers a trend toward consolidation.

(H) If 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.

~~(F)~~ (I) If 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 ~~increase the price~~ of ~~health care services~~, or undermine the financial stability or competitive effectiveness of a health care entity located in this state, ~~or limit access to health care services in California~~.

(b) Timing of Review of Notice.

For purposes of this subsection, a notice shall be deemed complete by the Office on the date when all of the information required by section 97439 of these regulations has been submitted to the Office by all health care entities who are parties to the transaction and required to submit under section 97435(b) (the complete filing by all required parties is deemed receipt of a complete notice). Within 60 days of a complete notice, the Office shall inform each party to a noticed transaction of any determination to initiate a cost and market impact

review pursuant to 127507.2(a)(1) of the Code, subject to the following conditions, if applicable:

(1) The Office and the submitter may agree to a later date by mutual agreement which shall be in writing and specify the date to which the Office and the parties have agreed.

(2) The 60-day period shall be tolled during any time period in which the Office has requested further information from the parties to a material change transaction and it is awaiting the provision of such information.

(3) The Office may choose to toll the 60-day period during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.

(4) Should the scope of the transaction materially change from that outlined in the initial notice, the 60-day period may be restarted by the Office.

(5) Should the Office grant a request to expedite pursuant to section 97440.

(c) Request for Review of Determination to Conduct Cost and Market Impact Review.

(1) Within 10 business days of the date of a determination that a cost and market impact review is required, ~~a submitter~~ the submitters of the notices for the same transaction may collectively request review of the Office's determination. The request shall:

(A) Be in writing;

(B) Be signed by ~~the~~ all requesting submitters;

(C) Be sent to the Director with a copy to the Office;

(D) Be ~~provided to~~ consolidated with all other submitters involved in the transaction;

(E) Set forth specifically and in full detail the grounds upon which submitter(s) considers the determination to be in error; and

(F) State the reason(s) why the submitter(s) asserts a cost and market impact review is not warranted.

(2) The request will be denied if it contains no more than a request for a waiver of a cost and market impact review, unsupported by specific facts.

(3) Within 5 business days of receipt of a request for redetermination, the Director may:

(A) Decline review and uphold the determination that a cost and market impact review is required; or

(B) Grant the request and waive a cost and market impact review.

(4) The Director may extend this period for one additional 5-day period if the Director needs additional time to complete the review.

(5) The determination of the Director, either upholding the original determination or substituting an amended determination, is final.

(d) Timeline for Completion of Cost and Market Impact Review

The Office shall complete a cost and market impact review within 90 days of the final decision by the Office to conduct a cost and market impact review, subject to subsections (d)(1) through (3):

(1) The Office may extend the 90-day period by one additional 45-day period if it needs additional time to complete the review.

(2) Should the Office determine it requires additional documentation or information to complete its review, it may toll either of the time periods set forth in subsection (d)(1) for any time period in which it is awaiting the provision of such documentation or information from the parties to the transaction or is awaiting the provision of information subpoenaed pursuant to section 127507.2(a)(4) of the Code.

(3) The Office may choose to toll either of the time periods set forth in subsection (d)(1) during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.

(e) Factors Considered in a Cost and Market Impact Review

A cost and market impact review shall examine factors relating to a health care entity's business and its relative market position, including, but not limited to:

(1) The effect on the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care.

(2) The effect on the quality of health care services to any of the communities~~y~~ affected by the transaction.

(3) 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.

(4) The effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board.

(5) The effect on competition for workers and the impact on the labor market.

(6) 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.

~~(5)~~ (7) 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).

~~(6)~~ (8) 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.

~~(7)~~ (9) Any other factors the Office determines to be in the public interest.

(f) Preliminary Report of Findings.

(1) Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings pursuant to

subdivision (a)(5) of section 127507.2 of the Code.

(2) Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report.

(g) Final Report of Findings.

The Office shall issue a final report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code within 30 days of the close of the comment period in paragraph (f)(2) of this regulation, unless the Office extends this time for good cause shown. Good cause means a finding based upon a preponderance of the evidence there is a factual basis and substantial reason for the extension. Good cause may be found, for instance, when the Office requires additional time to review and evaluate written comments regarding the preliminary report.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127500.5, 127502.5, 127507, and 127507.2, Health and Safety Code.

§ 97442. Market Power or Market Failure Determinations.

This Article does not preclude the Office from conducting a cost and market impact review of any health care entity based on the Director's request pursuant to sections 127502.5 and 127507.2 of the Code.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127500.5, 127501, 127502.5, 127507, and 127507.2, Health and Safety Code.

October 17, 2023

Sent via email:
CMIR@HCAI.CA.GOV

Mark Ghaly, M.D.
Chair, Office of Health Care Affordability
1215 O Street
Sacramento, CA 95814

Re: Comments on OHCA's Revised Draft CMIR Regulations

Dear Secretary Ghaly and OHCA Board Members:

The California Association of Health Plans (CAHP) and the Association of California Life and Health Insurance Companies (ACLHIC) appreciate the opportunity to provide comments in response to OHCA's revised draft **Cost and Market Impact Review (CMIR) regulations**. CAHP represents 44 public and private health care service plans (plans) that collectively provide coverage to over 28 million Californians. ACLHIC is a state trade association representing many of the largest life and health insurers doing business in California.

CAHP and ACLHIC have previously provided significant comments to OHCA in response to the first comment period for these regulations. We appreciate many of the revisions OHCA has made to the proposed CMIR rulemaking; however, we continue to be concerned that the requirements of the proposed rule greatly exceed the scope of the enacting statute in several critical areas. This letter highlights key concerns on behalf of our member health plans and insurers, and we urge OHCA to adopt our recommendations. Unless the following issues are adequately addressed, the CMIR regulations, as proposed, could lead to serious unintended consequences, including market dysfunctions that will increase the cost of care, make it more complicated, and act as a barrier to innovation.

In addition to the issues stated below, attached is a spreadsheet of detailed comments and recommendations on various components of the proposed rulemaking.

Issue No. 1: The Proposed CMIR Regulations Provide an Overly Broad Scope of Entities to be Captured Under the Law

We applaud OHCA's revisions to remove management services organizations (MSOs) from the definition of "health care entity," to improve the definition of "transactions," and to clarify that transactions conducted in the regular course of business and corporate restructuring are not included in the definition of "material change transaction." While we recognize and support the Office's efforts to help clarify the language, several important issues remain to be addressed.

There is significant concern among our members that the proposed regulations exceed the authority provided under existing law as it relates to transactions outside of the state by a health care entity. Despite our priorly stated concerns, the proposed rule continues to expand the definition of "health care entitity" to broadly include affiliates or other entities that control or have financial responsibility for a health care entity. This provides an unlimited and overly broad scope of entities to be captured under the law. The proposed regulation goes far beyond the existing authority of the state to monitor and place requirements on market transactions outside of the state.

We encourage OHCA to adopt the following recommendations to remedy this issue:

Recommendations:

- Strike §97441 (a)(I): "If 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."
- Revise §97431(g) "Health care entity": "Health care entity means any entity that delivers or furnishes health care services in California."
- Revise §97431(h) "Health care services" definition: (1) Include "in the state of California" in the definition. (2) Remove (h)(6). OHCA's logic to remove MSOs in the updated version was correct. OHCA should follow through on that and eliminate (h)(6) because these are services that are supporting functions for a given health plan, including that they can be outsourced.
- Revise §97435 (c) "Circumstances requiring filing" to clearly indicate that all circumstances relate to healthcare services, revenue, and assets in California. This includes (c)(1) to note that "transaction concerns the provision of health care services in California." This also includes (c)(7) to state "related to the provision of health care services in California." (c)(9) and (c)(10) should also clarify that this is "health care services in California."
- Revise §97435 (c)(8): The purpose of this provision is to capture private equity transactions. However, if we look at public companies as an example, the language as currently written will pull in all of the company's transactions since the form of ownership will be public. This needs to be revised.

The impacts of the CMIR regulations are excessive. The language should not extend past the confines of California law and should focus only on circumstances and transactions impacting health care services or assets delivered or located within California.

Issue No. 2: Health Plans and Insurers Still Have Concerns Regarding the Requirement to Submit Valuation Documentation and the Lack of Confidentiality Protections

Our members are very concerned about the confidentiality provisions in the proposed CMIR rulemaking. As written, the rule would fail to offer adequate protections for highly sensitive, confidential documentation that, in any other circumstances, would never be shared with the public.

We understand the need for transparency, but without limiting language to protect highly sensitive documents from entering the public sphere, the CMIR regulations pose a direct threat to entities' rights to keep proprietary information confidential and out of the wrong hands.

We encourage OHCA to adopt the following recommendations to alleviate these concerns:

Recommendations:

- Strike § 97439 (c)(3) "Documentation related to valuation of transaction": This is highly confidential. It is never shared with the other party to the transaction and never made public. Health plans and insurers would not share their valuation with the other party. External parties or competitors might use this information adversely. This is completely outside the scope of what can reasonably be expected and has only ever been seen in one specific circumstance: that being if the transaction is under FTC review and falls within certain parameters, it may be provided to the FTC under HSR, but only under strict confidentiality. It is a priority to remove this.
- Revise the regulation so that non-public financial information remains confidential consistent with DMHC practice. For example, financial information disclosed in a public filing would not be confidential, but all other information would remain confidential. This would also be consistent with the Massachusetts approach as described below.
- Updated §97439 (d)(2) struck out "financial documents." This needs to be brought back in.
- Generally speaking, all documentation submitted must be made confidential. We recommend replicating the Massachusetts regulation 7.09: Confidentiality.
    - *The Commission shall keep confidential all nonpublic information and documents obtained in connection with a Notice of Material Change or a Cost and Market Impact Review and shall not disclose the information or documents to any person without the consent of the Provider or Payer that produced the information or documents, except in a Preliminary Report or Final Report if the Commission believes that such disclosure should be made in the public interest after taking into account any privacy, trade secret or anti-competitive considerations. The confidential information and documents shall not be public records and shall be exempt from disclosure under M.G.L. c. 4, § 7 cl. 26 or M.G.L. c. 66, § 10. Nonpublic information and documents shall not include information included on the Notice of Material Change form itself, prescribed by and filed with the Commission.*

Issue No. 3: Without Further Changes to the Timeline for Review, the Uncertainty and Delay of a CMIR Can Be Crippling for Transactions

The timing provisions under § 97441 are very concerning as the potential extensions and uncertainty are additional barriers to innovative health care delivery in California. The timelines proposed are significantly longer than those set forth in the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), and similar health care market impact regulations in Massachusetts and Oregon. If subjected to a CMIR, the process could last well over six months, which seems unreasonable, especially when coupled with OHCA's discretion to prolong the process further. The proposed

regulations would permit tolling review periods and delaying the transaction indefinitely. This could deter transactions and have the countereffect of limiting competition.

We strongly urge OHCA to adopt the revisions provided in our initial round of comments, as reflected in the attachment.

Issue No. 4: Thresholds for Qualifying Transactions Still Remain Far Too Low

As expressed by CAHP, ACLHIC, and several other stakeholders in the initial public comment period for the proposed CMIR rulemaking, the dollar thresholds for material change transactions under § 97435 (b) remain too low and will result in the Office receiving a burdensome volume of filings. **OHCA should raise these thresholds in accordance with prior stakeholder feedback** and preferably convert them to a percent of total revenue to allow for equitable impact of the filing requirements in relation to an organization's size and finances. Thresholds that are too low would pull in a vast number of smaller transactions that should never go to a CMIR, and would fail to account for the sheer size of California and the inflation that has occurred since Massachusetts set the stage for these thresholds.

In addition to the issues mentioned above, please see the attached worksheet for a comprehensive summary of plan feedback in response to each section of the proposed rulemaking.

Ultimately, California's market is a bellwether of competition and choice, providing millions access affordable health care. OHCA is tasked with monitoring the impact of consolidation and promoting competitive markets in a manner that supports the efforts of the Attorney General, the DMHC, and CDI. We must not lose sight of this scope, and OHCA should revise the CMIR regulations to avoid introducing further complexities and inefficiences to a massive system like that of California. We appreciate OHCA's consideration of health plans' comments about these important regulations and we believe that adopting our recommendations will lead to success in our collective efforts to create a sustainable health care system.

Sincerely,

Anete Millers
Director of Regulatory Affairs
California Association of Health Plans

Steffanie Watkins
Vice President of Health Policy
Association of California Life and Health Insurance Companies

Enclosure: OHCA Revised Draft CMIR Regulations Worksheet – 10-17-23 (CAHP-ACLHIC Comments).pdf

OHCA Revised Draft CMIR Regulations – CAHP & ACLHIC Comments (10-17-23)			
Section	**Page #**	**Regulation Text**	**Comment**
22 CCR § 97431. Definitions.	1-2	**§ 97431(a) and (g): Definition of "Affiliate," Definition of "Health Care Entity"** (a) "Affiliation" or "affiliate" refers to a situation in which an entity controls, is controlled by, or is under common control with another legal entity in order to collaborate for the provision of health care services. For purposes of this Article, a clinical affiliation does not include a collaboration of clinical trials, graduate medical education programs, health professions training programs, health sciences training programs, or other education and research programs. (g) "Health care entity" shall: (1) Have the meaning set forth in section 127500.2(k) of the Code; (2) Include pharmacy benefit managers as set forth in sections 127501(c)(12) 25 and 127507(a) of the Code; ~~(3) Include a management services organization, which qualifies as a "payer" for the purposes of these regulations;~~ (3) Include any parents, affiliates, subsidiaries, or other entities that perform the functions of a health care entity and either: (i) control, govern, or are financially responsible for the health care entity or (ii) 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; and (4) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in 127500.2(p)(6) of the Code. For purposes of these regulations, any health care entity entering into	**§ 97431(a) and (g): Definition of "Affiliate," Definition of "Health Care Entity"** • The Proposed Rule expands the definition of "health care entity" to broadly include affiliates or other entities that control or have financial responsibility for a health care entity. This provides an unlimited and overly broad scope of entities to be captured under the law. ○ To limit the broad scope of this definition, please consider clarifying or adding additional parameters around what is meant by "collaborate for the provision of health care services" within the definition of the related term "Affiliate" at §97431(g). • The Proposed Rule defines "health care entity" to include management services organizations ("MSOs") "which qualify as a 'payer.'" One interpretation of this definition is that it deems an MSO to be a payer for purposes of these regulations. Designation of MSOs as subject to payer rules for the purpose of the regulations, however, does not appear to substantively change the treatment of MSOs. Please confirm the purpose for which OHCA proposes to treat MSOs as "payers." • **UPDATED COMMENT:** We appreciate the removal of MSOs from the definition of "health care entity," but further revisions are needed to clarify the language to focus only on circumstances and transactions impacting health care services or assets delivered or within California. We recommend:

		a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435. (h) See definition of "Health care services"	○ Revise §97431(g) "Health care entity": "Health care entity means any entity that delivers or furnishes health care services in California." ○ Revise §97431(h) "Health care services" definition: (1) Include "in the state of California" in the definition. (2) Remove (h)(6). OHCA's logic to remove MSOs in the updated version was correct. OHCA should follow through on that and eliminate (h)(6) because these are services that are supporting functions for a given health plan, including that they can be outsourced.
22 CCR § 97431. Definitions.	2	**§ 97431(j): Definition of "Management Services Organization"** ~~(j) "Management services organization" means an entity that provides administrative or management services for a health care entity, not including the direct provision of health care services. Administrative or management services include, but are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.~~	**§ 97431(j): Definition of "Management Services Organization"** • The phrase "other services and support" used in this definition is overly broad. Management services organizations (MSOs) and third-party administrators (TPAs) are included in the Proposed Rule's definition of "health care entity;" thus the definition appears to be circular. This concept does not make sense and seems to have no practical effect. TPAs are not payers—rather, they are administrative services providers that deliver support for self-insured health plans. Similarly, MSOs are not payers—there are two types and neither is a payer. Furthermore, MSOs and TPAs may not necessarily be involved in the sale of products. • Please consider removing MSOs and TPAs from the definition or, at a minimum, clarifying the meaning of "other services and support" to prevent unintentionally broadening the scope of entities captured by the law. • **UPDATED COMMENT:** We appreciate the removal of MSOs from the definition of "health care entity."

22 CCR § 97431. Definitions.	3	**§ 97431(p): Definition of "Transaction"**
		
		(p) "Transaction" includes mergers, acquisitions, affiliations, or other agreements involving a health care entity, or the provision of health care services in California that involve a transfer of assets (sell , lease, exchange, option, encumber, convey, or dispose) or control, responsibility, or governance of the assets or operations of the health care entity in whole or in part to one or more entities.
			§ 97431(p): Definition of "Transaction"
			
			• This definition is overly broad and needs both more specificity, and a more limited scope of the types of transactions it applies to. As currently written:
			  ○ The definition will include a large number of contracts health plans and health care providers enter into for the purpose of ensuring they can meet access standards or otherwise provide care.
			  ○ The dollar amount thresholds are low, especially given that healthcare services, in general, are expensive.
			  ○ Some of the triggers for filing requirements turn on information about contracting counterparties that may not be known or collected by the filing entity (e.g., those parties' corporate/governance structures, financial information, etc.)
			• We would recommend:
			  ○ Explicitly excluding Professional Services Agreements, basic real estate leases, and other ordinary course/routine agreements that are negotiated regularly.
			  ○ Clarifying that there should be a limit to "lease, exchange, option, encumber…" or explicit carve-outs.
			  ○ Raising the dollar thresholds significantly to ensure that routine transactions are not captured in the process. OHCA should focus its efforts in requiring market transaction notices for transactions of a certain material size. We would recommend the 2023 FTC thresholds. In

			2023, the FTC will increase the size-of-transaction threshold from $101 million to $111.4 million. The revised $111.4 million size-of-transaction threshold applies to transactions in which the acquiring party will hold voting securities, non-corporate interests, or assets valued at or above $111.4 million (as measured using the HSR Act's rules and regulations). The HSR "size of parties" threshold generally requires that one party to the transaction have annual net sales or total assets of $222.7 million or more (up from $202 million in 2022), and that the other party have annual net sales or total assets of $22.3 million (up from $20.2 million). ○ Overall limiting the definition so it is targeted only at corporate combinations or sales, not a pre-review and oversight of routine operations. Stakeholders are appropriately concerned about smaller transactions falling under the threshold where several smaller transactions can lead up to a market failure or consolidation. In these cases, the market transaction notices do not need to be the mechanism for capturing these market failures. Rather, these market failures can be identified through the THCE process by stakeholders as well as by identifying health care entities that consistently fail to meet the cost benchmark.

22 CCR § 97435. Material Change Transactions	4	**§ 97435(b): Health Care Entities Subject to Filing Requirements/Notice Exemptions** (b) Who must file. A health care entity shall file a written notice of a transaction with the Office if the transaction involves any parties listed in subsections (b)(1) through (b)(3) under any one or more of the circumstances set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the Code: (1) A health care entity with annual revenue, as defined in subsection (d), of at least $25 million or that owns or controls California assets of at least $25 million; or (2) 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 involved in a transaction with any health care entity satisfying subsection (b)(1); or (3) A health care entity located in or serving at least 50% of patients who reside in a health professional shortage area, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section 5.1), available at https://data.hrsa.gov.	**§ 97435(b): Health Care Entities Subject to Filing Requirements/Notice Exemptions** • The materiality thresholds are far too low based on realistic and ongoing market conditions, both locally and nationally. • As currently set, basic contracting for specialty care to achieve network adequacy could trigger a review. • The volume of filings that would be triggered by the current thresholds would be overwhelming for OHCA to review. • OHCA should consider raising the dollar amount for the health care entity and having a percent of revenue materiality threshold for transactions. • We also note that 22 CCR § 97435(b)(2) of the Proposed Rule appears redundant - if a transaction is between two health care entities – one with an annual revenue exceeding $25 million and one with an annual revenue exceeding $10 million – this transaction would already be subject to review under 22 CCR § 97435(b)(1). We would recommend deleting (b)(2). • The Proposed Rule is notably silent with respect to exemptions from the notice, aside from referencing the statute.
22 CCR § 97435. Material Change Transactions	4-5	**§ 97435(c): Materiality Thresholds** (c) Circumstances requiring filing. A transaction is a material change pursuant to section 127507(c)(1) of the Code if any of the following circumstances exist: (1) The proposed fair market value of the transaction is $25 million or more and the transaction concerns the provision of health care services.	**§ 97435(c): Materiality Thresholds** • The Proposed Rule defines materiality thresholds for transactions; the materiality thresholds, however, are extremely low and would capture most transactions (since only one standard needs to be triggered), even if they are de minimis. In addition, metrics for evaluating cost and market impacts omit any consideration of the transactions' impacts on parties' ability to meet access or

		(2) The transaction is likely to increase annual revenue of any health care entity that is a party to the transaction by at least $10 million or 20% of annual revenue at normal or stabilized levels of utilization or operation. (3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 20% or more of the assets of any health care entity in the transaction. (4) The transaction involves a transfer or change in control, responsibility, or governance of the submitter, as defined in subsection (e). (5) 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. (6) The transaction involves the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health services in California that is projected to have at least $25 million in annual revenue at normal or stabilized levels of utilization or operation, or have control of assets related to the provision of health care services valued at $25 million or more. (7) The transaction involves a health care entity joining, merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services where any health care entity has at least $10 million in annual revenue as defined in subsection (d). ~~For purposes of this subsection, a clinical affiliation does~~	other regulatory requirements, or any likely positive impacts the transaction may have. OHCA should better delineate and describe the standards it will use for its evaluations. As written, this list is so broad that it would necessitate a filing in almost every transaction. • **UPDATED COMMENT:** Each of the paragraphs in this subdivision should be clarified to indicate that only California-derived revenue, or California-based assets/operations should be considered in determining whether a filing is required under the proposed regulations. "Circumstances requiring filing" should be revised to clearly indicate that all circumstances relate to healthcare services, revenue, and assets in California. This includes (c)(1) to note that "transaction concerns the provision of health care services in California." This also includes (c)(7) to state "related to the provision of health care services in California." (c)(9) and (c)(10) should also clarify that this is "health care services in California." • (c)(1) and (c)(2) should be revised/eliminated and the focus should mirror the 2023 FTC thresholds. • For (c)(3), the recommendation would be to eliminate this section. For the qualifying FTC thresholds, OHCA can include a substantial change of all assets as a change in control event. This can then capture those transactions where the acquirer does not want the entity itself but essentially is acquiring the entity's assets. If (c)(3) is kept in the rulemaking, the 20% disposition or transfer of assets is extremely low; the standard should be much higher, i.e., 75%. • (c)(4) should be revised to focus on transactions which result in a true change in control of a health care entity.

		~~not include a collaboration on clinical trials or graduate medical education programs~~. (8) The transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to change from a physician owned to private equity-owned and publicly held to a privately held form of ownership. (9) 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). (10) 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 tn 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).	As such, filing should be required only where a party is acquiring more than 50% of the voting securities or voting power of a health care entity (whether by stock purchase, merger, affiliation, or otherwise). A filing should not be required in circumstances where a non-controlling equity stake is acquired or where the consideration paid in connection with the transaction is immaterial. • **UPDATED COMMENT:** For (c)(5), this section is not necessary per the above recommendation to key off of the FTC thresholds. Additionally, it is unclear how OHCA would define "normal or stabilized" revenue, accounting for the subjectivity of what would be considered normal or stabilized. • In addition, regarding management services organizations (MSOs) we agree with the CA Medical Association (CMA) and others that the OHCA rule extends beyond the statute to include all MSOs as payers. Almost any MSA could get picked up if it involves any sort of affiliation (even if existing and the MSA is a re-negotiation) or if it involves any "other organization." • For (c)(6), $25 million in annual revenue for some organizations could be immaterial. For (c)(6) and (c)(7), we would recommend aligning values to FTC thresholds. • **UPDATED COMMENT:** For (c)(8), we recommend eliminating. This is too broad and will pull in a large number of transactions that should never go to a CMIR. Regarding many smaller transactions adding up to a market failure, this can be captured in a CMIR as a market failure and in reviewing health entities' THCE. The purpose of this provision is to capture private equity transactions. However, if we look at public companies as an example, the language as currently written will pull in

			all of the company's transactions since the form of ownership will be public. If not eliminated, this section should still be substantially revised. • For (c)(9), it is unclear what the intended type of transaction here is. It should not matter if a transaction has the same parties who may have previously undertaken a different transaction over the course of a decade, so long as the transaction does not otherwise trigger notice under the Proposed Rule. We recommend eliminating this section.
22 CCR § 97435. Material Change Transactions	6	**§ 97435(d): Revenue Definition** (d) Revenue. For purposes of this section, revenue means the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years, as follows: (1) For health care service plans, revenue as reported to the Department of Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b). (2) For health insurers, revenue as reported to the Department of Insurance pursuant to Insurance Code section 931. (3) For hospitals, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Hospitals," incorporated by reference in 22 CCR 97018. (4) For long-term care facilities, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Long-Term Care Facilities," incorporated by reference in 22 CCR 97019.	**§ 97435(d): Revenue Definition** • The term "revenue" is defined quite broadly to aggregate revenue of all "affiliates." If there are multiple California entities at issue in a national platform, the thresholds could be easily triggered. Moreover, the limitations on the definition of "affiliate" are unclear – would a holding company owning multiple independent businesses have to aggregate the revenue?

		(5) For risk-bearing organizations required to register and report to the DMHC, revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2. (6) For other providers or provider organizations, net patient revenue, which includes the total revenue received for patient care, including: (A) Prior year third-party settlements; (B) Revenue received (inclusive of withholds, refunds, insurance services, capitation, and co-payments) from a health care entity or other payer to provide health care services, for all providers represented by the provider or provider organization in contracting with payers, for all providers represented by the provider or provider organization in contracting with payers; (C)Fee for service revenue; or (D)Revenue from shared risk and all incentive programs. (7) For management services organizations, all payments and revenue received from health care entities to provide administrative or management services. Administrative or management services include, but are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.	

22 CCR § 97435. Material Change Transactions	7	**§ 97435(e): Control Definition** (e) Control, responsibility, or governance. For purposes of this section, a transaction will transfer or change control, responsibility, or governance if: (1) There is a substitution or addition of a new corporate member or members that transfers more than 10% of the control of, responsibility for, or governance of a health care entity; or (2) There is a substitution of one or more members of the governing body of a health care entity, or any arrangement, written or oral, that would transfer full or partial voting control of the members of the governing body of a health care entity; or (3) The transaction would result in the transfer of more than 10% of the administrative or operational control or governance of at least one entity that is a party to the transaction.	**§ 97435(e): Control Definition** ○ The Proposed Rule defines "change control, responsibility, or governance" to include a transaction that would result in the transfer of more than 10% of the administrative or operational control or governance of at least one entity that is party to the transaction, which is an extremely low threshold. For example, what if one board member was added as a representative of a member on a 10-person board, but would not change the majority governance rights? ○ For comparison, the California Corporations Code defines "control" as follows: ▪ **Cal. Corp. Code §160** (a)"Control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a corporation. (b) "Control" in Sections 181, 1001, and 1200 means the ownership directly or indirectly of shares or equity securities possessing more than 50 percent of the voting power of a domestic corporation, a foreign corporation, or another business entity. ▪ **Cal. Corp. Code §5045 (Nonprofit)** "Control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a corporation.

22 CCR § 97435. Material Change Transactions	7	**§ 97435(f): Corporate Restructuring Exception** ~~(f) A transaction is not a material change transaction if the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under common control with, all other parties to the transaction, such as a corporate restructuring.~~	**§ 97435(f): Corporate Restructuring Exception** • The Proposed Rule includes an exception for corporate restructuring, we note that a corporate restructuring involving the formation of a new entity, such as a holding company, within the same organizational structure, would fall under the exception.
22 CCR § 97437. Pre-Filing Questions.	7	**§ 97437: Pre-Filing Questions** Health care entities that are unsure if they must file a notice under this Article may 3 contact the Office at CMIR@hcai.ca.gov.	**§ 97437: Pre-Filing Questions** • Section 97437 allows for pre-filing questions to be asked of the agency. For full transparency and consistency, the agency should update this part of the regulation and commit to periodically publishing the questions and agency responses to these questions so that all potential submitters benefit from the same (and consistent) guidance. This will also help OHCA staff reduce some influx of ongoing questions.
22 CCR § 97439. Filing of Notices of Material Change Transactions.	8-12	**§ 97439(b)-(c): Form and Contents of Public Notice and Supporting Documents** (b) Form and Contents of Public Notice. A health care entity submitting a notice ("submitter") shall indicate which threshold(s) and circumstance(s) are met, pursuant to section 97435(b) and (c), respectively, and provide the following information to the Office for public posting on the Office's website: (1) General information about the transaction and entities in the transaction, including the following information regarding the submitter: (A) Business Name (B) Business Website	**§ 97439(b)-(c): Form and Contents of Public Notice and Supporting Documents** • The Proposed Rule's contents of public notice are extremely onerous; the vast volume of paperwork would be overly burdensome for parties to the transaction and OHCA, as it will be inundated with paper. • It is also worth considering the intersection with the HSR (Hart-Scott-Rodino Act) filing process – many documents requested by OHCA may be duplicative of an HSR filing. OHCA's requests should be more narrowly tailored. Specific recommendations for section 97439(b) on the "Form and Content of Public Notice" include the following:

		(C) Business Mailing Address (D) 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). (i) 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. (ii) For health care service plans, health insurers, risk-bearing organizations, or fully integrated delivery systems, include number of enrollees county in the last year. (E) Federal Tax ID # and tax status as for-profit or non-profit (F) California health care licenses 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. (G) Contact person, title, e-mail address, and mailing address for public inquiries.	• For (b)(5)(G), while "payer" is defined to include entities other than insurers and plans (e.g., MSO, TPA, Medicare, Medi-Cal), this section is written for insurers and plans. MSO and TPAs may not necessarily be involved in sale of products. • For (b)(7), we recommend removing entirely. There are significant reasons why other reviewing entities do not require broad narrative responses. Broad narrative responses can lead to confusion, and OHCA should consider adopting an approach similar to what the FTC and DOJ do federally. If, following receipt of an HSR filing, the FTC or DOJ wants narrative responses, they typically accomplish this through investigational interviews. This is preferred because the responder can add additional color and qualify/clarify their response in real-time to address agency questions and concerns. From a workflow standpoint, if OHCA has significant questions following receipt of an application, the agency could seek additional information from the submitter through this type of follow-up. Such an approach would help streamline OHCA's review process while also preserving the confidentiality of the submitter. • It is also unclear why a "summary of terms" is needed when the agency will already have this information via other documentation. • For (b)(11), we recommend removing entirely for the reasons given above. In addition, this is extremely broad and all encompassing. We recognize that OHCA is trying to obtain a market failures category from many smaller transactions, but this is not the recommended approach to get at those dynamics. Again, regarding many smaller transactions adding up to a market failure, this can be

		(2) 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 (3) Description of all other entities involved in transaction and if any other health care entities will be submitting a notice. For each entity involved in the transaction, describe, to the extent the submitter has access to the information, the following: (A) The entity's business (including business lines or segments); (B) Ownership type (corporation, partnership, limited liability corporation, 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); (D) Annual revenues for prior three years; (E) Current county or counties; (F) If a health care provider is involved in 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	captured in a CMIR as a market failure and in reviewing health entities' THCE as described above. • (b)(12)(B) should be eliminated. • (b)(12)(E) should be eliminated. This can be a catch-22 in anti-trust litigation where an entity may or may not be listed here as a competitor, but this could then be used in other anti-trust forums. • (b) (13) should be eliminated for a significant number of reasons. This is a very broad definition. Many discussions happen and never materialize. It can have unintended consequences where a patient might see that a practice is for sale and leave. Specific recommendations for section 97439(c) on the "Documents to be Submitted with Notice" include the following: • For (c)(1), we recommend taking out term sheets. These are non-binding and not the definitive agreements which the agency would have. This can be misleading and will only lead to confusion by the agency. • For (c)(2), we recommend taking out these contacts. Can OHCA provide clarity as to why it needs this information? • (c)(3) should address confidentiality. Balance sheets must be confidential, which we believe is the intention. • In (c)(5), the terms "certified" and "footnotes" are problematic. Smaller entities have unaudited financial statements and would not have auditor certification or GAAP footnotes. Can OHCA provide more detail as to why it needs the prior three years? • For (c)(7), OHCA is asking for a copy of the documentation filed with the Federal Trade Commission pursuant to the Hart-Scott-Rodino Antitrust Improvement Act (HSR). Specifically, a copy of the

		patients, quantity of services provided in the prior year); (G) Primary and threshold languages, as determined by the Department of Health Care Services, used; (H) If a payer, 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 (I) For all health care entities, include a description of the business addresses, if known, of any new entity(ies) that will be formed as a result of the transaction. (4) Proposed or anticipated date of transaction closure (5) Description of transaction, which shall include the following: (A) The goals of the transaction; (B) A summary of terms of the transaction; (C) A statement of why the transaction is necessary or desirable; (D) General public impact or benefits of the transaction, including quality and equity measures and impacts; (E) Narrative description of the expected competitive impacts of the transaction; and	premerger notification and report form and any attachments. This must be automatically deemed confidential by OHCA. It is already confidential in filing with the FTC. • For (c)(8) and (c)(9), we would recommend removing both. As stated above on other requirements, the proposed regulation seeks numerous narrative responses along with any documentation supporting such narrative responses. These narrative responses are not required by other antitrust review agencies (e.g., the FTC and DOJ's pre-merger review process) and are unlikely to provide OHCA with useful information. Broad narrative responses can lead to confusion, and OHCA should consider adopting an approach similar to what the FTC and DOJ do federally. If, following receipt of an HSR filing, the FTC or DOJ wants narrative responses, they typically accomplish this through investigational interviews. This is preferred because the responder can add additional color and qualify/clarify their response in real-time to address agency questions and concerns. From a workflow standpoint, if OHCA has significant questions following receipt of an application, the agency could seek additional information from the submitter through this type of follow-up. Such an approach would help streamline OHCA's review process while also preserving the confidentiality of the submitter. • **UPDATED COMMENT:** We understand the need for transparency, but without limiting language to protect highly sensitive documents from entering the public sphere, the CMIR regulations pose a direct threat to entities' rights to keep proprietary information confidential and out of the wrong hands. We continue to recommend that OHCA adopt the following:

		(F) Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public. (6) 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. (7) Whether the proposed transaction has been the subject of any court proceeding and, if so, the: (i) Name of the court; (ii) Case number; and (iii) Names of the parties (8) 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: (A) Counties where services are performed; (B) 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; (C) 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;	○ Strike § 97439 (c)(3) "Documentation related to valuation of transaction": This is highly confidential. It is never shared with the other party to the transaction and never made public. Health plans and insurers would not share their valuation with the other party. External parties or competitors might use this information adverse. This is completely outside the scope of what can reasonably be expected and has only ever been seen in one specific circumstance: that being if the transaction is under FTC review and falls within certain parameters, it may be provided to the FTC under HSR, but only under strict confidentiality. It is a priority to remove this. ○ Revise the regulation so that non-public financial information remains confidential consistent with DMHC practice. For example, financial information disclosed in a public filing would not be confidential, but all other information would remain confidential. This would also be consistent with the Massachusetts approach as described below. ○ Generally speaking, all documentation submitted must be made confidential. We recommend replicating the Massachusetts regulation 7.09: Confidentiality.

		(D) Community needs assessments, charity care, and community benefit programs; (E) Medi-Cal and Medicare. (9) If this transaction is a merger or acquisition, ddescription of any other prior mergers or acquisitions that satisfy all of the following: (A) Involved; (B) Involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and (C) Were closed in the last ten years. (10) Description of potential post-transaction changes to: (A) Ownership, governance, or operational structure. (B) Employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections. (C) City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties. (D) 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). (E) Competition within 20 miles of any physical facility offering comparable patient services.	

(13) 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.

(c) Documents to Be Submitted with Notice. Except for documents submitted pursuant to subsection (c)(1), if a submitter is submitting a document in response to either subsections (b) or (c), a submitter may reference the page number or section of that submission in response to another subsection. Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable:

(1) 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;

(2) 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);

(3) Documentation related to valuation of transaction;

(4) Contact information for any individuals signing or responsible for the transaction or side or related agreements;

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

(6) 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; (7) Existing documentation identifying the number of patients per zip code or enrollees per zip code in the last year. (8) 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; (9) 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; ~~(7) 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;~~ (10) Any documentation related to the mitigation of any potential adverse impacts of the transaction on the public; and (11) Any analytic support for and/or documents supporting the submitter's responses to the narrative answers provided.	
22 CCR § 97439. Filing of Notices of Material Change Transactions.	12-13	**§ 97439(d): Confidentiality of Documents Submitted with Notice** (d) Confidentiality of Documents Submitted with Notice. All of the 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 designation in accordance with paragraphs (1) through (3) below. (1) A submitter of a notice pursuant to this section may designate portions of a notice and any documents or information thereafter submitted by the submitter in support of the notice as confidential. The submitter shall file two versions of the notice. One shall be marked as "Confidential" and shall contain the full unredacted version of the notice or supporting materials and shall be maintained as such by the Office and Department.	**§ 97439(d): Confidentiality of Documents Submitted with Notice** • The Proposed Rule does not automatically designate any documents as confidential even though Cal. Health & Safety Code Section 127507.2(c)(1) puts the onus on OHCA to not disclose the confidential information or documents to any person without the consent of the source of the information or documents, except in a preliminary report or final report, and only if OHCA believes that disclosure should be made in the public interest after taking into account any privacy, trade secret, or anticompetitive considerations. We recommend that OHCA revise the proposed regulations to deem certain documents automatically confidential, similar to what the DMHC does as to financial record filings. Additionally, we believe OHCA should treat all documents filed during the process as confidential until the preliminary report or final report is issued, and only

		The second version of the notice shall be marked as "Public" and shall contain a redacted version of the notice or supporting materials (from which the confidential portions have been removed or redacted) and may be made available to the public by the Office. (2) Marked-confidential versions of stock purchase agreements, ~~financial documents~~, compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office. (3) A submitter claiming confidentiality in respect of portions of a notice, or any documents not specified above thereafter submitted in support of the notice, shall include a justification that provides a reasonably detailed statement of the grounds enumerated in (i) through (iv) of this paragraph, below, on which confidentiality is claimed, a statement of the specific time for which confidential treatment of the information is necessary, and a statement that the information has been confidentially maintained by the entity. A request for confidentiality shall state whether any of the following applies: (i) Whether the information is proprietary or of a confidential business nature, including trade secrets (as defined in California Civil Code section 3426.1(d)), and whether the release would be damaging or prejudicial to the business concern; (ii) Whether another state or federal agency deems the filed document confidential and, if so, for what period of time; () Whether the information is confidential based on statute or other law; or	consider treating certain documents as public records after OHCA has weighed the public interest as well. This is similar to the DMHC only making application filing records available to the public after an application is complete, or the DMHC not making the audit records in a Financial Review public but only the final report. • HSR filings, for example, are treated as confidential by the federal government, but do not appear to be afforded the same level of confidentiality by OHCA. OHCA should consider the fact that most entities captured by this review process are private health care entities and requiring these entities to disclose sensitive information without the guaranty of confidentiality would be unreasonably burdensome and inconsistent with federal law. • Additionally, the Proposed Rules provide that "stock purchase agreements" may be marked confidential and then deemed so by OHCA – would asset purchase agreements, merger agreements or other types of purchase agreements be treated similarly? • (d)(2) essentially paraphrases the requirements of Gov. Code sections 7922.630, 7922.640, and 7927.705, but we would suggest it be more clear that this is being done in compliance with the PRA in order to have PRA precedents apply to HCAI. CAHP and ACLHIC recommend that the start of d(2) be revised to make it clear the list of documents is not exhaustive for what is deemed confidential by the agency. In determining what is confidential, OHCA should consider how information could be used adversely by competitors in order to understand public harm/benefit in rejecting a request for confidential treatment.

		(iii) Whether the information is such that the public interest is served in withholding the information. (4) If a request for confidential treatment is granted or denied, the submitter will be notified in writing. If a request for confidential treatment is granted, the information will be marked "Confidential'' and kept separate from the public file. With the exception of the Attorney General as provided in section 127502.5(c)(4) of the Code, the Office and the Department shall keep confidential all nonpublic information and documents designated as confidential pursuant to this section.	• Section (d)(2) should also be revised in a manner to require HCAI to notify the submitting party in the event confidentiality is not granted with sufficient time for a party to appeal under an HCAI-developed appeal process or seek judicial intervention. • **UPDATED COMMENT:** We continue to emphasize the above concerns about confidentiality of documents submitted. We understand the need for transparency, but without limiting language to protect highly sensitive documents from entering the public sphere, the CMIR regulations pose a direct threat to entities' rights to keep proprietary information confidential and out of the wrong hands. We also note that the updated §97439 (d)(2) struck out "financial documents." We urge OHCA to bring this back into the language.
22 CCR § 97439. Filing of Notices of Material Change Transactions.	13	**§ 97439(e): Notification of Changes** (e) Notification of Changes. A submitter shall notify the Office within five business 36 days if the transaction is amended, altered, or cancelled. The Office may require 37 a submitter to re-notice any material changes in accordance with the procedures 38 set forth in section 97435.	**§ 97439(e): Notification of Changes** • The changes may require re-notice. The use of "may" without any standard for requiring creates the perception that the entire process is arbitrary. This could be used for extensions (see 97441 (d)(2)).
22 CCR § 97439. Filing of Notices of Material Change Transactions.	13	**§ 97439(f): Reimbursement for Costs** (f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by submitting a written request at any time after submission of the notice and until the Office issues its final report, as described in section 97441. The Office will remain entitled to collect any costs incurred in connection with any reviews up until the first business day after the withdrawal notice is received, pursuant to 127507.4 of the Code.	**§ 97439(f): Reimbursement for Costs** • The Proposed Rule references the statutory authority to collect any costs incurred in connection with reviews (including, with respect to independent experts or consultants hired by OHCA to review the transaction). While the statute provides that contract costs shall not exceed an amount that is "reasonable and necessary" to conduct the review, there is no limit on such spending.

			• We encourage OHCA to impose an explicit limit on the amount that entities are required to reimburse OHCA, as the "reasonable and necessary" standard is too vague.
22 CCR § 97441. Cost and Market Impact Reviews.	15, 17	**§ 97441(a) and (e): Determination of Whether to Conduct a Cost and Market Impact Review ("CMIR"); Factors Considered in a Cost and Market Impact Review** (a) Office Determination Whether to Conduct a Cost and Market Impact Review. (1) In determining whether to conduct a cost and market impact review based on the Office's finding a noticed material change 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, the Office will consider the factors set forth in subsection (a)(2). (2) The Office shall base its decision to conduct a cost and market impact review on any one or more of the following factors: (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. (B) If the transaction may result in a negative impact on costs for payers, purchasers, or consumers, including the ability to meet any	**§ 97441(a) and (e): Determination of Whether to Conduct a Cost and Market Impact Review ("CMIR"); Factors Considered in a Cost and Market Impact Review** • The Proposed Rule clarifies factors behind determination to conduct a CMIR, and factors considered during a CMIR. The Proposed Rule, however, fails to clarify factors in which a reviewing authority (e.g., DMHC, CDI, or AG) can refer a transaction to OHCA for a CMIR (as allowed under the statute), even if the transaction appears to be exempt under the statute. The uncertainty and delay of a CMIR can be crippling for transactions – OHCA should clarify under what circumstances a transaction may be referred to it by DMHC, CDI or the AG. • The Proposed Rule does not cover referral of transactions to the AG. OHCA should establish limitations and/or standards for referring out transactions to the AG, as the statutory language grants OHCA broad discretion to do so for any "anticompetitive behavior, or effects." • Section (e)(5) lists the following factor for a CMIR: "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)." We recommend removing this provision. As stated above for Section 97439(b)(11) [form and content

		health care cost targets established by the Health Care Affordability Board. (C) If the transaction may lessen competition or tend to create a monopoly in any geographic service areas impacted by the transaction. (D) If the transaction may lessen competition for workers or may negatively impact the labor market. (E) If the transaction directly affects a general acute care or specialty hospital. (F) If the transaction may negatively impact the quality of care. (G) If the transaction is part of a series of similar transactions by the health care entity or entities or furthers a trend toward consolidation. (H) If 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. (I) If 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. (e) Factors Considered in a Cost and Market Impact Review. A cost and market impact review shall examine factors relating to a health care entity's business and its relative market position, including, but not limited to:	for the public transaction notice], this is extremely broad and all encompassing. We recognize that OHCA is trying to build a market failures analysis from many smaller transactions, but this is not the recommended approach to get at those dynamics. Again, regarding many smaller transactions adding up to a market failure, this can be captured in a CMIR as a market failure and in reviewing health entities' THCE as described above.

		(1) The effect on the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care. (2) The effect on the quality of health care services to any of the communities affected by the transaction. (3) 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. (4) The effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board. (5) The effect on competition for workers and the impact on the labor market. (6) 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. (7) 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). (8) 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. (9) Any other factors the Office determines to be in the public interest	

22 CCR § 97441. Cost and Market Impact Reviews.	15-18	**§ 97441(b)-(d), (f)-(g): Timing of Review of Notice** (b) Timing of Review of Notice. For purposes of this subsection, a notice shall be deemed complete by the Office on the date when all of the information required by section 97439 of these regulations has been submitted to the Office by all health care entities who are 38 parties to the transaction and required to submit under section 97435(b) (the 39 complete filing by all required parties is deemed receipt of a complete notice). Within 60 days of a complete notice, the Office shall inform each party to a noticed transaction of any determination to initiate a cost and market impact review pursuant to 127507.2(a)(1) of the Code, subject to the following conditions, if applicable: (1) The Office and the submitter may agree to a later date by mutual agreement which shall be in writing and specify the date to which the Office and the parties have agreed. (2) The 60-day period shall be tolled during any time period in which the Office has requested further information from the parties to a material change transaction and it is awaiting the provision of such information. (3) The Office may choose to toll the 60-day period during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction. (4) Should the scope of the transaction materially change from that outlined in the initial notice, the 60-day period may be restarted by the Office. (5) Should the Office grant a request to expedite pursuant to section 97440.	**§ 97441(b)-(d), (f)-(g): Timing of Review of Notice** • The timing provisions under Section 97441 are very concerning as the potential extensions and uncertainty are additional barriers to innovative health care delivery in CA. The timelines proposed are significantly longer than those set forth in the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), and similar health care market impact regulations in Massachusetts and Oregon. If subjected to a CMIR, the process could last well over six months – which seems unreasonable – especially when coupled with OHCA's discretion to prolong the process further. The proposed regulations would permit tolling review periods and delaying the transaction indefinitely. This could deter transactions and have the countereffect of limiting competition. Some examples of concerning provisions include: ○ The requirement for a 60-day review from a "complete" application is potentially problematic, as it's unclear how difficult it will be to have the application deemed complete and the discretion to determine that status is completely situated with OHCA. ○ If there's a determination that a cost and market impact review is needed, this takes an additional 90 days (assuming extensions don't apply to toll the timeline.) ○ The comprehensive list of information that has to be submitted to support the application under 97439(b) is so detailed that parties will be unable to begin preparing it ahead of time, as it is unlikely all of this information will be available. This means the 60-day timeline can't begin expeditiously to mitigate the possibility that the

		(c) Request for Review of Determination to Conduct Cost and Market Impact Review. (1) Within 10 business days of the date of a determination that a cost and market impact review is required, the submitters of the notices for the same transaction may collectively request review of the Office's determination. The request shall: (A) Be in writing; (B) Be signed by all requesting submitters; (C)Be sent to the Director with a copy to the Office; (D)Be consolidated with all other submitters involved in the transaction; € Set forth specifically and in full detail the grounds upon which submitter(s) considers the determination to be in error; and (F) State the reason(s) why the submitter(s) asserts a cost and market impact review is not warranted. (2) The request will be denied if it contains no more than a request for a waiver of a cost and market impact review, unsupported by specific facts. (3) Within 5 business days of receipt of a request for redetermination, the Director may: (A) Decline review and uphold the determination that a cost and market impact review is required; or (B) Grant the request and waive a cost and market impact review. (4) The Director may extend this period for one additional 5-day period if the Director needs additional time to complete the review. (5) The determination of the Director, either upholding the original determination or substituting an amended determination, is final. (d) Timeline for Completion of Cost and Market Impact Review The Office shall complete a cost and market impact review within 90 days of the final decision by the Office to conduct a	review process doesn't impede the progress on making the change. • OHCA's broad discretion to toll timelines in the Proposed Rule should be limited or removed. The timeline for review (at the very latest) should tie to the outside date of the agency that referred the transaction to OHCA. We'd recommend that OHCA have 30 days to review a market transaction notice and notify parties if a CMIR will be conducted. If entities are not notified by OHCA within 30 days, they can move forward on the transaction. • A related issue on timing is that the Proposed Rule adds a process for an informal pre-filing determination of whether an entity must file a notice; OHCA should consider imposing a timeframe on its response (e.g., 10 days) and provide further details regarding what must be submitted to receive a determination. • The proposed CMIR regulation requires health care entities planning a material change in ownership or governance to provide OHCA with 90-days' advance notice of the change. We believe that the 90-day timeline described is intended to be 90 days prior to *closing* as opposed to 90 days prior to *signing*. However, the proposed regulation is unclear and should be revised for clarity. • Section 97439(e) allows that the Office may require a submitter to re-notice any material changes. The use of "may" without any standard for requiring makes the entire process appear arbitrary. Our concern with this is that OHCA can essentially draw out any given transaction indefinitely without standards per the extensions allowed for in Section 97441 (d)(2).

		cost and market impact review, subject to subsections (d)(1) through (3): (1) The Office may extend the 90-day period by one additional 45-day period if it needs additional time to complete the review. (2) Should the Office determine it requires additional documentation or information to complete its review, it may toll either of the time periods set forth in subsection (d)(1) for any time period in which it is awaiting the provision of such documentation or information from the parties to the transaction or is awaiting the provision of information subpoenaed pursuant to section 127507.2(a)(4) of the Code. (3) The Office may choose to toll either of the time periods set forth in subsection (d)(1) during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction. (f) Preliminary Report of Findings. (1) Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code. (2) Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report. (g) Final Report of Findings. The Office shall issue a final report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code within 30 days of the close of the comment period in paragraph (f)(2) of this regulation, unless the Office extends this time for good cause shown. Good cause means a finding based upon a preponderance of the evidence there is a factual basis	• For (f), the draft rulemaking states that the preliminary report goes to the parties and the public. Ideally it should go to the parties first to review for factual inaccuracies. • **UPDATED COMMENT:** We continue to emphasize the above concerns regarding timing and strongly urge OHCA to adopt the revisions provided in these comments. The timing provisions under § 97441 are very concerning as the potential extensions and uncertainty are additional barriers to innovative health care delivery in California. The timelines proposed are significantly longer than those set forth in the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), and similar health care market impact regulations in Massachusetts and Oregon. If subjected to a CMIR, the process could last well over six months, which seems unreasonable, especially when coupled with OHCA's discretion to prolong the process further. The proposed regulations would permit tolling review periods and delaying the transaction indefinitely. This could deter transactions and have the countereffect of limiting competition.

		and substantial reason for the extension. Good cause may be found, for instance, when the Office requires additional time to review and evaluate written comments regarding the preliminary report.	

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October 17, 2023

Submitted electronically via CMIR@HCAI.CA.GOV

Megan Brubaker
Engagement and Governance Manager
Office of Health Care Affordability
Department of Health Care Access and Information
2020 West El Camino Ave., Suite 1200
Sacramento, CA 95833

Re: Cost and Market Impact Review Revised Draft Regulations

Dear Ms. Brubaker:

On behalf of Kaiser Permanente, I am submitting comments on the Office of Health Care Affordability ("OHCA") Cost and Market Impact Review ("CMIR") revised draft regulations.

Kaiser Permanente shares the Department's commitment to improving access to high-quality, affordable health care for all Californians and we appreciate OHCA's continued work to promulgate implementing regulations for this new program. We appreciate the revisions made to the draft regulations based on stakeholder feedback and the opportunity to comment again on the rules. The exclusion from review of ordinary course transactions is an important and welcome change.

We remain concerned, however, that the requirements outlined in the draft regulations apply to such a broad range of transactions that the regulations will negatively impact organizations' ability to enter into and efficiently complete critical transactions to improve health care operations and help manage health care costs. For example, we are concerned that the revised draft regulations would allow OHCA to toll review of transactions for up to 250 days or possibly a year or longer pending any other state or federal reviews or generally while OHCA requests and analyzes additional information from the parties. In addition, it appears that the CMIR regulations still may be interpreted to somehow apply to out-of-state transactions, which would exacerbate the negative and chilling impact on transactions that do not have any impact on the delivery of health care services in California and exceeds the intent of the OHCA statute.

We respectfully request OHCA consider the attached redlined amendments to the revised draft regulations. We summarize our amendments as follows:

- Clarification and definition of what constitutes "California assets" and "California-derived revenue" as those terms are used throughout the regulations, and corresponding edits to apply those terms and concepts consistently, including in the definition of Health Care

Entity, to appropriately focus the regulations on transactions directly impacting the delivery of health care services in California. Related edits to clarify the application of the regulations to California transactions are included in various provisions, including to the definitions of "Health care services" and "Transaction."

- Proposed revision to certain material change transaction thresholds to percentage of revenue measures to more appropriately reflect materiality in relation to the scope and scale of the subject health care entity(ies).

- Proposed deletion of Sec. 97435(e)(3) which would, if adopted as drafted, impact day to day operations and management of health care entities. We believe that transfers of control and governance are adequately addressed in the preceding regulation sections.

- Consistent with the OHCA statute, we propose changes to Sec. 97441 to include, as part of the Office's determination of whether to conduct a Cost and Market Impact Review ("CMIR") and its conduct of a CMIR, appropriate consideration of a transaction's positive market and competitive factors.

- Deletion of tolling of the decision to conduct a CMIR, or of a CMIR itself, pending other state or federation regulatory or agency or court reviews of the subject transaction, or during a discretionary determination of document production completion, which would unduly burden transaction parties with excessive delays through the CMIR process.

Kaiser Permanente appreciates OHCA's consideration of our comments on the revised draft regulations. Please contact me at Deborah.Espinal@kp.org if we may provide additional information or answer any questions.

Sincerely,

Deborah Espinal

Deborah Espinal
Vice President, Enterprise Regulatory Services

Attachment: KP's Redline of Regulations

Cc: Elizabeth Landsberg, Director, Department of Health Care Access and Information
Vishaal Pegany, Deputy Director, Office of Health Care Affordability
Sheila Tatayon, Asst. Deputy Director, Office of Health Care Affordability

Title 22, California Code of Regulations
Division 7. Health Planning and Facility Construction

Chapter 11.5. Promotion of Competitive Health Care Markets; Health Care Affordability
Article 1. Material Change Transactions and Pre-Transaction Review.

§ 97431. Definitions.

As used in this Article, the following definitions apply:

(a) "Affiliation" or "affiliate" refers to a situation in which an entity controls, is controlled by, or is under common control with another legal entity in order to collaborate for the provision of health care services. For purposes of this Article, a clinical affiliation does not include a collaboration on clinical trials, graduate medical education programs, health professions training programs, health sciences training programs, or other education and research programs.

(b) "California assets" refers to tangible or intangible assets (other than monetary assets) allocated primarily to the provision of health care services in California.

~~(b)~~(c) "Cost and market impact review" shall mean the review conducted by the Office pursuant to section 127507.2 of the Health and Safety Code ("the Code").

~~(c)~~(d) "Culturally competent care" means the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients.

~~(d)~~(e) "Department" shall mean the Department of Health Care Access and Information.

~~(e)~~(f) "Director" shall mean the director of the Department of Health Care Access and Information.

~~(f)~~(g) "Fully integrated delivery system" shall have the meaning set forth in section 127500.2(h) of the Code.

~~(g)~~(h) "Health care entity" shall be an entity with California assets that provides health care services and:

(1) Have the meaning set forth in section 127500.2(k) of the Code;

(2) Include pharmacy benefit managers as set forth in sections 127501(c)(12) and 127507(a) of the Code;

(3) Include any parents, affiliates, subsidiaries, or other entities that perform the functions of a health care entity and either:

(i) control, govern, or are financially responsible for the health care entity or

(ii) 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; and

(4) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in

127500.2(p)(6) of the Code. Any health care entity entering into a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435.

~~(h)~~(i) "Health care services," for purposes of this Article, are services provided in California for the care, prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health (mental health or substance use disorder) condition, illness, injury, or disease, including but not limited to:

(1) Acute care, diagnostic, or therapeutic inpatient hospital services;
(2) Acute care, diagnostic, or therapeutic outpatient services;
(3) Pharmacy, retail and specialty, including any drugs or devices;
(4) Performance of functions to refer, arrange, or coordinate care;
(5) Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and
(6) Technology associated with the provision of services or equipment in paragraphs (1) through (5) above, such as telehealth, electronic health records, software, claims processing, or utilization systems.

~~(i)~~(j) "Hospital" shall mean any facility that is required to be licensed under subdivision (a), (b), or (f) of section 1250 of the Code, except a facility operated by the Department of State Hospitals or the Department of Corrections and Rehabilitation.

~~(j)~~(k) "Material change transaction," as used in section 12507(c)(1) of the Code, shall mean a transaction (as defined in this section), which meets the requirements of section 97435(c). "Material change transaction" does not include:

(1) Transactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity.
(2) Situations in which the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under common control with, all other parties to the transaction, such as a corporate restructuring.

~~(k)~~(l) "Notice" shall refer to the notice of a material change transaction as set forth in section 97435.

~~(l)~~(m) "Office" shall mean the Office of Health Care Affordability established by section 127501 of the Code.

~~(m)~~(n) "Payer" shall have the meaning set forth in section 127500.2(o) of the Code.

~~(n)~~(o) "Physician organization" shall have the meaning set forth in section 127500.2(p) of the Code.

~~(o)~~(p) "Provider" shall have the meaning set forth in section 127500.2(q) of the Code.

~~(p)~~(q) "Transaction" includes mergers, acquisitions, affiliations, or other agreements involving a health care entity, ~~or~~and the provision of health care

services in California, that involve a transfer of California assets (sell, lease, exchange, option, encumber, convey, or dispose) or control, responsibility, or governance of the assets ~~or operations~~ of the health care entity in whole or in part to one or more entities. For purposes of this subsection, a transaction does not include contracts or arrangements between Payers and Providers for the delivery of and payment for health care services.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Sections 127500.2, 127507, and 127507.2, Health and Safety Code.

§ 97433. Scope.

Sections 97435 through 97441 govern the procedure for filing notices of material change transactions and the Office's criteria and procedure for review of material change transactions and cost and market impact reviews, if deemed necessary.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Sections 127500.5,127507, and 127507.2, Health and Safety Code.

§ 97435. Material Change Transactions.

(a) A health care entity (hereinafter referred to as a "submitter") who meets the criteria of subsection (b) shall provide the Office with notice of a transaction at least 90 days before the closing date of the transaction, for those transactions expected to close on or after April 1, 2024. For purposes of section 127507(c)(2) of the Code, the phrase "entering into the agreement or transaction" refers to the closing date.

(b) Who must file. A health care entity who is a party to a transaction shall file a written notice of the transaction with the Office if the party meets the thresholds in subsections (b)(1) through (b)(3) under any one or more of the circumstances set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the Code.

(1) A health care entity with annual revenue, as defined in subsection (d), of at least $25 million or that owns or controls California assets of at least $25 million; or

(2) 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 involved in a transaction with any health care entity satisfying subsection (b)(1); or

(3) A health care entity located in a designated mental health or primary care health professional shortage area within California, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of

Federal Regulations (commencing with section 5.1), available at https://data.hrsa.gov.

(c) Circumstances requiring filing. A transaction is a material change transaction pursuant to section 127507(c)(1) of the Code if any of the circumstances in paragraphs (1) through (10) below exist.

(1) The proposed fair market value of the transaction is ~~$25 million~~equivalent to 20% or more of the annual revenue of a health care entity party to the transaction and the transaction ~~concerns~~directly impacts the provision of health care services in California.

(2) 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.

(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of any health care entity in the transaction and involves the provision of health care services in California.

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

(5) 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.

(6) The transaction involves the formation of a new health care entity, affiliation, partnership, joint venture, or parent corporation for the provision of health services in California that is projected to ~~have at least $25 million in~~increase the California-derived annual revenue of a health care entity party to the transaction by 20% or more at normal or stabilized levels of utilization or operation, or transfer control of California assets related to the provision of health care services valued at $~~25~~ 1 ~~m~~billion or more.

(7) The transaction involves a health care entity joining, merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services in California where any health care entity has at least $~~10~~250 million in annual California-derived revenue as defined in subsection (d).

(8) The transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to change from a physician owned to private equity-owned and publicly held to a privately held form of ownership in California.

(9) 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, and the transactions involve the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of any health care entity in the transaction, or the transactions are more likely than not to increase annual California-derived revenue of any health care entity that is a party to the transaction by 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation. 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).

(10) 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, and 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 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation. 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).

(d) Revenue. For purposes of subsection (b) of this section, “revenue” means the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years, ~~as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed,~~ as follows:

(1) For health care service plans, revenue as reported to the Department of Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).

(2) For health insurers, revenue as reported to the Department of Insurance pursuant to Insurance Code section 931.

(3) For hospitals, net patient revenue, as reported to the Department in accordance with the “Accounting and Reporting Manual for California Hospitals,” incorporated by reference in 22 CCR 97018.

(4) For long-term care facilities, net patient revenue, as reported to the Department in accordance with the “Accounting and Reporting Manual for California Long-Term Care Facilities,” incorporated by reference in 22 CCR 97019.

(5) For risk-bearing organizations required to register and report to the DMHC, revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.

(6) For other providers or provider organizations, net patient revenue, which includes the total revenue received for patient care, including:

(A) Prior year third-party settlements;
(B) Revenue received (inclusive of withholds, refunds, insurance services, capitation, and co-payments) from a health care entity or other payer to provide health care services, for all providers represented by the provider or provider organization in contracting with payers, for all providers represented by the provider or provider organization in contracting with payers;
(C) Fee for service revenue; or
(D) Revenue from shared risk and all incentive programs.

For pharmacy benefit managers, all payments and revenue received from health care entities to provide pharmacy benefit management services.

(e) Control, responsibility, or governance. For purposes of this section, a transaction will directly or indirectly transfer control, responsibility, or governance in whole or in part of a material amount of the assets or operations of a health care entity to one or more entities if:

(1) The transaction would result in the transfer of 25% or more of the voting power of the members of the governing body of a health care entity, such as by adding one or more members, substituting one or more members, or through any other type of arrangement, written or oral; or

~~(2)~~ The transaction would vest voting rights significant enough to constitute a change in control such as supermajority rights, veto rights, and similar provisions even if ownership shares or representation on a governing body are less than 25%; ~~or~~

~~(3)~~(2) ~~The transaction would result in the transfer of 25% or more of the administrative or operational control or governance of the management and policies of at least one health care entity that is a party to the transaction.~~

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Section 127500.2, 127507, Health and Safety Code.

§ 97437. Pre-Filing Questions.
Health care entities that are unsure if they must file a notice under this Article may contact the Office at CMIR@hcai.ca.gov.

Note:
Authority: Sections 127501, 127501.2, and 127507, Health and Safety Code.
Reference: Section 127507, Health and Safety Code.

§ 97439. Filing of Notices of Material Change Transactions.

(a) A notice of material change transaction pursuant to section 127507 of the Code required to be filed under this section (“notice”) shall be made under penalty of perjury using the portal on the Office’s website at

www.hcai.ca.gov/login. A health care entity or its agent filing in the portal shall create a portal account by inputting a first and last name, valid email account, display name, and password, and submit a system-generated verification code. Alternatively, the health care entity or agency may use an existing media account from Microsoft or Google to access the portal. In making any narrative statements in response to subsection (b), if any documents support the assertion, the health care entity making the assertion shall, pursuant to subsections (c) and (d), provide and cite the document, including the section or page number of the document.

(b) Form and Contents of Public Notice. A health care entity submitting a notice ("submitter") shall indicate which threshold(s) and circumstance(s) are met, pursuant to section 97435(b) and (c), respectively, and provide the following information to the Office for public posting on the Office's website:

(1) General information about the transaction and entities in the transaction, including the following information regarding the submitter:

(A) Business Name

(B) Business Website

(C) Business Mailing Address

(D) 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).

(i) 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).

(ii) 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.

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

(F) California health care licenses 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 California facilities, services provided in California, and professions involved in the transaction.

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

(2) 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;

(3) Description of all other entities involved in transaction and if any other health care entities will be submitting a notice. For each entity involved in the transaction, describe, to the extent the submitter has access to the information, the following:
   (A) The entity's business (including business lines or segments);
   (B) Ownership type (corporation, partnership, limited liability corporation, 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;
   (C) Governance and operational structure (including ownership of or by a health care entity);
   (D) Annual revenues for prior three years;
   (E) Current county or counties of operation;
   (F) If a health care provider is involved in 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);
   (G) Primary and threshold languages, as determined by the Department of Health Care Services, used;
   (H) If a payer, 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
   (I) For all health care entities, include a description of the business addresses, if known, of any new entity(ies) that will be formed as a result of the transaction.

(4) Proposed or anticipated date of transaction closure;

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

(6) 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.

(7) Whether the proposed transaction has been the subject of any court proceeding and, if so, the:
  (i) Name of the court;
  (ii) Case number; and
  (iii) Names of the parties

(8) 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:
  (A) Counties where services are performed;
  (B) 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;
  (C) 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;
  (D) Community needs assessments, charity care, and community benefit programs; and
  (E) Medi-Cal and Medicare.

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

(10) Description of potential post-transaction changes to:
  (A) Ownership, governance, or operational structure.
  (B) Employee staffing levels, job security or retraining policies, employee wages, benefits, working conditions, and employment protections.
  (C) City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties.
  (D) 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).
  (E) Competition within 20 miles of any physical facility offering comparable patient services.

(2) 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.

(c) Documents to Be Submitted with Notice. Except for documents submitted pursuant to subsection (c)(1), if a submitter is submitting a document in response to either subsections (b) or (c), a submitter may reference the page number or section of that submission in response to another subsection. Submitters shall upload the following documents in machine readable portable document format (.pdf), with sections bookmarked, as applicable:

(1) 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;

(2) 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);

(3) Documentation related to valuation of transaction;

(4) Contact information for any individuals signing or responsible for the transaction or side or related agreements;

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

(6) 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;

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

(8) 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;

(9) 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;

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

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

(d) Confidentiality of Documents Submitted with Notice. All of the 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 designation in accordance with paragraphs (1) through (3) below.

(1) A submitter of a notice pursuant to this section may designate portions of a notice and any documents or information thereafter submitted by the submitter in support of the notice as confidential. The submitter shall file two versions of the notice. One shall be marked as "Confidential" and shall contain the full unredacted version of the notice or supporting materials and shall be maintained as such by the Office and Department. The second version of the notice shall be marked as "Public" and shall contain a redacted version of the notice or supporting materials (from which the confidential portions have been removed or redacted) and may be made available to the public by the Office.

(2) Marked-confidential versions of stock purchase agreement(s), financial documents, compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office.

(3) A submitter claiming confidentiality in respect of portions of a notice, or any documents not specified above thereafter submitted in support of the notice, shall include a justification that provides a reasonably detailed statement of the grounds enumerated in (i) through (iv) of this paragraph, below, on which confidentiality is claimed, a statement of the specific time for which confidential treatment of the information is necessary, and a statement that the information has been confidentially maintained by the entity. A request for confidentiality shall state whether any of the following applies:

(i) Whether the information is proprietary or of a confidential business nature, including trade secrets (as defined in California Civil Code section 3426.1(d)), and whether the release would be damaging or prejudicial to the business concern;

(i) Whether another state or federal agency deems the filed document confidential and, if so, for what period of time;

(ii) Whether the information is confidential based on statute or other law; or

(iii) Whether the information is such that the public interest is served in withholding the information.

(4) If a request for confidential treatment is granted or denied, the submitter will be notified in writing. If a request for confidential treatment is granted, the information will be marked "Confidential'' and kept separate from the public file. With the exception of the Attorney General as provided in section 127502.5(c)(4) of the Code, the Office and the Department shall keep confidential all nonpublic information and documents designated as confidential pursuant to this section.

(e) Notification of Changes. A submitter shall notify the Office within five business days if the transaction is amended, altered, or cancelled. The Office may require a submitter to re-notice any material changes in accordance with the procedures set forth in section 97435.

(f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by submitting a written request at any time after submission of the notice and until the Office issues its final report, as described in section 97441. The Office will remain entitled to collect any costs incurred in connection with any reviews up until the first business day after the withdrawal notice is received, pursuant to 127507.4 of the Code.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127507, 127507.2, and 127507.4, Health and Safety Code.

§ 97440. Request for Expedited Review.

(a) A submitter may request the Office expedite its review of a notice of a material change transaction by providing the Office, concurrently with the submission required by section 97435:
(1) A detailed explanation of the conditions necessitating expedited review;
(2) Any documentation substantiating the necessity of expedited review; and
(3) The date by which the submitter requests the Office complete its review.

(b) A submitter shall demonstrate that either of the conditions in subsections (b)(1) or (2) exist to obtain expedited review:
(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.
(3) As used in subsection (b)(1), "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 ~~waiver~~expedited review and the transaction is necessary to ensure continued health care access in the relevant markets.

(c) A submitter may request information to be held confidential in accordance with section 97439(d).
(d) The Office will grant or deny the request based on whether the submitter has sufficiently demonstrated conditions for expedited review exist and the transaction is immediately required to mitigate such conditions.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127507.2Health and Safety Code.

§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Review; Findings.

(a) Office Determination Whether to Conduct a Cost and Market Impact Review.
(1) In determining whether to conduct a cost and market impact review based on the Office's finding a noticed material change 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, the Office will consider the factors set forth in subsection (a)(2).
(2) The Office shall base its decision to conduct a cost and market impact review on any one or more of the following factors:
(A) If the transaction may result in a negative or positive impact on the availability or accessibility of health care services, including the health care entity's ability to offer culturally competent care.
(B) If the transaction may result in a negative or positive 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.
(C) If the transaction may lessen or increase competition or tend to create a monopoly in any geographic service areas impacted by the transaction.
(D) If the transaction may lessen or increase competition for workers or may negatively impact the labor market.
(E) If the transaction directly negatively or positively affects a general acute care or specialty hospital.
(F) If the transaction may negatively or positively impact the quality of care.
(G) If the transaction is part of a series of similar transactions by the health care entity or entities ~~or~~ and furthers a trend toward consolidation.
(H) If 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.

(l) If the transaction between a health care entity located in this state and an out-of-state entity may negatively or positively impact affordability, quality, or limit or increase access to health care services in California, or undermine or enhance the financial stability or competitive effectiveness of a health care entity located in this state,.

(b) Timing of Review of Notice. For purposes of this subsection, a notice shall be deemed complete by the Office on the date when all of the information required by section 97439 of these regulations has been submitted to the Office by all health care entities who are parties to the transaction and required to submit under section 97435(b) (the complete filing by all required parties is deemed receipt of a complete notice). Within 60 days of a complete notice, the Office shall inform each party to a noticed transaction of any determination to initiate a cost and market impact review pursuant to 127507.2(a)(1) of the Code, subject to the following conditions, if applicable:

(1) The Office and the submitter may agree to a later date by mutual agreement which shall be in writing and specify the date to which the Office and the parties have agreed.

~~(2)~~ The 60-day period shall be tolled during any time period in which the Office has requested further information from the parties to a material change transaction and it is awaiting the provision of such information.

~~(3)~~(2) ~~The Office may choose to toll the 60-day period during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.~~

~~(4)~~(3) Should the scope of the transaction materially change from that outlined in the initial notice, the 60-day period may be restarted by the Office.

~~(5)~~(4) Should the Office grant a request to expedite pursuant to section 97440.

(c) Request for Review of Determination to Conduct Cost and Market Impact Review.

(1) Within 10 business days of the date of a determination that a cost and market impact review is required, the submitters of the notices for the same transaction may collectively request review of the Office's determination. The request shall:

(A) Be in writing;
(B) Be signed by all requesting submitters;
(C) Be sent to the Director with a copy to the Office;
(D) Be consolidated with all other submitters involved in the transaction;
(E) Set forth specifically and in full detail the grounds upon which submitter(s) consider the determination to be in error; and
(F) State the reason(s) why the submitter(s) asserts a cost and market impact review is not warranted.

(2) The request will be denied if it contains no more than a request for a waiver of a cost and market impact review, unsupported by specific facts.
(3) Within 5 business days of receipt of a request for redetermination, the Director may:
(A) Decline review and uphold the determination that a cost and market impact review is required; or
(B) Grant the request and waive a cost and market impact review.
(4) The Director may extend this period for one additional 5-day period if the Director needs additional time to complete the review.
(5) The determination of the Director, either upholding the original determination or substituting an amended determination, is final.

(d) Timeline for Completion of Cost and Market Impact Review The Office shall complete a cost and market impact review within 90 days of the final decision by the Office to conduct a cost and market impact review, subject to subsections (d)(1) through (3):
~~(1)~~ The Office may extend the 90-day period by one additional 45-day period if it needs additional time to complete the review.
~~(2) Should the Office determine it requires additional documentation or information to complete its review, it may toll either of the time periods set forth in subsection (d)(1) for any time period in which it is awaiting the provision of such documentation or information from the parties to the transaction or is awaiting the provision of information subpoenaed pursuant to section 127507.2(a)(4) of the Code.~~
~~(3)~~(1) ~~The Office may choose to toll either of the time periods set forth in subsection (d)(1) during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.~~

(e) Factors Considered in a Cost and Market Impact Review A cost and market impact review shall examine factors relating to a health care entity's business and its relative market position, including, but not limited to:
(1) The effect on the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care.
(2) The effect on the quality of health care services to any of the communities affected by the transaction.
(3) The effect of lessening or increasing competition or tending to create a monopoly which could result in raising or lowering prices, reducing or increasing quality or equity, restricting or improving access, or innovating less or more.
(4) The effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board.
(5) The effect on competition for workers and the impact on the labor market.
(6) 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.

(7) 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).
(8) 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.
(9) Any other factors the Office determines to be in the public interest.

(f) Preliminary Report of Findings.
(1) Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code.
(2) Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report.

(g) Final Report of Findings. The Office shall issue a final report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code within 30 days of the close of the comment period in paragraph (f)(2) of this regulation, unless the Office extends this time for good cause shown. Good cause means a finding based upon a preponderance of the evidence there is a factual basis and substantial reason for the extension. Good cause may be found, for instance, when the Office requires additional time to review and evaluate written comments regarding the preliminary report.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127500.5, 127502.5, 127507, and 127507.2, Health and Safety Code.

§ 97442. Market Power or Market Failure Determinations.
This Article does not preclude the Office from conducting a cost and market impact review of any health care entity based on the Director's request pursuant to sections 127502.5 and 127507.2 of the Code.

Note:
Authority: Sections 127501 and 127501.2, Health and Safety Code.
Reference: Sections 127500.5, 127501, 127502.5, 127507, and 127507.2, Health and Safety Code.

AMERICA'S PHYSICIAN GROUPS
Taking Responsibility for America's Health

APG Comments on Revised CMIR Draft Regulations October 17, 2023

Submitted electronically to CMIR@HCAI.CA.GOV

America's Physician Groups is a national association representing more than 335 physician groups with approximately 170,000 physicians providing care to nearly 90 million patients. APG's motto, 'Taking Responsibility for America's Health,' represents our members' commitment to clinically integrated, coordinated, value-based healthcare in which physician groups are accountable for the costs and quality of patient care. We appreciate the opportunity to comment on these much-improved draft CMIR regulations.

We appreciate the revisions to key areas of the regulations, including the following:

Addition of the Expediated Review Section: The addition of this section for financially distressed provider organizations is beneficial. We would further suggest that the threshold of severe financial distress being substantial likelihood of bankruptcy is quite high. Waiting for a practice to go bankrupt may be too late as the time from substantial 1likelihood to being in bankruptcy may be very short. Then, once in bankruptcy the challenge of completing a transaction is compounded due to imposition of a bankruptcy trustee. The trustee is not bound by these provisions. In the meantime, the practice may have to shut clinics and patients will be scrambling to find care. We suggest that the threshold lowered to "a risk of business failure and the demonstration of the likelihood of insolvency or bankruptcy within 12 months."

Second, we suggest the addition of another trigger in this section about a request for expedited review *where there's a significant reduction in the provision of critical health care services within a geographic region or regions* (such as a rural setting). It is common for both the DMHC and bankruptcy trustees to coordinate the sale or merger of distressed provider entities. An organization facing this situation should be able to file an expedited form that indicates they have been mandated to sell and/or merge at the direction of another government entity or court.

Third, we suggest a further condition for expedited review in cases where the DMHC or DHCS require an organization to increase its provider network to meet network adequacy requirements. This is a frequent occurrence. OHCA could create a form that requires the Submitter to include documentation of the mandate as a justification for acquisition of additional provider practices.

Fourth, we suggest that provider organizations and facilities that assume financial and utilization risk in partnership with payers, and that are measured for quality and equity outcomes by governmental departments (CMS, DMHC, DHCS, and eventually, HCAI) have

already documented a history of responsible cost control within the health care system. As cited in the recent draft Alternative Payment Model Standards and Implementation Guidance, citing the transition to HCP-LAN Category 4A, 4B and 4C as a desirable payment model for adoption by providers. Therefore, transactions involving providers that meet these conditions should be incented under OHCA through the provision of expedited review. This further incentive would encourage greater adoption of HCP-LAN category 4 payment models across the provider market in California. Greater adoption of such payment arrangements has been previously cited by the U.C. Berkeley School of Public Health and the Berkeley Healthcare Forum and the Petris Center as a potential cost savings of over $100 billion to the California Health Care System. [1] There is already precedent for this provision within OHCA's legislative framework, since hospital facilities that include organized labor workforce do not have the portion of their labor cost increases counted under the established cost growth target methodology, creating an incentive for greater adoption of organized labor workforces. As stated in Appendix V to the Berkeley Forum Report:

> *Based on these studies, we assumed annual expenditure reductions would range from a low of 2.8% to a high of 7.3% in the commercially insured and Medi-Cal populations, while the annual expenditure reductions would range from 0.5% to 1.4% in the Medicare population[2].*

Adoption of expedited review incentives would encourage the increasing use of provider networks and delivery systems that share in cost-growth control strategies, accelerating the success of the OHCA program.

Fifth, we suggest that an outside time limit for notification of the acceptance or rejection of the request for expedited review by the Office within a reasonable time period, such as five calendar days.

Treatment of Management Service Organizations: Thank you for the revision deleting an MSO as a payer organization under the regulation at Section 97431(j).

Definition of "Material Change Transaction" Under the Regulation: Thank you for the clarification and narrowing of scope for this provision at revised Section 97431(J). This will help to reduce filings that would be of marginal relevance to the main purpose of the OHCA legislation, including corporate restructuring activities.

Definition of "Transaction" Under the Regulation: Thank you for the clarification of a "transaction" at revised Section 97431(p) to delete the phrase "or other agreements" from the definition, which narrows the application of this provision and reduces the potential for ambiguity.

[1] *A New Vision for California's Healthcare System: Integrated Care and Aligned Financial Incentives, Berkeley Healthcare Forum, Shortell, et al. February 2013; See also, Appendix II. California's Delivery System Integration and Payment System (Methodology), April 2013; Appendix V. Global Budget/Integrated Care Systems (Initiative Memorandum), April 2013; Financing Universal Coverage in California: A Berkeley Forum Roadmap, Health Affairs Blog, Sheffler, et al. March 29, 2018; California Regional Health Care Cost and Quality Atlas: IHA.org.*

[2] *Appendix V, supra, at page 2. Sections*

AREAS OF CONCERN:

1) **Submitter performance as a precondition to streamlined review:** We note that OHCA did not accept our prior suggestion that monetary thresholds of $25 million under subsection 97435(b) and (c). We therefore strongly suggest that if OHCA has previously determined that the Submitter is reasonably within the cost-growth target thresholds that extensive review and costly compliance requirements are not productive, and pose the risk of increasing administrative costs within the health care system. Creating incentives for providers to stay within the adopted cost targets is as effective means of achieving the affordability goals of OHCA, if not more effective, than cumbersome, extensive, and somewhat ambiguous filing requirements. It would also streamline the growth of the OHCA bureaucracy within state government, which can and will consume significant financial resources that could be used to greater effect within the health care system. *Massachusetts, for example, has taken active steps to control the growth of its oversight bureaucracy within the same target percentage that it sets for its market participants.* We therefore suggest the following additional language is added to Section 97440(b)(4):

   > *(4) The submitter has reasonably demonstrated that it has a recent history of financial performance within the adopted cost-growth target, derives the majority of its operational revenue through advanced payment methodologies as defined under the HCP-LAN and that the proposed transaction does not pose a reasonable likelihood of increased costs to the health care market*

2) **Sections 97435(c)(9) & (10):** The 10-year lookback as written appears to address the gaming scenario of using serial transactions to avoid the transaction notice requirements. We understand the intent of this provision. However, it remains cumbersome and expensive, because it can apply to prior transactions involving the acquisition of a single provider within a network, which is an everyday occurrence, and necessary for the active compliance with statutory, regulatory, and DHCS MCP contract requirements. The current provision in 97439(b)(9)(C) will require the disclosure of every one of a physician group's transactions, *regardless of size*, for the past 10 years every time there is a transaction that triggers the low threshold requirements of $25 and $10 million, respectively. The provision in (9) does not limit the size of the transactions closed over the 10-year period and is not limited to transactions with the same parties. But the problem is that a party could close several transactions over a 10-year period that have no negative market impact. What matters is the current market performance of the acquiring entity and the acquired entity, regardless of how many deals closed over the last 10 years *at the time of the filing of the material transaction*. If the parties are not outliers within the adopted target, why would this information be relevant?

   Moreover, the language is cumbersome with respect to reorganizations that attempt to streamline legacy organizations within a single entity.[3] The language treats the series of

[3] *We understand that "reorganizations" have been removed from the definition of "material transactions" in this revised draft. However, this subsection appears to potentially undermine that clarification.*

transactions as one for purposes of the revenue and control thresholds (with incorrect subsection references). The provision requires that a Submitter represent whether all the prior transactions for the past 10 years trigger the revenue and asset thresholds of $25 and $10 million. For example, if a "type of transaction" is a clinic acquisition, then all clinic acquisitions conducted within the last 10 years would be added together with the proposed transaction to determine if it meets the revenue thresholds of subsections (b) and (c). How can this be accomplished? Does the Submitter apply present value to past transactions? What valuation formula? This is very costly and time consuming for health care entities that are now required to control their administrative overhead within current cost growth targets.

APG therefore suggests the following alternative language: Strike the original draft subsection (9) and the revised draft subsections (9) and (10), to the following language:

> Circumstances requiring filing. A transaction or a series of transactions involving the same parties on both sides of the transactions or the affiliates of such parties for the same health care services is a material change transaction pursuant to section 127507(c)(1) of the Code, if any of the following circumstances in paragraphs (1) through (8) below exist:

3) **Time Period for CMIR Under Section 97441(d)**: It is important to create predictability and ease of compliance within all regulatory development. There is a significant need to ensure that the final version of these regulations creates certainty and predictability of review within the 90-day time period. APG strongly suggests that the Office should only be able to extend the 90-day review period by up to 45 days if it demonstrates the reasonable need for additional time. There should be a time limit for review, after which the Office has passed on the requirement to review. There is precedent for this kind of review period cap within the Knox Keene Act, Section 1373.65(b), which requires the DMHC to pass on the review of a block transfer within 7 days of filing or it is deemed approved.

4) **Circumstances requiring a filing of notice of a material transaction:** Revised subsection 97435(c) includes new, broader provisions requiring a filing, especially subsection (c)(5) that requires a filing where California-derived revenue of any providers in the transaction increase by $10 million or 20% of the existing (?) annual revenue, historically. This provision is vague enough to mean that a newly created provider health care entity, like a restricted licensee, would meet this trigger, and yet that entity is assuming global risk for its services in conjunction with a payer, and therefore decreasing the overall health care spend in California. This is the key underlying reason for our prior comment under Areas of Concern, subsection 1), that a submitter that that is contributing to the affordability of services within the health care system is not subjected to the detailed and onerous review provisions of this regulation, because that represents both a barrier to entry and a barrier to innovation on the part of providers.

5) **Treatment of Confidentiality**: Governor Newsom recently vetoed AB 616, which would have made the confidential financial records of physician organizations publicly available upon request, and yet even with the revisions presented in this version to section 97439(d),

a health care entity would remain subject to the disclosure of its confidential and proprietary financial information if it files for a material transaction under this regulation and is denied confidentiality. The risk of that disclosure represents a real and significant chilling effect for provider market participants to undertake transactions that would potentially expose their financial condition to competitors or others. California has a rich tradition of innovation in its managed care market. This single subsection of the revised regulation poses a threat to the continuation of that tradition, and therefore APG renews its request for a blanket grant of confidentiality for all filings made subject to the terms of this regulation.

Thank you for the opportunity to provide comments on this revised draft version of the CMIR regulations. We are available for questions at your convenience.

Sincerely,

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October 17, 2023

Megan Brubaker
Engagement and Governance Manager
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Sent via email: CMIR@hcai.ca.gov

SUBJECT: CHA Comments on the Revised Draft "Material Change Transactions and Pre-Transaction Review" Regulations

Dear Ms. Brubaker:

On behalf of our more than 400 hospital and health system members, the California Hospital Association (CHA) thanks the Office of Health Care Affordability (office) for the opportunity to comment on the revised October 9, 2023, version of the draft Material Change Transactions and Pre-Transaction Review regulations. We appreciate the office's commitment to a robust public process by providing advance notice and an opportunity for stakeholder feedback on the draft proposed regulations.

The updated draft regulations make important strides in the right direction, for which we sincerely thank the office. However, we continue to have significant concerns with various parts of the updated version regulations that remain unchanged, as well as recommended technical amendments to revised provisions. As the office finalizes its draft regulations on the cost and market impact review (CMIR) process, we urge it to consider ways to reduce the expense, time, and uncertainty that the process will add health care entities and the potential for overly burdensome regulations to ultimately undermine the office's concomitant goals of promoting affordable, clinically integrated, value-based, whole-person care.

Specifically, we recommend that the office further focus its regulatory powers on addressing its core statutory mandate of *analyzing transactions likely to have significant effects* on the health care market. Then, over time and using its streamlined (emergency) rulemaking power, the office may progressively expand the scope of its market oversight functions if, and to the extent that, experience shows this is needed.

Below is an Executive Summary of our central concerns and feedback, followed by our detailed comments, analysis, and requested revisions. In addition to the changes described in this letter, we have

attached a redline version of the revised regulations to show some recommended technical changes. The technical changes on the attached redline are self-explanatory and not described in this letter.

Executive Summary

The revised October 9, 2023, draft CMIR regulations include meaningful positive changes, for which we thank the office. However, CHA has a number of significant remaining concerns with the CMIR regulations as currently drafted. We ask for a number of meaningful changes to ensure the regulations accord with the office's authorizing statute and prevent avoidable and widespread negative impacts on California's health care providers and their patients. In addition to the changes described in this letter, we have attached a redline version of the revised regulations to show some recommended technical changes. The technical changes on the attached redline are self-explanatory and not described in this letter.

Further Focus on the Most Impactful Transactions. As drafted, the regulations establish noticing and materiality requirements that would capture an a large number of market and operations activities that extend beyond what was intended by the authorizing legislation. We urge the office to make additional changes to narrow the draft regulations and focus its efforts on transactions likely to have significant effects on the health care market, reduce the uncertainty around when filing is required by health care entities, and ultimately lighten the burden placed on health care entities—including small and rural entities—seeking business and operational relationships to continue delivering accessible and high-quality care in their communities.

- **We Applaud the Exemption of Transactions in the Ordinary Course of Business.** The former version of the draft regulations would have required routine changes in business operations to go through the CMIR process. For example, basic activities like a hospital contracting with a health plan to be an in-network provider, updating an electronic medical record system, securing a loan, or leasing new medical office space would have been covered. The revised regulations by-and-large address this flaw in the prior version by categorically exempting transactions in the usual and regular course of business from the definition of a transaction. We thank the office for this critically needed change. We ask the office to clarify that this exemption extends to "ordinary and customary *financing* transactions" to avoid notices relating to the ordinary financing of a providers' operations, such as taking out a loan to purchase a large piece of medical equipment or bond financing a capital improvement project.

  Conform to the Materiality Requirements in Statute. State statute requires notice of a material change only when a health care entity transfers "*a material amount* of its assets to one or more entities" or transfers control, responsibility, or governance of "*a material amount* of the assets or operations to one or more entities." In other words, each circumstance requiring a filing must include a threshold dollar amount of assets and/or a threshold measure of control *that is being transferred.* Several of the conditions requiring notice of a material change under the regulations fail to comply with this statutory imperative. They instead mention a dollar amount or percentage for a resulting revenue increase, resulting new revenue, or a new form of ownership. The regulations conflate a "material transfer" with "material resulting revenue." We recommend various amendments to conform the regulations to statute and ensure filings are required only when a material amount of assets or control is transferred.
- **Establish Reasonable Asset Transfer Materiality Thresholds Pegged to Inflation**. We maintain that the $25 million threshold for providing notice is much too low, neither recognizing the size of California nor the 30% inflation that has occurred since Massachusetts set the precedent for this threshold. To prevent ever smaller transactions (in real dollar terms) from falling under the review process, CHA recommends that any adopted threshold be updated regularly to account for

inflation. To address both these concerns we recommend adopting the Federal Trade Commission benchmark. If the office does not adopt this benchmark, we recommend applying a standalone inflation adjustment to whatever dollar thresholds are adopted.

- **Conform With Generally Accepted Definition of "Control."** The draft regulations now define a change in control as a transaction that transfers more than 25% of the control of a health care entity. This threshold is still far too low. A person or corporation with a 25% interest in a health care entity does not control the health care entity. Moreover, the threshold belies substantial legal precedent as to the meaning of "control." Both the California Corporations Code and the Federal Trade Commission set a 50% threshold for defining control. As a rule of statutory construction, the Legislature is presumed to know existing law when enacting new laws. As such, they undoubtedly knew the definition of "control" and chose to use that term in the governing statute. We recommend the 50% threshold be adopted.

Establish Clear and Speedy Timelines for CMIR. We thank the office for proposing an expedited review process for transactions intended to save financially distressed providers and prevent losses in access. However, we remain concerned that the CMIR process would take a minimum of 250 days for transactions subject to full review—over two months longer than Oregon's comparable deadline. This would add hundreds of thousands of dollars to the cost of transactions and produce a chilling effect on prospective collaborations, regardless of how beneficial the arrangement would be to California patients and communities. We again urge the office to expedite and clarify its timelines for the CMIR process. Specifically, we request several practical changes to deadlines to reduce the timeline to 200 days—comparable to that in other states. We further ask the office to clarify the office's missing deadline for publishing preliminary reviews, establish reasonable protections against overly long and potentially unrestricted tolling against the office's deadlines, and adopt additional reasonable rules that hold the office accountable to achieving its deadlines.

Establish Reasonable Fees for CMIR Activities. Existing governmental reviews of arrangements among health care entities regularly entail hundreds of thousands of dollars in costs to reimburse government agencies for their use of outside consultants and experts. Because government agencies simply pass along these costs to regulated entities, the fees charged by consultants to government agencies often greatly exceed the amounts these same consultants charge directly to health care entities for similar work. For this reason, and to comply with statutory requirements, it is critical for the office to put in place reasonable protections regarding the fees that will be charged to health care entities under the CMIR process. We again ask the office to amend the regulations to ensure that fees charged are reasonable and accord with the economical costs of conducting a review.

Ensure Benefits of Proposed Transactions Are Given Appropriate Consideration. The office's authorizing statute requires that the benefits of proposed transactions be considered in the CMIR process. However, the revised regulations remain silent on whether and how the office will consider these benefits. The regulations must be revised to affirm and enumerate the office's responsibilities to give the benefits of proposed transactions their proper consideration.

Clearly Formulate Criteria for Determining Whether to Conduct a Full CMIR. While the draft regulations list the factors the office will consider when determining whether to conduct or waive a full CMIR, they continue to provide no clarity about how the office will evaluate those factors. In fact, the draft regulations allow the office to make arbitrary decisions about which transactions will be subject to a CMIR based entirely on lax speculation. As a result, health care entities would have little to no ability to anticipate whether an intended transaction would receive a waiver within 60 days or be delayed by 250 or

more days. We strongly encourage the office to conform these criteria with the statutory imperative requiring the office to review transactions likely to have significant effects on the market.

Reasonable Information Submission Requirements for Parties to a Transaction. We remain concerned that the information submission requirements on parties to a transaction place unnecessary burdens on health care entities, increase compliance costs, and exacerbate the risk that sensitive and confidential information will be released into the public domain. Accordingly, the information submission requirements — as currently drafted — should be scaled back to balance the office's need for information with the negative impacts that overly onerous reporting requirements would have on health care entities' basic market activities. In addition to several other requested changes, we recommend the office limit the submission requirements accompanying an initial notice of a material change to those of Massachusetts and Oregon, as well as California state agencies, including the Department of Justice. Additional information necessary to inform a full CMIR should be collected only when the office elects to conduct a full review following a waiver decision. Finally, we ask for technical changes to the definition of revenues for information submission purposes.

Protect Sensitive Non-Public Information Provided to the Office. We appreciate that the office has the difficult task of balancing public transparency with the parties' rights to keep sensitive proprietary information confidential. CHA recommends that Hart-Scott-Rodino filings, competitively sensitive information, and contact information for individuals other than the designated public contact be deemed confidential. In addition, we request that the office provide an opportunity for the submitter to appeal the denial before the office makes the information public.

Detailed Comments

Focus on the Most Impactful Transactions

The office's authorizing statute establishes a clear intent for the office to "analyze those transactions likely to have significant effects" on the health care market (Health & Safety Code Section 127507(a)). To faithfully operationalize this intent and allow the office to devote its limited resources to where it can achieve the greatest impact, it must establish reasonable noticing and materiality thresholds.

The revisions to the draft regulations took a meaningful step in the right direction. However, many definitions still lack clarity or are overbroad. In addition, many transactions described in the regulation lack a materiality threshold for the amount of assets/control *transferred* (as required by the statute), and instead describe a materiality threshold related to post-transaction revenue or ownership form. Conflating these two concepts results in a regulation that fails to comply with its statutory authority. We describe these concerns in more detail below.

Clarify Who Counts as a Health Care Entity and an Affiliate. The office proposes to adopt a definition of a "health care entity." However, the office's governing statutory authority already defines this term in Health & Safety Code Section 127500.2(k): A "health care entity" is a "payer, provider, or a fully integrated delivery system." The regulations exceed this statutory authority by adding — in Section 97431(g)(3) — other entities to this definition:

> *"parents, affiliates, subsidiaries, or other entities perform the functions of a health care entity and either:*
>
> *(i) control, govern, or are financially responsible for the health care entity or*

(ii) *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;"*

In addition to exceeding statutory authority, this definition is circular: *"(g) Health care entity shall: … Include any … entities that perform the functions of a health care entity and …"* This language provides no clarity as to which entities are considered health care entities, and which are not.

Moreover, it remains unclear what being "financially responsible" for another entity means (g)(3)(i) and (ii). One of the legal benefits of incorporation, for example, is that the corporation alone is responsible for its financial obligations — the owners are not individually responsible, and neither are the employees. This limits the potential liability of the corporation. We are not aware of separate legal entities being financially responsible for each other, and do not understand what types of relationships the office is referring to.

We recommend that paragraph (g)(3) be deleted in its entirety. Instead, the regulations throughout should say *"health care entity and its affiliates that provide, arrange, or pay for, health care services"* only where including affiliates is appropriate in context. The regulations may wish to add a definition of "affiliate" by borrowing the definition of "affiliate" from Corporations Code Section 150:

> *"A corporation is an 'affiliate' of, or a corporation is 'affiliated' with, another specified corporation if it directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with the other specified corporation."*

For this regulation package, the word "corporation" above could be replaced with "health care entity."

If paragraph (g)(3) is retained, we request that the office define or explain what is meant by an entity being "financially responsible" for another entity and remove the circular language.

We also recommend clarifying how to count the number of physicians to determine whether a physician organization has 25 physicians. Physician organizations typically have owners, employees, and contractors; some physicians may be full time while others are part time; and some physicians treat patients while others are administrators. We suggest that the office adopt language stating,

> *"For purposes of determining the number of physicians, a physician organization shall count full-time equivalent physicians who provide direct patient care."*

In addition, these or future regulations must clarify how a physician group will know whether it is a "high-cost outlier."

In sum, it is troubling that the definition of "health care entity" remains ambiguous. Every regulation must be crystal clear about who it applies to. Clarifying this definition is essential to a lawful regulation that informs regulated entities and the public about who must comply.

Clarify That Ordinary Financing Activities Do Not Require Notice. CHA greatly appreciates the exclusion of "transactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity." This clarification serves to better implement the intent of the enabling statute, avoids enormous burdens from being placed on health care entities trying to conduct basic operational activities, and prevents the office from being inundated with an unmanageable number of transaction notices.

Remove Value-Based Arrangements. We recommend that Section 97431 (j)(1) also explicitly exclude "ordinary and customary financing transactions." For example, most purchases of expensive medical equipment involve a loan (from the manufacturer or another lender) with the equipment serving as collateral. It is not clear from the revised regulatory language whether these purchases would be considered "typical in the day-to-day operations," so we recommend explicitly excluding such loans. Alternatively, the office could clarify the phrase "typical in the day-to-day operations" to include these types of transactions.

In addition, CHA recommends that an exception be added for any transaction that meets a value-based safe harbor of the federal anti-kickback statute or a value-based exception of the Stark law. Experts from the Centers for Medicare & Medicaid Services and the Office of Inspector General have determined that such safe harbors and exceptions promote the quality of care while simultaneously reducing the costs of care. Including such an exception will align state and federal law and further the purpose of the office to promote clinically integrated, value-based care, and ultimately improve care quality and reduce care costs.

Exempt Publicly Traded Stock Purchases From Definition of Transactions. Finally, CHA recommends that an exception be added to the definition of "transaction" for acquisitions of a publicly-traded company. A health care entity has no ability to notify the office –in advance – if an investor acquires a significant portion of stock available for public purchase on the New York Stock Exchange or other exchange.

Streamline Which Party(ies) Must Provide Notice. The regulations call for duplicate submitters/submissions for a single transaction in many cases. Instead, the regulations should clearly identify one submitter who would be responsible for gathering and submitting the information needed about other parties to the transaction. It is inefficient for both the parties and the office to call for duplicate submissions.

Clarify Materiality Thresholds in Accordance with Statute. Section 97435(c)(1), which requires notice for transactions valued at $25 million or more, remains problematic for several reasons.

- It covers mergers, acquisitions, affiliations and agreements involving health care entities that take place totally outside California. This can be fixed by revising the definition of "transaction" in Section 97431(p) as follows: *"mergers, acquisitions, affiliations, or agreements involving a health care entity, ~~or~~ and the provision of health care services in California …"* Alternatively, Section 97435 could be revised as follows: *"The proposed fair market value of the transaction is $25 million or more and the transaction concerns the provision of health care services in California."* (Either way, the definition of "health care services" should be revised to include payment activities, as described below.)

- The $25 million threshold in Section 97435(c)(1) remains too low. It fails to recognize the size of California as well as the significant inflation that has occurred since the out-of-state agencies the office is modeled after established their respective thresholds. The $25 million threshold appears to be based on the one adopted by Massachusetts in 2015. Since that year, the U.S. has experienced 30% cumulative inflation for all goods and services. As a result, Massachusetts has experienced more and more transactions falling under its threshold that were not intended to be subject to review. In addition, the Massachusetts health care marketplace is much smaller than California's — Massachusetts serves only 7 million people, compared with California's nearly 40 million people. While $25 million may have been material in Massachusetts eight years ago, it is

not an appropriate threshold today in California. In fact, such a threshold would capture transactions that account for five thousandths of one percent of total California health expenditures. Moreover, to prevent ever smaller transactions, in real dollar terms, from falling under the review process, CHA also recommends that any threshold that is adopted be pegged to an inflation index or other benchmark. To address both these concerns we recommend adopting the Federal Trade Commission benchmark.

CHA recommends the following language be substituted for the proposed language:

> *(c)(1) The total value of the transaction impacting California assets exceeds the then-current thresholds specified by the United States Federal Trade Commission pursuant to Section 18a of Title 15 of the United States Code.*

If the office elects against adopting our recommended benchmark, we recommend that the office apply an inflation adjustment applicable to the threshold in (c)(1) and to all other dollar thresholds established in the rule. For the revenue-based thresholds, for example, the lack of an inflation adjustment would cause transactions worth a mere $7 million in today's terms to exceed the relevant thresholds and require notice within 10 years, an unwarranted 30% devaluation of the threshold. For simplicity purposes, the dollars figures might be adjusted on a multiyear rather than annual basis, such as once every 5 years.

Paragraph (c)(1) does not apply to payers — it applies only to transactions that concern "the provision of health care services." However, as we read it, the definition of "health care services" does not include payment activities. The legislature's intent in enacting the governing statute was to apply to all health care entities equally. If the office intends for the phrase "services … including but not limited to … (6) technology associated with provision of services or equipment in paragraphs (1) through (5) above" to loop in payers/payment activities, this is very unclear. CHA recommends adding the following language to the end of Section 97431(h):

"Health care services" also includes activities related to payment for the services listed above.
The legislature's intent in enacting the governing statute was to apply to all health care entities equally.

Ensure Covered Transactions Include Only Those That Transfer a Material Amount of Assets or Control. The governing statute (Health & Safety Code Section 127507(c)). requires that the *amount of assets/control transferred* be of a "material amount":

> *(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.*

We appreciate that the regulations have been revised to require that a business arrangement involve a transfer of assets or control in order to be considered a "transaction." However, paragraphs 97435(c)(2) and (c)(5) do not establish that a material amount of assets or control must be transferred. These paragraphs conflate a material amount of *assets transferred* with a material amount of *increase in the*

revenue of a party post-transfer. These are not the same thing. The regulations must contain a materiality threshold *of assets or control transferred* so that parties know when they must file a notice with the office. (Paragraph (c)(7) has the same problem, as described later in this letter.)

As an example, suppose a large medical center donates (transfers) an asset worth $50,000 (perhaps a used mammography machine) to a rural health clinic. Has the medical center transferred a "material amount" of assets, which would require notice to the office? The regulation does not answer this question — meaning that the medical center does not know if it must file a notice with the office or not. How much the recipient's revenue may increase does not inform the medical center of whether it has transferred a material amount of assets, which is a statutory prerequisite to requiring that a notice be filed with the office.

If the office wishes to include an additional threshold related to resulting revenue increases (in addition to identifying materiality for the assets/control transferred), we recommend a threshold that equals *the greater* of the absolute dollar amount or a percentage (which would help prevent the situation below). Continuing the above example, let's specify that the rural health clinic believes it will be able to attract additional patients and thus increase its revenues by 20% (perhaps from $200,000 per year to $240,000 per year). While this transaction results in an increase of 20% or more of annual revenue, this is not material in today's health care marketplace. It is unreasonable to require notice to the office in these situations.

Also, we know from experience with the Attorney General's office that just putting together the notice requires about $75,000 - $100,000 in outside legal costs, plus considerable time/money on the part of the submitter's employees. Unless amended, this regulation would spell the end of many donations of medical equipment and many other small transactions that improve access to care.

Paragraph (c)(5) has a similar problem — it does not identify the amount of control of assets/operations that must be transferred to constitute a "material" change.

We think that the office is concerned about transactions that result in a provider that contracted directly/separately with payers prior to the transaction becoming part of consolidated/combined contracting with another provider(s) who is a party to the transaction, with the same contracted rates for all such providers. If this is what the office intends to cover with paragraph (c)(5), we request this language be used. If this is not the type of arrangement office is regulating in this language, we request clarification.

Paragraphs (c)(2) and (c)(5) have additional problems:

- They require a great deal of speculation by the parties. We instead recommend that notice requirements be based on objective criteria, not speculation about the future. The office should focus on the amount of assets or control *transferred* (as required by statute), not future post-transfer revenue.
- If the office chooses to include a future revenue threshold in addition to clarifying the amount of assets/control transferred, how far in the future must/can the parties look to determine "normal" or "stabilized" level of operations? For health care facilities that serve a growing community, this could be eight to ten years in the future. The office should specify whether the parties should use year 1 dollars or year 10 dollars (inflation adjustment).

- If a transaction is expected to increase revenue at one facility, but decrease revenue at another facility, should entities use the net increase to determine whether a notice is required? These regulations should be clear.

In sum, we are concerned that several of the paragraphs under subdivision (c) still don't identify a material amount of assets/control that must be transferred in order to trigger a notice to the office. CHA recommends that paragraphs (c)(2) and (c)(5) be deleted. Alternatively, to fulfill its statutory mandate, the office must specify what constitutes a material amount of assets/control *transferred*. This lack of clarity must be rectified so that regulated entities and the public understand when they must go through the CMIR process. The office can also (optionally) include a threshold amount of resulting revenue (or revenue increase) if it wishes – but that alone is insufficient.

Conform to Statute and Clarify Noticing Requirements Related to Asset Sales. Paragraph (c)(3) of Section 97435 requires an entity to provide notice of a transaction involving 25% or more of the assets of "any" health care entity in the transaction. However, the authorizing statute (Health & Safety Code Section 127507(c)(1)(a)) allows only "its" assets to be considered — meaning the submitter's assets — not other entities' assets. Paragraph (c)(3) must be revised to comply with the statutory authority.

In addition, the 25% threshold remains too low and will capture transactions beyond the intent of the legislation — which is to analyze transactions likely to have "significant effects" on the health care market. Let's say a physician has a stroke and can no longer practice medicine. He wishes to sell his practice to a large physician organization. This transaction would involve the sale of 100% of the assets of the individual physician, and thus would require notice to the office. First, this physician may not be able to wait the many months it would take to have the physician organization prepare and submit the notice and have the office review it. He and his family may need income immediately. More importantly, it would be prohibitively expensive for the physician organization to hire an attorney to develop the notice. The practice assets may barely be worth the cost to prepare the notice. This regulation will, in practicality, make many physician practices worthless. We expect this provision would equally negatively affect skilled nursing facilities and other smaller entities.

CHA recommends that this provision be deleted or at least revised to appropriately consider smaller entities. The transfer of a small physician practice, even if it involves 100% of the physician's assets, is not "significant" in California's health care marketplace. We also recommend that the office adopt a higher threshold for larger entities (for example, more than 50% of assets), which would capture significant transactions. Finally, CHA recommends that paragraph (c)(3) be clarified to mean the fair market value of assets (rather than acquisition cost, book value, or replacement cost of assets). Most significant transactions will be subject to a fair market value analysis or fairness opinion, and using fair market value also aligns with the fair market value requirement in laws that apply to health care entities (such as Stark and the anti-kickback statute and their CA equivalents). The Federal Trade Commission also uses fair market value for Hart-Scott-Rodino filings.

CHA recommends the following language be substituted for the proposed language:

> *(c)(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of more than 50% of the submitter's total California assets, at fair market value, unless this amount is less than the then-current thresholds specified by the United States Federal Trade Commission pursuant to Section 18a of Title 15 of the United States Code.*

Clarify When the Formation of a New Entity Requires Notice. Paragraph (c)(6) of Section 97435 (regarding formation of a new health care entity) raises the same concerns as discussed in our comments above about paragraphs (c)(2) and (c)(5). This provision fails to specify what amount of assets or control must be transferred during the process of forming the new entity in order for the transaction to be considered "material" and thus require notice.

Stated in other words, the governing statute and the proposed regulations require a business arrangement to involve a transfer of assets or control (of assets or operations) in order to be considered a "transaction" as defined in Section 97431(p). However, paragraph (c)(6) does not provide a materiality threshold for the transfer of assets or control. It conflates a material amount of *assets transferred* with a material amount of *post-transfer revenue or control of assets*. These are not the same thing.

In addition, this criterion requires a great deal of speculation by the parties and the time horizon is unclear. Finally, it requires that the new health care entity be related to the provision of health care services, and the definition of "health care services" in Section 97431(h) currently does not include payment activities. We request that paragraph (c)(6) be deleted.

Clarify Which Affiliations Require Notice. Paragraph (c)(7) of Section 97435 requires notice when a transaction involves a health care entity "joining, merging, or affiliating" with another health care entity related to the provision of health care. This paragraph suffers from the same legal infirmity as paragraphs (c)(2) and (c)(5). While the regulations have been revised to require a "transfer" of assets/control as a prerequisite to the existence of a "transaction" (as required by the enabling statute), paragraph (c)(7) fails to identify a "material amount" that must *be transferred* to require notice (as required by Health & Safety Code Section 127507(c)). Instead, this paragraph looks only at the size of one of the parties (in terms of revenue). This does not fulfill the office's statutory mandate to identify which transactions involve the *transfer* of a *material amount* of assets/control. (See our discussion of paragraphs (c)(2) and (c)(5) above for further explanation.)

In addition, the word "joining" lacks clarity. Does this provision mean that notice to the office is required each time a Kaiser hospital "joins" with the Permanente Medical Group to undertake a health care activity that isn't exempted as a day-to-day operation? This would, by definition, include any new health care activity. Is notice to the office required before Sharp "joins" with San Diego Imaging Medical Group to conduct free mammograms in an underserved community? All of these named entities have at least $10 million in annual California-derived revenue. As you can see from these two quick examples, the use of the word "joining" makes paragraph (c)(7) exceedingly broad, requiring notice to the office in situations not intended to be covered by governing statute.

CHA strongly recommends deleting the word "joining." In addition, although the word "affiliating" isn't defined in the regulations, we assume it has the same meaning as "affiliation" or "affiliate" as defined in Section 97431(a). We recommend revising this paragraph to so indicate.

We note that this paragraph requires that the transaction be "related" to the provision of health care services. We request the office clarify which types of transactions "relate" to the provision of health care services and which do not. We also reiterate our concern that the definition of "health care services" does not include payers/payment activities.

If the above recommendations are taken, then paragraph (c)(7) would be substantially the same as paragraph (c)(1). In other words, this paragraph may not be needed at all.

Reasonably Scope Oversight of "Serial Transactions." We appreciate the intent behind the changes to the serial transactions requirement in paragraph (c)(9) of Section 97435, which take steps toward reasonably scoping this criterion. However, the provision as amended lacks clarity. We believe that the office intends to capture a series of transactions that, separately, are not considered "material change transactions," but in aggregate represent a material change. If this is indeed what the office intends, we recommend the adoption of language similar to the Attorney General's language in Title 11, California Code of Regulations, Section 999.5(a)(9):

> *(9) If a nonprofit corporation has engaged in multiple agreements or transactions, in a manner designed to avoid Attorney General review under section 999.5 of these regulations, all of the multiple agreements or transactions shall be considered and analyzed as a single transaction for any purpose under these regulations.*

Of course, some revisions would need to be made to this language, but the concept is clear. If the Attorney General language is not adopted, other revisions to this provision are needed. As currently written, paragraph (c)(9) is unclear as to what transactions are "related" and when health care services are "related." For example, for purposes of tax law, transactions are "related" when they are interdependent or conditioned upon one another — that is, one would not be done but for the other. We request that the office clarify what it means by "related."

In addition, the revenue thresholds in subdivision (b) refer to the revenue of a single health care *entity*, not to a single or multiple *transactions*, so it's unclear why subdivision (b) is referenced. And because the definition of a "health care entity" already includes the entity's affiliates, it's unclear why affiliates are referenced.

It is also not clear whether the term "entities affiliated with the same entities" means only "health care entities" or also includes non-health care entities? Finally, it appears that payers and payment activities are not covered by this paragraph as the transaction must involve the provision of "health care services."

We note that the draft U.S. Department of Justice and Federal Trade Commission merger guidelines state that when a merger is part of a series of multiple acquisitions, the agencies may examine the entire series, and consider the entire series when making their approval or denial decision. However, the agencies do not require a transaction that is part of a series to submit a notice unless it meets another triggering requirement.

If the office wishes to finalize a provision regarding serial transactions that cumulatively constitute a material change, the regulatory language must be more precise. In addition, the 10-year lookback period is too long — what happened 10 years ago is hardly relevant today, given the fast pace of change in the health care marketplace. Also, given turnover in hospital executive suites and changes in outside counsel, the parties very well may not know nor have records of such old transactions. CHA recommends a three to five year period instead.

Finally, payers are not covered by this paragraph (because the definition of 'health care services" doesn't include payment activities), which is contrary to legislative intent that all health care entities be on a level playing field.

Conform With Generally Accepted Definition of Control. Subdivision (e) of Section 97435 defines the circumstances in which a transaction is deemed to transfer or change control, responsibility, or

governance of a health care entity for purposes of submitting a notice. CHA believes that the threshold of 25% in paragraphs (1) and (3) is too low and lacks consistency with other state and federal laws. A person or corporation with 25% voting power does not have control over the health care entity.

As noted in our prior letter, he generally accepted definition of "control" refers to having a *majority* interest in a company or on a board thereby being able to make all corporate decisions. California Corporations Code Section 160(b) defines "control" to mean "the ownership directly or indirectly of shares or equity securities possessing more than 50 percent of the voting power of a domestic corporation, a foreign corporation, or an other [sic] business entity." See also California Corporations Code Section 5045, defining "control" as "the power to direct … the management and policies of a corporation.) As a rule of statutory construction, the Legislature is presumed to know existing law when enacting new laws.[1] As such, it undoubtedly knew the definition of "control" and purposely chose to use that term in the governing statute. If it meant for notices to be submitted to the office for merely a change in minority interest (especially as low as 25%), it would have used different language.

We note that the California attorney general's regulations implementing almost identical statutory language ("an agreement or transaction will 'transfer control, responsibility, or governance' if…") uses the term "control" to mean a majority interest. It appears that the office borrowed the language from the California attorney general's regulations (11 CCR Section 999.5(a)(3)(A)) but arbitrarily reduced it to a 25% threshold, which undermines the statutory intent to capture only material changes of control. Again, if the California Legislature wanted to require notices to be submitted to the office for a change of a minority interest (especially as low as 25%), it would not have copied the attorney general's governing statute without change.

The Federal Trade Commission defines control as either: *"(i) holding 50 percent or more of the outstanding voting securities of an issuer or (ii) in the case of an unincorporated entity, having the right to 50 percent or more of the profits of the entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity…"* or *"having the contractual power presently to designate 50 percent or more of the directors…"* (16 CFR Section 801.1(b)) The draft U.S. Department of Justice and Federal Trade Commission merger guidelines state that the agencies will consider whether a partial acquisition may affect competition. However, the agencies do not lower the threshold for triggering a notice of material change. Partial acquisitions of voting authority are a factor to consider when reviewing a transaction, not a trigger for noticing a transaction that would otherwise not require review.

CHA recommends changing the threshold to "more than 50%."

In addition, the criterion described in paragraph (2) of Section 97435(e) will serve to pick up any transaction that transfers less than 50% control but includes other provisions that do effectively transfer control (assuming the "25%" is changed to "50%").

The term "administrative or operational control or governance" in Section 97435(e)(3) lacks clarity. Health care entities hire a chief executive officer (CEO) to exercise administrative and operational control. Does this paragraph mean that the office must be noticed when a new CEO is hired? When a new chairman of the board is appointed? It doesn't make sense for a health care entity to provide an

[1] "It is a settled principle of statutory construction that the Legislature is deemed to be aware of statutes and judicial decisions already in existence, and to have enacted or amended a statute in light thereof. Courts may assume, under such circumstances, that the Legislature intended to maintain a consistent body of rules and to adopt the meaning of statutory terms already construed." (People v. Scott (2014) 58 Cal.4th 1415; internal citations and quotation marks omitted.)

extensive notice to the office for this, and to wait to install the new executive while the office conducts a review. In addition, how does one calculate 25% of "administrative or operational control or governance"? CHA recommends deleting this paragraph.

We request that the regulations clarify what "significant enough" means in paragraph (e)(2) of Section 97435. For example, how many action items must one party have veto rights over to constitute "significant enough" control or change in control?

Finally, we note that health care entities cannot control their directors. For example, a hospital cannot prevent its directors from resigning – even if 25% of them resign simultaneously. In such cases it would be impossible for a health care entity to provide 90 days' advance notice.

CHA recommends the following language be added to the proposed language:

> *However, a health care entity is exempt from the noticing requirements if it experiences a transfer or change in control, responsibility, or governance as described above but cannot provide 90 days' advance notice due to factors beyond its control. Any updates or appointments related to the composition of governing bodies or boards, such as the conclusion of the term of a board member or members pursuant to applicable corporate bylaws, or the appointment of a new president or chief executive officer or any other health care entity executive by the governing body shall not be considered a transfer or change in control, responsibility, or governance.*

Ensure Payer Transactions Are Covered. As noted above, several of the circumstances requiring filing that are listed in Section 97435(c) include the condition that they involve "the provision of health care services." For example, paragraph (c)(1) states that notice is required for any transaction valued at $25 million or more that "concerns the provision of health care services." (See also paragraphs (c)(6), (c)(7), and (c)(9).) However, the definition of "health care services" does not include payment for health care. Therefore, the listed paragraphs would never apply to transactions undertaken by health plans, insurers, or other payers. We do not believe this comports with the intent of the legislature. CHA recommends adding the following language to the end of Section 97431(h):

> *"Health care services" also includes activities related to payment for the services listed above.*

Clear and Speedy Timelines for CMIRs

We are disappointed that no changes were made to the CMIR timelines, with the notable exception of the creation of an expedited review process for financially distressed entities. We reiterate our request for the office to expedite and clarify its timelines for the CMIR process to prevent the discouragement of constructive collaborations, prolonged uncertainty surrounding the outcome of a proposed transaction, and inadvertently raising health care costs.

As drafted, finalizing a transaction under the full CMIR process would take a minimum of **250 days** — assuming no delays — which equates to more than eight months after an initial notice of a material change has been filed. This is over a month longer than the Massachusetts Health Policy Commission's comparable deadline, and over two months (nearly 40%) longer than that of the Oregon Health Authority. Below, we offer recommendations on how to expedite the timelines for completing reviews, clarify ambiguous deadlines, and improve the process for critical and time-sensitive transactions that are necessary to protect access to care.

We Applaud the Establishment of an Expedited Review Process for Urgent Transactions. We thank the office for proposing to create an expedited process for urgent transactions. This new provision will protect access to care by providing a level of assurance that the review of urgent transactions will be completed before the entity is forced to close its doors or service lines. We offer technical amendments to this section in the attachment.

Reduce Time Allotted for CMIRs. The draft regulations would still provide the office 130 days between making a determination to conduct a full CMIR and completing its review. This is more time than is reasonably necessary to conduct a standard CMIR — and for difficult reviews the office can extend the deadline. We maintain our recommendation of shortening the following deadlines for completion of the CMIR:

- From 90 days to 60 days or less for completion of a preliminary CMIR following a determination to conduct a full review (subdivision (d) of Section 97441)
- From 30 days to 15 days or less for issuing a final report following the close of a comment period (subdivision (g) of Section 97441)
- From 45 days to 30 days or less for an extension on the deadline to complete a preliminary CMIR (paragraph (d)(1) of Section 97441)

These changes ultimately would align the office's CMIR timelines more closely with those upon which the office is modeled, reducing the timeline for completing a review (with no delays) from an aggregate 250 days to roughly 200 days.

Consider Expediting Additional Deadlines. In addition to our various recommendations to reasonably accelerate and clarify the review timelines, we maintain our request for the office to consider expediting additional deadlines pursuant to its authority under subparagraph (a)(3)(B) of Health & Safety Code Section 127507.2. First and foremost, it is unclear why a transaction should not be able to be closed until 60 days after the conclusion of the complete CMIR process. This is twice as long as the Massachusetts equivalent. We ask the office to shorten this waiting period to 30 days.

Additionally, we ask the office to consider shortening the time it takes to notify health care entities of its determination of whether to conduct a full CMIR from 60 days to 30 days following notice, which would be consistent with the deadlines established for both Oregon and Massachusetts' review programs.

Establish Reasonable Conditions on Extensions and Tolling While Awaiting Information. Extensions of the already lengthy CMIR process must be the exception and not the rule. To ensure this, appropriate parameters should be placed on the triggering of an extension pursuant to paragraph (d)(1) of Section 97441. We recommend the two following conditions be placed on the triggering of an extension:

- The value of the transaction is twice the current threshold of the U.S. Federal Trade Commission (the materiality threshold we recommend above)
- No later than 10 days prior to the non-extended deadline to complete the CMIR, the office provides notice to the parties and posts on its website a clear and enumerated explanation of the reasons why an extension is needed and why the office believes the extension will not cause undue harm to the parties to the transaction and California residents at-large.

Additionally, paragraph (d)(2) of Section 97441 gives the office the power to delay a transaction for an unlimited period of time if, in its sole discretion, it determines a notice or any supplemental information provided is incomplete. This is problematic given the expansive, subjective, and speculative nature of the information required in the notices and the authority of the office to request more information, again at

its sole discretion. To address these shortcomings in the regulation, we continue to recommend the office place the following conditions on tolling while awaiting more information:

- Tolling, while the office awaits additional information, should be limited to circumstances where the parties have failed to provide objective, factual information relevant to the CMIR. Tolling shall not occur if the office awaits additional information of a speculative or subjective nature, such as relates to the potential competitive and quality-of-care outcomes of a prospective transaction, provided the party to a transaction has made a good-faith effort to provide such required information from its subjective perspective.
- The office shall clearly inform the submitter of any information missing from a notice of a material transaction within seven days of a notice's submission.
- Tolling, while the office awaits any missing information, may only begin 10 days after the office has clearly informed the submitter of the precise nature and content of such missing information.

Finally, if the office decides to extend its deadline for issuing the final report as permitted in Section 97441(g), it should notify the parties in writing and include in the notification the factual basis and substantial reason for the extension.

Remove Tolling Authority While Awaiting Review from Other Government Agencies. The office's market oversight efforts are intended to complement the state and federal governments' pre-existing related efforts, including those by the attorney general and the Department of Managed Health Care. We remain concerned that the involvement of multiple regulatory bodies will result in duplication of efforts, overextended timelines, unnecessary costs, and worse, inconsistent agency positions or timelines. These worries are amplified by the current draft regulations, which allow the office to toll its deadline while another government agency completes its review.

The rationale for this authority remains unclear, given how referrals to and from these external entities are intended to occur under statute. For referrals from the attorney general to the office, tolling has no place since the attorney general is awaiting information from the office to proceed in its own review. Referrals from the office to the attorney general should only occur after the office has conducted a full review and therefore has the information and analysis it needs to make a referral. Here again, tolling would be counterproductive to the purpose of expeditiously preparing to make a referral.

Similarly, it is unclear why tolling should occur during a court proceeding—and it is contraindicated given the office's role of providing information to the public. Because court cases often take years to conclude, such tolling would add yet more time and cost to a transaction and discourage the formation of fruitful collaborations.

For these reasons, we maintain our request that the office remove its tolling authority while awaiting reviews from other government agencies or an end to court proceedings.

Clarify the Office's Deadline for Publishing Its Preliminary Review. We appreciate that the draft regulations take seriously the need to clarify the deadlines associated with completing a CMIR, including in areas where deadlines were absent in the authorizing statute. However, the revised draft regulations still neglect to establish a deadline for issuing a preliminary CMIR report following the completion of the review. Paragraph (f)(1) of Section 97441 states that, "Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings…" The meaning of "upon" in this provision is unclear and allows for an indefinite period of time to lapse between (1) completion of the review and (2) issuance of the preliminary CMIR report. We ask this provision to be amended as follows:

Upon completion of a cost and market impact review and no later than the deadline established for the completion of the preliminary CMIR report pursuant to subdivision (d) of Section 97441, the Office shall make factual findings and issue a preliminary report of its findings…

Green Light Transactions If Office Does Not Meet Regulatory Deadlines. Under the current draft regulations, health care entities have little to no recourse in the event the office fails to meet a regulatory deadline. To prevent such delays and give assurance that the process will not be unduly prolonged, we urge the office to plainly state that transactions may be consummated without risk of further review if the office fails to meet its regulatory deadlines.

Specifically, we ask the office to add the following provision to Section 97441 of the draft regulation:

(h) A transaction may be closed five days after the office has failed to meet one of the following deadlines unless the office timely notified all parties of an extension or tolling of one of the following deadlines:
(1) The deadline to inform parties to a transaction of the decision to initiate a cost and market impact review, pursuant to subdivision (b)
(2) The deadline to complete a cost and market impact review pursuant to subdivision (d)
(3) *The deadline to issue a final report pursuant to subdivision (g).*

Require Timely Responses to Pre-Filing Questions. We appreciate the office establishing a process for health care entities to submit pre-filing questions. To provide assurance that the pre-filing questions will be answered in a timely manner, we request that the office establish a 10-day deadline for its response. We further request that this provision be expanded to specify that health care entities may use this process to ask other questions about the CMIR process, including, for example, what specific information is required in a notice of material change. Email is imperfect for complex transactions; real time conversations may simplify matters for both potential submitters and the office.

CHA continues to recommend the following language be added to the proposed language:

Section 97437. Health care entities that are unsure if they must file a notice under this Article or that have other questions related to filing a notice may contact the Office at CMIR@hcai.ca.gov or (xxx) xxx-xxxx. The office shall automatically acknowledge receipt of an email and provide an answer within 10 calendar days.

Establish Reasonable Fees for CMIR Activities

Existing governmental reviews of collaborations among health care entities regularly entail hundreds of thousands of dollars in costs to reimburse government agencies for their use of outside consultants and experts. Because government agencies simply pass along these costs to regulated entities, the fees consultants charge to government agencies often greatly exceed the amounts these same consultants charge directly to health care entities for similar work. In recent years, we have heard of egregious increases in the amounts charged through government agencies that are entirely incommensurate with the complexity of the transactions.

It remains critical that the office charged with promoting health care affordability put in place reasonable protections regarding the fees that will be charged to health care entities under the CMIR process. Moreover, the enabling statute dictates that the office do so via regulation: paragraph (c)(3) of Health & Safety Code Section 127507 requires the office 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." The revised draft regulations include provisions fulfilling the first and third of these statutory mandates, but neglect to establish appropriate fees that allow health care entities to reasonably anticipate the potential costs of the CMIR process, or assurances that the fees will, in fact, be appropriate. We ask the office to include in the next revision of the regulations a provision that would ensure that fees charged are reasonable and accord with the economical costs of conducting a review. Specifically, we ask the office to add a new subdivision (g) in Section 97435 that reads as follows:

(g) Fees.

(1) The office shall not assess a fee on health care entities for the submission of a notice of material change or to reimburse the office for state employee labor costs or other internal expenses for conducting a cost and market impact review.

(2) The office may assess a fee on a health care entity that has filed a notice of material change that does not receive a waiver from a cost and market impact review. The fee shall not exceed the reasonable, direct, and actual costs of conducting that entity's cost and market impact review charged by external consultants and advisors to the office.

(A) To determine reasonable costs on a total and hourly basis for conducting a cost and market impact review, the office shall conduct and publish on its website a survey of the usual costs of conducting similar reviews by other California state agencies and out-of-state agencies that implement a similar cost and market impact review process. The survey shall also assess costs charged by consultants directly to health care entities for analyses similar to or supportive of cost and market impact reviews. The survey shall stratify costs by the size or complexity of the market transaction under review.

(B) Following the completion of the survey pursuant to subparagraph (g)(2)(A), the office shall establish a maximum schedule for fees charged to health care entities for the completion of a cost and market impact review. The maximum fees shall be stratified to account for the differences in costs associated with transactions of different sizes or complexity.

Ensure Benefits of Proposed Transactions Are Given Appropriate Consideration

The office's authorizing statute requires that the benefits of proposed transactions be considered in the CMIR process. The draft regulations remain silent on whether and how the office will consider these benefits. To this end and to fulfill its statutory mandate, we continue to ask the office to revise the beginning of subdivision (e) of Section 97441 of the draft regulations to state:

> *A cost and market impact review shall examine factors relating to a health care entity's business, ~~and~~ its relative market position, and the benefits of the proposed transaction to consumers of health care services, including, but not limited to:.*

We further ask the office to add the following criterion as a factor to be considered in a cost and market impact review to the end of subdivision (e) of Section 97441:

> *(8) The benefits of increased access to health care services, higher quality, or more efficient health care services resulting from the transaction.*

Clearly Formulate Criteria for Determining Whether to Conduct a Full CMIR

Authorize Full Reviews Only When Significant Market Impacts Are Likely. The governing statute authorizes the office to conduct a CMIR if:

> *The office finds that a material change noticed pursuant to Section 127507* ***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…* (Health & Safety Code Section 127507.2(a); emphasis added)

While paragraph 97441(a)(2) lists the factors the office would consider when determining whether to conduct a CMIR, it provides no clarity about how the office will evaluate those factors. As a result, health care entities would have little to no ability to anticipate whether an intended transaction will be delayed by 60 days or 250 or more days. Moreover, the draft regulations would allow the office to make entirely arbitrary decisions about which transactions will be subject to a CMIR.

We maintain our request for the office to establish clear and objective criteria via regulation to clarify when a CMIR will be required. Specifically, CHA recommends amending Section 97441(a)(2) as follows, with the purpose of ensuring that the waiver criteria conform to the statute's overarching intent for the office to analyze transactions "likely to have significant effects:"

> *(2) The Office ~~may~~ shall base its decision to conduct a cost and market impact review on any one or more of the following factors:*
> *(A) If the transaction ~~may result in a negative impact on~~ is likely to significantly reduce the availability or accessibility of health care services needed by the community, including the health care entity's ability to offer culturally competent care.*
> *(B) If the transaction ~~may result in a negative impact on~~ is likely to significantly increase costs for payers, purchasers, or consumers~~, including the ability to meet any~~ beyond the health care cost targets established by the Health Care Affordability Board.*
> *(C) If the transaction ~~may~~ is likely to significantly lessen competition or ~~tend to~~ create a monopoly in any geographic service areas impacted by the transaction.*
> *~~(D) If the transaction directly affects a general acute care or specialty hospital.~~*
> *(E) If the transaction ~~may negatively impact~~ is likely to significantly reduce the quality of care.*
> *(F) If the transaction between a health care entity located in this state and an out-of-state entity ~~may~~ is likely to significantly increase the price of health care services or significantly limit access to health care services in California.*

In addition, we take exception to the automatic inclusion of any transaction involving a general acute care or specialty[2] hospital in the list of factors for deciding whether to conduct a full review (in Section 97441(a)(2)). This shows a preconceived bias by the office against hospitals and hospital transactions, which is undeserved. The California marketplace has more than 400 hospitals — and more than half are losing money on operations. In contrast, five health plans control 70% of the California market and have more than $225 billion in annual revenues.

Convey Rationale for Determination to Conduct a Full Review. We appreciate the office's inclusion of a process for health care entities to contest the office's determination that a full CMIR is required, as described in subdivision (c) of Section 97441. However, while the draft regulations require the office to inform the parties of its determination, they do not require the office to provide specific information about the basis for the office's determination. As a result, health care entities wishing to utilize the

[2] We believe the office means "special" hospital, not "specialty" hospital. A special hospital is defined in Health & Safety Code Section 1250(f). We are not aware of a legal definition of "specialty" hospital in state or federal law.

contestation process would not have sufficient information about the specific findings they should contest to support a reconsideration of the office's decision. We request the office revise subdivision (b) of this section as follows:

> *(b) Timing of Review of Notice. For purposes of this subsection, a notice shall be deemed complete by the Office on the date when all of the information required by Section 97439 of these regulations has been submitted to the Office. Within 60 days of a complete notice, the Office shall inform each party to a noticed transaction of any determination to initiate a cost and market impact review pursuant to Section 127507.2(a)(1) of the Code.; This notice shall contain detailed information regarding the basis of the office's determination to initiate a cost and market impact review, including summaries of its assessments related to the factors listed under paragraph (a)(2) of this section. The deadline for informing parties pursuant to this subdivision is subject to the following conditions, if applicable*:

In addition, CHA recommends that you strike paragraph (c)(5) of Section 97441 (stating that the Director's determination is final) or revising it to clarify that the Director's determination is the final decision *of the office*. The office should not purport to limit the parties' access to the judicial system.

Reasonable Information Submission Requirements for Parties to a Transaction

The information submission requirements — as currently drafted — would impose enormous burdens on health care entities seeking to collaborate and should be scaled back to balance the office's need for information with the negative impacts that overly onerous reporting requirements would have on health care entities' basic market activities.

Keep the Changes to Reporting on Counties and Other States Served. Many health care providers provide incidental services to patients beyond their typical operating area, particularly through the growing modality of telehealth. Reporting on every location where patients are served, such as their counties of residence, would have been entirely impractical, duplicative of other information requests, and of limited use to the office. Accordingly, we thank the office for the deletion of paragraphs (b)(3) and (b)(4) of section 97439.

Clarify Revenue Reporting Definition. The revised regulations include an amendment to subdivision (d) of section 97435 to indicate that revenue should be reported *"as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed."* This amendment is both unclear and unaligned with the subsequent paragraphs that specify preexisting reporting requirements that should be adhered to when reporting revenue. First, requiring revenue to be reported "as it was generate or occurred and not when "booked, accrued, or taxed" would appear to prescribe reporting on a cash basis. However, "generated" could alternatively mean when the service occurred generating the payment. Additionally, at least for revenue reporting pursuant to paragraph (d)(3) of the draft regulations and 22 CCR 97018, hospitals are required to use accrual accounting (see Section 1101 of Chapter 1000 of the Accounting and Reporting Manual). Thus, if we are correct in assuming that subdivision (d) requires cash accounting, this contradicts the requirement in paragraph (d)(3) that requires accrual accounting for hospitals based on existing regulations. We recommend at minimum two amendments. First, we ask that the office amend the preface of subdivision (d) to clarify that revenue is to be reported when payment is exchanged (or, if accrual accounting is the intent, to state that revenue should be attributed to when a service occurred or good was delivered). In doing so, we would caution the office against using terms such as "generated" that could be interpreted to invoke either cash or accrual accounting. Additionally, amendments should clarify that regardless of what is prescribed in the preface of subdivision (d), the requirements in

paragraphs (1) through (7) are operative where applicable and supersede any conflicting treatment in the preface.

Establish Distinct Information Submission Requirements for Notices and Full CMIRs. State statute establishes two distinct review processes for transactions based on their significance and potential impact: a 60-day review process for transactions that receive a waiver from the full CMIR and those that receive a full review. The information submission requirements should mirror this two-track process. At the least, we recommend the office limit the information submission requirements accompanying an initial notice of a material change to those of Massachusetts, Oregon, and California state agencies (including the Department of Justice). Additional information necessary to inform a full CMIR process should be collected only when the office elects to conduct a full review following a waiver decision. Detailed information that would be required at the outset under the draft regulations that should instead be collected following the decision to initiate a full review includes:

- Competition within 20 miles of any physical facility offering comparable patient services pursuant to subparagraph (b)(12)(E) of Section 97439. (This reflects a minimum recommended change. Alternatively, we recommend this requirement be stricken given that it represents a portion of analysis appropriate for the office to produce through the CMIR process.)
- Seismic compliance status pursuant to subparagraph (b)(12)(D) of Section 97439
- Prospective staffing changes pursuant to subparagraph (b)(12)(B) of Section 97439
- Post-transaction impacts on Medi-Cal and Medicare pursuant to subparagraph (b)(10)(G) of Section 97439
- City or county contracts pursuant to subparagraph (b)(12)(C) of Section 97439
- Information that stratifies patients served by geography, age, gender, race, ethnicity, preferred language, disability status, and payer as required in the following subparagraphs of Section 97439: (b)(1)(D)(i), (b)(5), and (b)(10)(C)
- With the exception of the copies of current agreements required in paragraph (c)(1) of Section 97439, all the documentation required under subdivision (c) (term sheets and other preliminary documents should not be required if a final definitive contract has been reached that states that it supersedes all prior discussions and includes all agreements between the parties, which is usually the case.)

We further ask the office to adopt a provision allowing it to waive any information submission requirement upon request from a health care entity. Such a waiver process could be utilized either during the standard 60-day review process or under the expedited review process established pursuant to Section 97440. This flexibility would be crucial in the latter instance for financially distressed entities that do not have the financial or administrative capacity to comprehensively respond to the extensive information submission requirements in this regulation.

Place Reasonable Limits on Prior Transactions That Must Be Reported. We thank the office for its changes to (new) paragraph (b)(9) of Section 97439 pertaining to reporting on prior transactions. While the updated language represents a tangible improvement, our concerns remain. Large health care entities have conducted untold numbers of small and immaterial market transactions within the last decade. Tracking each of these transactions has not been a requirement of any government agency or an activity undertaken by these entities. Accordingly, they have no way of complying with the requirement even as amended. We urge the office to further revise this requirement as follows:

- Apply the office's and materiality thresholds, or, for the latter, a modified version thereof, to this provision — otherwise, the purchase of a small physician group would be covered
- Limit the lookback period to three years — a sufficient period through which to gain insight into potential serial transactions

- Make the requirement prospective for material transactions occurring on or after Jan. 1, 2024, so that health care entities can be prepared to comply

Require Information Submission About Parties to the Transaction Only. New paragraph (b)(3) of Section 97439 requires the submitter to provide voluminous information about "all other entities involved in the transaction." This phrase is overly expansive, potentially requiring information to be submitted about an unlimited range of third parties—whether completely independent from the parties or affiliated with them. These entities could include, for example, real estate agents, escrow companies, law firms, appraisers, lenders, and others. Even limiting this phrase to all other "health care" entities "involved in" the transaction would be overly broad, particularly since the term "involved in" is so vague. For a hospital, this could include dozens of entities. We continue to recommend the office limit the information submission requirements to information about the *parties* to the transaction. The office has the ability to request additional information if needed later.

Narrow the Scope of the Reporting of Licensure. We appreciate the revision to subparagraph (b)(1)(F) of Section 97439 to clarify that the submitter(s) must provide information only for licenses related to health care (not business licenses, elevator permits, etc.). However, we note that the requirement to provide license *numbers* was deleted from the first sentence but retained in the second sentence. We urge the office to delete the requirement to provide license *numbers* when the submitter is a hospital. This information is not useful to the office and would be onerous for hospitals to collect. For example, let's say that a large health system acquires a physical therapy practice. That large health system will have hundreds of health care licenses: pharmacy licenses, drug room licenses, a license for each automated drug delivery system (a pill counting/storage machine), a centralized hospital packaging pharmacy license, a sterile compounding pharmacy license, a license for each mammography machine, etc. None of these licenses is relevant at all to the office in analyzing the transaction. And certainly knowing the license *numbers* is irrelevant.

CHA recommends that the office add the following language to Section 97439(b)(1)(F):

> *However, if the submitter is a hospital or hospital system, license numbers are required only for the licenses issued by the California Department of Public Health pursuant to Section 1250 of the Health and Safety Code or the equivalent for hospitals located in other states.*

Limit Required Notification of Changes to Those That Are Significant. Subdivision (e) of Section 97439 requires the submitter to notify the office if a transaction is amended, altered, or canceled. This provision should be revised to require notification to the office only of "material" or "significant" amendments or alterations.

Protect Sensitive Non-Public Information Provided to the Office

Health care entities maintain large amounts of data to manage their finances and operations, fulfill their patients' clinical needs, and compete in the health care marketplace. Protecting the confidentiality of these data is critical. Most entities subject to this review process are private health care entities; requiring them to disclose sensitive information without the guarantee of confidentiality would be unreasonably burdensome and inconsistent with federal law regarding transaction review. We appreciate that the office has the difficult task of balancing public transparency with the parties' rights to keep sensitive proprietary information confidential.

The revisions to the provisions requiring justifications for confidentiality are troubling. The notice to the office should not call for a legal brief on confidentiality. It should be obvious that certain financial

information, revenue projections, proposed benefits and efficiencies, mitigation actions, and growth strategies must be kept confidential and would give others an unfair advantage if they knew it. In most cases, the underlying agreement(s) will be sufficient for the public to evaluate the transaction. CHA recommends that the office reverse the revisions to subdivision (d) of Section 97439.

CHA recommends that Hart-Scott-Rodino filings be included in the "deemed confidential" list in paragraph (d)(2) of Section 97439, as well as the names and contact information (phone numbers and email addresses) for individuals who sign or are responsible for the transaction or any side agreements (Section 97439(c)(2) (except for the designated public contact person described in Section 97439(b)(G)). We note that Hart-Scott-Rodino filings are treated as confidential by the federal government. The draft regulations state that marked-confidential versions of stock purchase agreements will be deemed confidential by the office. We recommend clarifying that all similar agreements (including merger agreements, affiliation agreements, purchase agreements, and other definitive agreements) be deemed confidential as well.

In addition, we request that the office establish provide an opportunity for the submitter to appeal a denial of a confidentiality request before the office makes the information public.

Conclusion

While CHA appreciates the changes in the updated version of the draft CMIR regulations that move things in a positive direction, we continue to have significant concerns with the regulations as drafted. Accordingly, we are asking for further changes to properly scope the regulations and ensure they accord with the office's authorizing statute. Otherwise, these regulations will result in avoidable and widespread negative impacts on California's health care providers and their patients.

Thank you for the opportunity to comment on these important regulations.

Sincerely,

Ben Johnson

cc: Members of the Health Care Affordability Board:
David M. Carlisle, MD, PhD
Secretary Dr. Mark Ghaly
Dr. Sandra Hernández
Dr. Richard Kronick
Ian Lewis
Elizabeth Mitchell
Donald B. Moulds, Ph.D.
Dr. Richard Pan

Title 22, California Code of Regulations
Division 7. Health Planning and Facility Construction

Chapter 11.5. Promotion of Competitive Health Care Markets; Health Care Affordability

Article 1. Material Change Transactions and Pre-Transaction Review

Note: This document includes technical changes only. It does not include the substantive changes we have requested in our comment letter dated Oct. 17, 2023.

§ 97431. Definitions.

As used in this Article, the following definitions apply:

(a) "Affiliation," ~~or~~ "affiliate," or "affiliating" refers to a situation in which an entity controls, is controlled by, or is under common control with another legal entity in order to collaborate for the provision of health care services. For purposes of this Article, ~~a clinical~~ an affiliation does not include a collaboration on clinical trials, graduate medical education programs, health professions training programs, health sciences training programs, or other education and research programs.

(b) "California assets" refers to tangible or intangible assets (other than monetary assets) allocated primarily to the provision of health care services in California.

(b) "Cost and market impact review" shall mean the review conducted by the Office pursuant to section 127507.2 of the Health and Safety Code ("the Code").

(c) "Culturally competent care" means ~~the ability of providers and organizations to effectively deliver~~ health care services that meet the social, cultural, and linguistic needs of patients.

(d) "Department" shall mean the Department of Health Care Access and Information.

(e) "Director" shall mean the director of the Department of Health Care Access and Information.

(f) "Fully integrated delivery system" shall have the meaning set forth in section 127500.2(h) of the Code.

(g) "Health care entity" shall be an entity with California assets and shall:

(1) Have the meaning set forth in section 127500.2(k) of the Code;

(2) Include pharmacy benefit managers as set forth in sections 127501(c)(12) and 127507(a) of the Code;

(3) Include any parents, affiliates, subsidiaries, or other entities that perform the functions of a health care entity and either:

Commented [LR1]: The term "clinical affiliation" is not used in these regulations. We believe that OHCA means that an "affiliation" -- the term used in the regulations -- does not include such collaborations.

Commented [LR2]: Revised to be grammatically correct.

(i) control, govern, or are financially responsible for the health care entity or

(ii) 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; and

(4) Exclude physician organizations with less than 25 physicians, unless determined to be a high-cost outlier, as described in 127500.2(p)(6) of the Code. Any health care entity entering into a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435.

(h) "Health care services," for purposes of this Article, are services provided in California for the care, prevention, diagnosis, treatment, cure, or relief of a medical or behavioral health (mental health or substance use disorder) condition, illness, injury, or disease, including but not limited to:

(1) Acute care, diagnostic, or therapeutic inpatient hospital services;

(2) Acute care, diagnostic, or therapeutic outpatient services;

(3) Pharmacy, retail and specialty, including any drugs or devices;

(4) Performance of functions to refer, arrange, or coordinate care;

(5) Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and

(6) Technology associated with the provision of services or equipment in paragraphs (1) through (5) above, such as telehealth, electronic health records, software, claims processing, or utilization systems.

(i) "Hospital" shall mean any facility that is required to be licensed under subdivision (a), (b), or (f) of section 1250 of the Code, except a facility operated by the Department of State Hospitals or the Department of Corrections and Rehabilitation.

(j) "Material change transaction," as used in section ~~12507(c)(1) of the Code~~97435 of these regulations, shall mean a transaction (as defined in this section), which meets the requirements of section 97435(c). "Material change transaction" does not include:

Commented [LR3]: This term is not used in section 12507(c)(1) or 127507(c)(1) of the code. Did OHCA mean section 97435 of these regulations?

(1) Transactions in the usual and regular course of business of the health care entity, meaning those that are typical in the day-to-day operations of the health care entity.

(2) Situations in which the health care entity directly, or indirectly through one or more intermediaries, already controls, is controlled by, or is under common control with, all other parties to the transaction, such as a corporate restructuring.

(k) "Notice" shall refer to the notice of a material change transaction as set forth in section 97435.

(l) "Office" shall mean the Office of Health Care Affordability established by section 127501 of the Code.

(m)"Payer" shall have the meaning set forth in section 127500.2(o) of the Code.

(n) "Physician organization" shall have the meaning set forth in section 127500.2(p) of the Code.

(o) "Provider" shall have the meaning set forth in section 127500.2(q) of the Code.

(p) "Transaction" includes mergers, acquisitions, ~~affiliations,~~ or other agreements involving a health care entity, or the provision of health care services in California, that involve a transfer of California assets (sell, lease, exchange, option, encumber, convey, or dispose) or control, responsibility, or governance of the assets or operations of the health care entity in whole or in part to one or more entities. For purposes of this definition, a transaction does not include contracts or arrangements between payers and providers for the delivery of and reimbursement for health care services provided to individual patients, enrollees, or insureds.

Commented [LR4]: An affiliation is a relationship, not a transaction. As currently written, this doesn't make sense.

§ 97433. Scope.

Sections 97435 through 97441 govern the procedure for filing notices of material change transactions and the Office's criteria and procedure for review of material change transactions and cost and market impact reviews, if deemed necessary.

§ 97435. Material Change Transactions.

(a) A health care entity (hereinafter referred to as a "submitter") who meets the criteria of subsection (b) shall provide the Office with notice of a material change transaction as described in subsection (c) at least 90 days before the closing date of the transaction, for those transactions expected to close on or after April 1, 2024. For purposes of section 127507(c)(2) of the Code, the phrase "entering into the agreement or transaction" refers to the closing date. If a notice is filed and the material change transaction closes before April 1, 2024, the submitter may give written notice to the Office that the closing has occurred and the Office shall treat the notice as withdrawn. Any materials about the notice that were posted on the Office's website shall be removed therefrom and the materials will no longer be considered a public record.

(b) Who must file. A health care entity who is a party to a material change transaction shall file a written notice of the transaction with the Office if the party meets the thresholds in subsections (b)(1) through (b)(3) under any one or more of the circumstances set forth in subsection (c), unless exempted by subdivisions (d)(1) through (4) of section 127507 of the Code. If there is more than one submitter for a single material change transaction, two or more submitters may submit a single notice, so long as all required information for each submitter is provided.

(1) A health care entity with annual revenue, as defined in subsection (d), of at least $25 million or that owns or controls California assets of at least $25 million; or

(2) 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 ~~involved in~~a party to a transaction with any health care entity satisfying subsection (b)(1); or

(3) A health care entity located in a designated mental health or primary care health professional shortage area, as defined in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations (commencing with section 5.1), available at https://data.hrsa.gov.

(c) Circumstances requiring filing. A transaction is a material change transaction requiring notice pursuant to section 127507(c)(1) of the Code if any of the circumstances in paragraphs (1) through (10) below exist unless paragraph (j)(1) or (j)(2) of Section 97431 applies.

(1) The proposed fair market value of the transaction is $25 million or more and the transaction ~~concerns~~directly impacts the provision of health care services.

(2) 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.

(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of 25% or more of the total California assets of any health care entity in the transaction.

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

(5) 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.

(6) 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 control of California assets related to the provision of health care services valued at $25 million or more.

Commented [LR5]: The defined term in these regulations is "health care services," not "health services."

(7) The transaction involves a health care entity ~~joining,~~ merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services in California where any health care entity has at least $10 million in annual California-derived revenue as defined in subsection (d).

(8) The transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to change from a physician-owned to private equity-owned and publicly held to a privately held form of ownership in California.

(9) The transaction is part of a series of related transactions for the same or related health care services occurring over the past ~~ten~~three years involving the same health care entities or entities

affiliated with the same entities, and the transactions involve the sale, transfer, lease, exchange option, encumbrance, or other disposition of 25% or more of the total California assets of any health care entity that is party to the transaction, or the transactions are more likely than not to increase annual California-derived revenue of any health care entity that is a party to the transaction by 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation. The ~~proposed~~ transaction and its ~~related~~such prior transactions will constitute a single transaction for purposes of determining the ~~revenue thresholds in subsection (b) and~~ asset and control circumstances in subsection (c). However, notice is not required if the 25% of assets or the 20% of annual revenue is less than $25 million.

(10) 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~~three years, with a health care entity that provides the same or related health care services, and 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 20% or more of annual California-derived revenue at normal or stabilized levels of utilization . The ~~proposed~~ transaction and ~~its~~ such prior 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). However, notice is not required if the 20% of annual revenue is less than $25 million.

Commented [LR6]: The revenue thresholds in subsection (b) apply to health care entities, not to transactions. Since the revenue thresholds apply to health care entities, which is defined to include affiliates, we don't believe the stricken phrase is needed.

(d) Revenue. For purposes of subsection (b) of this section, "revenue" means the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years, as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed, as follows:

(1) For health care service plans, revenue as reported to the Department of Managed Health Care (DMHC) pursuant to 28 CCR 1300.84.1(b).

(2) For health insurers, revenue as reported to the Department of Insurance pursuant to Insurance Code section 931.

(3) For hospitals, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Hospitals," incorporated by reference in 22 CCR 97018.

(4) For long-term care facilities, net patient revenue, as reported to the Department in accordance with the "Accounting and Reporting Manual for California Long-Term Care Facilities," incorporated by reference in 22 CCR 97019.

(5) For risk-bearing organizations required to register and report to the DMHC, revenue as reported to the DMHC pursuant to 28 CCR 1300.75.4.2.

(6) For other providers or provider organizations, net patient revenue, which includes the total revenue received for patient care, including:

(A) Prior year third-party settlements;

(B) Revenue received (inclusive of withholds, refunds, insurance services, capitation, and co-payments) from a health care entity or other payer to provide health care services, for all providers represented by the provider or provider organization in contracting with payers, for all providers represented by the provider or provider organization in contracting with payers;

(C)Fee for service revenue; or

(D)Revenue from shared risk and all incentive programs.

(7) For pharmacy benefit managers, all payments and revenue received from health care entities to provide pharmacy benefit management services.

(e) Control, responsibility, or governance. For purposes of this section, a transaction will directly or indirectly transfer control, responsibility, or governance in whole or in part of a material amount of the assets or operations of a health care entity to one or more entities if:

(1) The transaction would result in the transfer of 25% or more of the voting power of the members of the governing body of a health care entity, such as by adding one or more members, substituting one or more members, or through any other type of arrangement, written or oral; or

(2) The transaction would vest voting rights significant enough to constitute a change in control such as supermajority rights, veto rights, and similar provisions even if ownership shares or representation on a governing body are less than 25%; or

(3) The transaction would result in the transfer of 25% or more of the administrative or operational control or governance of the management and policies of at least one health care entity that is a party to the transaction.

§ 97437. Pre-Filing Questions.

Health care entities that are unsure if they must file a notice under this Article may contact the Office at CMIR@hcai.ca.gov.

§ 97439. Filing of Notices of Material Change Transactions.

(a) A notice of material change transaction pursuant to section 127507 of the Code required to be filed under this section ("notice") shall be made ~~under penalty of perjury~~ using the portal on the Office's website at www.hcai.ca.gov/login. A health care entity or its agent filing in the portal shall create a portal account by inputting a first and last name, valid email account, display name, and password, and submit a system-generated verification code. Alternatively, the health care entity or agency may use an existing media account from Microsoft or Google to access the portal. In making any narrative statements in response to subsection (b), if any documents support the assertion, the health care entity making the assertion shall, pursuant to subsections

Commented [LR7]: Submitters cannot submit projections, estimates and information about other entities under penalty of perjury. We do not object to the requirement that current factual information about the submitter be provided under penalty of perjury, but other information should be submitted upon information and belief.

(c) and (d), provide and cite the document, including the section or page number of the document. Factual information about a submitter shall be provided by that submitter under penalty of perjury. Information about future events or other entities shall be provided by the submitter upon information and belief.

(b) Form and Contents of Public Notice. A health care entity submitting a notice ("submitter") shall indicate which threshold(s) and circumstance(s) are met, pursuant to section 97435(b) and (c), respectively, and provide the following information to the Office for public posting on the Office's website:

(1) General information about the transaction and ~~entities in~~parties to the transaction, including the following information regarding the submitter:

(A) Business Name

(B) Business Website

(C)Business Mailing Address

(D)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).

(i) 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).

(ii) 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.

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

Commented [LR8]: California law does not use a hyphen between "non" and "profit" (see the "Nonprofit Corporation Law," Corporations Code Section 5000 et seq.).

(F) California health care licenses 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 California facilities, services, and professions involved in the transaction.

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

(2) 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;

(3) Description of all other ~~entities involved in~~parties to the transaction and if any other health care entities will ~~be~~ submit~~ting~~ a notice. For each ~~entity involved in~~party to the transaction, describe, to the extent the submitter has access to the information, the following:

Commented [LR9]: The purpose of this revision is to exclude entities such as law firms, bankers, and others "involved in" a transaction. We do not believe OHCA wants or needs this detailed information about such entities.

(A) The entity's business (including business lines or segments);

(B) Ownership type (corporation, partnership, limited liability corporation, 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~~;

(C)Governance and operational structure (including ownership of or by a health care entity);

(D)Annual revenues for prior three years;

(E) Current county or counties of operation;

(F) If a health care provider is ~~involved in~~a party to the transaction, include a summary description of provider type(s), physical address of health care facilities owned, operated, or leased where patient services are provided by that provider, 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);

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

(H)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

(I) 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.

(4) Proposed or anticipated date of transaction closure;

(5) Description of transaction, which shall include the following:

(A) The goals of the transaction;

(B) A summary of terms of the transaction;

(C)A statement of why the transaction is necessary or desirable;

(D)General ~~public~~description of expected impact or benefits of the transaction, including quality, access, equity and efficiency ~~and equity measures and~~ impacts;

(E) ~~Narrative d~~Description of the expected competitive impacts of the transaction; and

(F) Description of any planned actions or activities to mitigate any potential adverse impacts of the transaction on the public.

(6) 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,

Commented [LR10]: We recommend deleting the word "measures" because this sentence refers to the future, and it is not possible to measure something that has not yet occurred.

Commented [LR11]: We recommend deleting the word "narrative" because we don't believe there's any difference between a "narrative description" and a "description." If OHCA perceives a difference, please clarify this language.

such as, but not limited to, the Federal Trade Commission or the United States Department of Justice.

(7) Whether the proposed transaction has been the subject of any court proceeding and, if so, the:

(i) Name of the court;

(ii) Case number; and

(iii) Names of the parties

(8) 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:

(A) Counties where services are performed;

(B) 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;

(C)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;

(D)The most recent ~~c~~community health needs assessments, charity care policies, and community benefit programs; and

(E) Any impact to Medi-Cal and Medicare patients.

(9) If this transaction is a merger or acquisition described in paragraph (c)(9) or (c)(10) of section 97435, description of any other prior mergers or acquisitions that satisfy all of the following:

(A) Involved the same or related health care services; and

(B) Involved at least one of the entities, or their parents, subsidiaries, predecessors, or successors, in the proposed transaction; and

(C)Were closed in the last ~~ten~~three years.

(10) Description of ~~potential~~expected post-transaction changes to:

(A) The parties' ~~O~~wnership or~~,~~ governance~~, or operational structure~~.

(B) The parties' ~~Employee~~ staffing levels, ~~job security or~~ retraining policies, employee wages, benefits, ~~working conditions,~~ and employment protections.

(C)City or county contracts regarding the provision of health care services between the parties to the transaction and cities or counties.

Commented [LR12]: The term "ownership structure" lacks clarity. Does OHCA want an organization chart? If so, it should say so here.

Commented [LR13]: "Job security" is the mental state of mind of an employee. There's no such thing as a policy about job security. Is OHCA asking about severance policies? Rehire rights? Something else? This should be deleted or clarified.

Commented [LR14]: What does OHCA want to know when it asks about "working conditions"? Please clarify.

(D)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).

(E) Competition within 20 miles of any physical facility offering comparable patient services.

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

(c) Documents to Be Submitted with Notice.

Except for documents submitted pursuant to subsection (c)(1), if a submitter is submitting a document in response to either subsections (b) or (c), a submitter may refer~~ence~~ to the page number or section of that submission in response to another subsection. Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable:

Commented [LR15]: Is it possible to reference a page number in an online portal submission? If not, please revise.

(1) 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;

(2) Copies of all current agreement(s) and term sheets (with accompanying appendices and exhibits) governing or ~~related to~~ otherwise reflecting the parties' rights and obligations pursuant to the proposed material change transaction (e.g., definitive agreements, affiliation agreements, stock purchase agreements);

(3) Documentation related to valuation of the transaction;

(4) Contact information for any individuals signing or responsible for the transaction ~~or side or related~~ agreements described in paragraph (2);

(5) If applicable and one has been prepared, any pro forma post-transaction balance sheet for any surviving or successor entity;

(6) 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;

(7) Existing documentation identifying the number of the parties' patients per zip code or enrollees per zip code in the last year.

(8) 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;

(9) 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 are expected or required to occur as a result of the transaction;

(10) Any documentation ~~related to the~~ of any mitigation of any potential adverse impacts of the transaction on the public; and

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

(d) The Office may waive the requirement to submit any information required by this section upon request by the submitter.

(d) Confidentiality of Documents Submitted with Notice.

All of the 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 or thereafter submitted and the Office accepts the designation in accordance with paragraphs (1) through (3) below or unless deemed confidential pursuant to paragraph (2) below.

(1) A submitter ~~of a notice pursuant to this section~~ may designate portions of a notice and any documents or information thereafter submitted by the submitter in support of the notice as confidential. The submitter shall file two versions of the notice. One shall be marked as "Confidential" and shall contain the full unredacted version of the notice or supporting materials and shall be maintained as such by the Office and Department. The second version of the notice shall be marked as "Public" and shall contain a redacted version of the notice or supporting materials (from which the confidential portions have been removed or redacted) and may be made available to the public by the Office. The submitter must submit the public notice via the portal, but may submit the confidential version via mail or other delivery service.

(2) Marked-confidential versions of stock purchase agreement(s), financial projections, compensation documents, contract rates, competitively sensitive information, and unredacted résumés are deemed confidential by the Office and are not subject to paragraph (3) below. "Competitively sensitive information" includes information provided to the Office pursuant to paragraphs (b)(5) and (b)(10) of this section, employee benefit information, recruitment and

incentive programs, strategic plans and projections, vendor preferences and pricing, and information protected by the attorney-client privilege or attorney work product privilege.

(3) A submitter claiming confidentiality in respect of portions of a notice, or any documents ~~not specified above~~ thereafter submitted (that are not deemed confidential pursuant to paragraph (2) above) in support of the notice, shall include a justification that provides a reasonably detailed statement of the grounds enumerated in (i) through (iv) of this paragraph, below, on which confidentiality is claimed, a statement of the specific time for which confidential treatment of the information is necessary, and a statement that the information has been confidentially maintained by the entity. A request for confidentiality shall state whether any of the following applies:

(i) Whether the information is proprietary or of a confidential business nature, including trade secrets (as defined in California Civil Code section 3426.1(d)), and whether the release would be damaging or prejudicial to ~~the business concern~~any party to the transaction;

(ii) Whether another state or federal agency or court deems the filed document confidential and, if so, for what period of time;

(iii) Whether the information is confidential based on ~~statute or other~~applicable law; or

(iv) Whether the information is such that the public interest is served in withholding the information.

(4) If a request for confidential treatment is granted or denied, the submitter ~~will~~shall be notified in writing prior to any public disclosure of the information. If a request for confidential treatment is granted, the information ~~will~~shall be marked "Confidential" and kept separate from the public file. With the exception of the Attorney General as provided in section 127502.5(c)(4) of the Code, the Office and the Department shall keep confidential all nonpublic information and documents designated as confidential pursuant to this section.

(e) Notification of Changes. A submitter shall notify the Office within five business days if the transaction is amended, altered, or cancelled. The Office may require a submitter to re-notice any material changes in accordance with the procedures set forth in section 97435.

(f) Withdrawal of Notice. A submitter may withdraw a notice for any reason by submitting a written request at any time after submission of the notice and until the Office issues its final report, as described in section 97441. The Office will remain entitled to collect any costs incurred in connection with any reviews up until the first business day after the withdrawal notice is received, pursuant to 127507.4 of the Code.

§ 97440. Request for Expedited Review.

(a) A submitter may request the Office expedite its review of a notice of a material change transaction by providing the Office, concurrently with the submission required by section 97435:

(1) A detailed explanation of the conditions necessitating expedited review;

(2) Any documentation substantiating the necessity of expedited review; and

(3) The date by which the submitter requests the Office complete its review.

(b) A submitter shall demonstrate that either of the conditions in subsections (b)(1) or (2) exist to obtain expedited review:

(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.

(3) As used in subsection (b)(1), "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 waiver and the transaction is necessary to ensure continued health care access in the relevant markets.

(c) A submitter may request information to be held confidential in accordance with section 97439(d).

(d) The Office ~~will~~shall grant or deny the request based on whether the submitter has sufficiently demonstrated conditions for expedited review exist and the transaction is immediately required to mitigate such conditions.

(e) The Office shall use best efforts to grant or deny the request by the date indicated by the submitter pursuant to paragraph (a)(3). The Office shall keep the submitter informed as to the likelihood of meeting this time frame and any alternative time frame.

(f) The Office shall notify the submitter in writing of its decision to grant or deny the request. If the request is granted, the transaction may close immediately.

§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Review; Findings.

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

(1) In determining whether to conduct a cost and market impact review based on the Office's finding a noticed material change 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, the Office ~~will~~shall consider the factors set forth in subsection (a)(2).

(2) The Office shall base its decision to conduct a cost and market impact review on any one or more of the following factors:

(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.

(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.

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

(D)If the transaction may lessen competition for workers or may negatively impact the labor market.

(E) If the transaction directly affects a general acute care or special~~ty~~ hospital.

Commented [LR16]: Health and Safety Code Section 1250(f) is a "special" hospital, not a "specialty" hospital. California law doesn't recognize any such thing as a "specialty" hospital.

(F) If the transaction may negatively impact the quality of care.

(G)If the transaction is part of a series of similar transactions by the health care entity or entities or furthers a trend toward consolidation.

(H)If 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.

(I) If 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.

(b) Timing of Review of Notice.

For purposes of this subsection, a notice shall be deemed complete by the Office on the date when all of the information required by section 97439 of these regulations has been submitted to the Office by all health care entities who are parties to the transaction and required to submit under section 97435(b) (the complete filing by all required parties is deemed receipt of a complete notice). Within 60 days of a complete notice, the Office shall inform each party to a noticed transaction of any determination to initiate a cost and market impact review pursuant to 127507.2(a)(1) of the Code, subject to the following conditions, if applicable:

(1) The Office and the submitter may agree to a later date by mutual agreement which shall be in writing and specify the date to which the Office and the parties have agreed.

(2) The 60-day period shall be tolled during any time period in which the Office has requested further information from the parties to a material change transaction and it is awaiting the provision of such information.

(3) The Office may choose to toll the 60-day period during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.

(4) Should the scope of the transaction materially change from that outlined in the initial notice, the 60-day period may be restarted by the Office.

(5) Should the Office grant a request to expedite pursuant to section 97440.

The Office shall notify the submitter in writing of its determination to conduct, or not to conduct, a cost and market impact review. If the Office determines a cost and market impact review is not required, the transaction may close immediately.

(c) Request for Review of Determination to Conduct Cost and Market Impact Review.

(1) Within 10 business days of the date of a determination that a cost and market impact review is required, the submitters of the notices for the same transaction may collectively request review of the Office's determination. The request shall:

(A) Be in writing;

(B) Be signed by all requesting submitters;

(C)Be sent to the Director with a copy to the Office;

(D)Be consolidated with all other submitters involved in the transaction;

(E) Set forth specifically and in full detail the grounds upon which submitter(s) consider the determination to be in error; and

(F) State the reason(s) why the submitter(s) asserts a cost and market impact review is not warranted.

(2) The request ~~will~~shall be denied if it contains no more than a request for a waiver of a cost and market impact review, unsupported by specific facts.

(3) Within 5 business days of receipt of a request for redetermination, the Director may:

(A) Decline review and uphold the determination that a cost and market impact review is required; or

(B) Grant the request and waive a cost and market impact review.

(4) The Director may extend this period for one additional 5-day period if the Director needs additional time to complete the review.

(5) The determination of the Director, either upholding the original determination or substituting an amended determination, is final.

(d) Timeline for Completion of Cost and Market Impact Review

The Office shall complete a cost and market impact review within 90 days of the final decision by the Office to conduct a cost and market impact review, subject to subsections (d)(1) through (3):

(1) The Office may extend the 90-day period by one additional 45-day period if it needs additional time to complete the review.

(2) Should the Office determine it requires additional documentation or information to complete its review, it may toll either of the time periods set forth in subsection (d)(1) for any time period in which it is awaiting the provision of such documentation or information from the parties to the transaction or is awaiting the provision of information subpoenaed pursuant to section 127507.2(a)(4) of the Code.

(3) The Office may choose to toll either of the time periods set forth in subsection (d)(1) during any time period in which other state or federal regulatory agencies or courts are reviewing the subject transaction.

(e) Factors Considered in a Cost and Market Impact Review

A cost and market impact review shall examine factors relating to a health care entity's business and its relative market position, including, but not limited to:

(1) The effect on the availability or accessibility of health care services to the community affected by the transaction, including the accessibility of culturally competent care.

(2) The effect on the quality of health care services to any of the communities affected by the transaction.

(3) 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.

(4) The effect on any health care entity's ability to meet any health care cost targets established by the Health Care Affordability Board.

(5) The effect on competition for workers and the impact on the labor market.

(6) 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.

(7) Whether the parties to the transaction have been parties to any other transactions in the past ~~ten~~three years that have been below the thresholds set forth in section 97435(b).

(8) 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.

(9) Any other factors the Office determines to be in the public interest.

(f) Preliminary Report of Findings.

(1) Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code. The Office shall provide a copy of any report prepared by an outside contractor and the preliminary report to the submitter at least 10 business days prior to issuing them publicly. The

submitter. The submitter must inform the Office of any inaccuracies in these reports within 5 business days of receipt. The Office shall correct any inaccuracies prior to making the documents public.

(2) Within 10 business days of the issuance of the preliminary report, the parties to the transaction and the public may submit written comments in response to the findings in the preliminary report.

(g) Final Report of Findings.

The Office shall issue a final report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code within 30 days of the close of the comment period in paragraph (f)(2) of this regulation, unless the Office extends this time for good cause shown. Good cause means a finding based upon a preponderance of the evidence there is a factual basis and substantial reason for the extension. Good cause may be found, for instance, when the Office requires additional time to review and evaluate written comments regarding the preliminary report.

§ 97442. Market Power or Market Failure Determinations.

This Article does not preclude the Office from conducting a cost and market impact review of any health care entity based on the Director's request pursuant to sections 127502.5 and 127507.2 of the Code.

HEALTH ACCESS CALIFORNIA

October 17, 2023

Elizabeth Landsberg, Director
Department of Health Care Access and Information

Vishaal Pegany, Deputy Director
Office of Health Care Affordability

Sheila Tatayon, Assistant Deputy Director
Office of Health Care Affordability
Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Attn.: Megan Brubaker, CMIR@HCAI.ca.gov

Re: Revised CMIR Regulations dated Oct. 9, 2023

Dear Ms. Landsberg, Mr. Pegany, and Ms. Tatayon,

Health Access California, the statewide health care consumer advocacy coalition committed to quality, affordable care for all Californians offers comments on the October 9, 2023, revised CMIR regulations. We very much appreciate the posting of the comment letters on the initial draft of the regulations and we have reviewed those comments in preparing these comments.

Health Access appreciates the opportunity to comment on the revised regulations. If enacted as revised, the regulations would provide important and needed oversight of a broad range of mergers, acquisitions and other transactions in health care.

While some of the revisions clearly reflect the limits of statutory authority in the existing law, several revisions unnecessarily limit the information to be provided or keep confidential that which is otherwise public. We seek further revision of these provisions. In summary, three areas are very troubling:

- First, the lookback language is now limited to same or similar services or same parties when some transactions that have been the most transformative of the health care market have involved different sectors or serial transactions.

- Second, all contract rates are deemed confidential even though existing federal rules make public negotiated rates for health plans, insurers and hospitals.
- Third, changing the threshold for change of control from 10% to 25% is troubling and the added language does not capture some of the circumstances in which a small share of control of voting power is concentrated in a few shareholders who are able to work together even while the overwhelming majority of voting rights is dispersed among a large number of shareholders.

Other changes are unfortunate as well as unnecessary to conform to statute:

- Asking for three years of revenues but only one prior year of services provided.
- Changing from zip codes served to counties served: Many California counties are geographically extensive and bigger than some states. Many entities only provide services or coverage in parts of counties.
- Including very specific detail in the regulation on the portal fails to recognize that technology changes over time.

Health Access appreciates the addition of an expedited review process in certain, narrowly defined circumstances. We appreciate the clarification on the authority of the Director undertake market reviews for market power and market failure, not just review of specific transactions. We also appreciate the inclusion of some of the specifics we proposed in our prior letter. We appreciate the specific inclusion of pharmacy benefit managers as provided by statute.

Health Access regrets that not all of our prior comments were accepted in these revisions, including lowering the threshold for review, including behavioral health in the definition of health services, requiring evidence of benefits, as well as additional provisions for public notice, public comment and public meetings. We ask that our recommendations on public notice, public comment and public meetings be considered again. We also offer an additional suggestion based on the comments of others with respect to pre-filing discussions.

We offer additional, more specific comments below.

Further Revisions: Very Problematic Provisions

- Material Change Transactions: Circumstances Requiring Filing:
  97435 (c) (9) and (10) and
  Review of Material Change Transaction Notice: 97441 (a) (1) (F) and (G)

Health Access strongly supported the prior version of these provisions. Nothing in the statute requires that these provisions be severely limited in this way. The revised language in 97435 (c) applies only to a "series of related transactions of the same or related health

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care services" "involving the same health care entity or entities" and "similar transactions" involving the same entities. If the revised language remains, OHCA would have missed some of the most important and transformative transactions in the prior period. Examples include:

- Aetna's acquisition of CVS[1]
- United's acquisition of Optum: this language would capture Optum's seriatim acquisition of physician practices but not the initial move by a health plan to acquire the entity[2].
- The acquisition by hospitals in Monterey of physician practices, ambulatory surgery and more: the language would capture subsequent transactions but not the initial move into a new line of business.

The revised language in Section 97441 (a) (2) (G) and (H) allows the Office to consider whether a "transaction may entrench or extend a dominant market position by any (single) health care entity" including "through vertical or cross-market mergers". Again, if the Office is not aware of the initial move into a new line of business or a new segment of the market, it will not be able to monitor whether a health care entity is "extending a dominant market position" until well after that dominant position is established.

As best we can determine, nothing in the statute requires the Office to limit the lookback at serial transactions. We recognize that other commenters objected vociferously to the prior language but the revised language seems an overreaction that fails to take into account market dynamics.[3] If there is a need to limit the reach of this provision, we would prefer that the time period for the lookback be shortened rather than limiting transactions to the "same or similar" services or parties. Others have suggested three years. We would suggest five years, with an ability to extend to ten years if evidence is adduced that suggests that is a more appropriate length of time for a particular transaction.

If OHCA adopts the revised language, it will miss some of the most important changes in the health care market. This is precisely the opposite of the intent of the legislation to provide a broad overview of market dynamics.

Health Access recommends: Do not limit prior transactions to the same or similar services or the same parties. If needed to manage workload of the parties and the Office, limit the period to five years with the ability to extend to ten years if warranted.

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[1] We recognize that this transaction was reviewed by DMHC and it was of a magnitude that exceeded the thresholds. The point is that these are two entities providing what had been seen as dissimilar services prior to the transaction.

[2] Since Optum might not have had California assets or California-derived revenue, this transaction might have escaped review under the current definitions. This transaction was not subject to review under the current DMHC authority.

[3] For example, see https://www.economist.com/business/2023/10/08/who-profits-most-from-americas-baffling-health-care-system?

- Exclusion of Contract Rates from Public Notice: Section 97439 (d) (2)

It is contrary to existing federal rules to have a blanket exclusion of contract rates from the publicly available data when existing federal law and rules, now litigated to the U.S. Supreme Court, require that negotiated rates for hospitals, health plans and insurers be publicly available. If the phrase "contract rates" in Section 97439 (d) (2) applies to agreed-upon amounts to be exchanged as a result of the transaction, please find another term or phrase to describe such amounts. If the phrase "contract rates" applies to negotiated rates to be paid to or by a hospital, health plan or insurer that are otherwise required to be public under federal law and rules, please clarify that the confidentiality of "contract rates" applies only to those rates that are not otherwise required to be public.

Health Access recommends: Do NOT treat as confidential "contract rates" which are otherwise required to be publicly available.

- Change for transfer of control from 10% to 25%: Section 97435 (e)

The raising of the threshold for transfer of control or governance from 10% of voting power to 25% fails to take into account corporate entities, for-profit or non-profit, in which voting rights are dispersed among a large number of shareholders who are unknown to each other while a small number of highly concentrated shareholders have effective control and a change in a small proportion of those controlling shareholders is a change in control. There are certainly numerous situations in which a small percentage of voting power can create control. This observation dates back at least to the work of Berle and Means in the 1920s on the nature of the corporation. We appreciate the effort in (e) (2) capture supermajority rights, veto rights or similar provisions but this is not sufficient in our view. For example, if 90% or more of the control is dispersed among a large number of shareholders with no ability to communicate with each other, as is often the case in sizable corporations, transfer of control of 10% or even less may be a functional transfer of control. The focus of some commenters on small organizations should not obscure the reality that some of the parties to these transactions will be some of the largest corporations in the world. For example, Amazon which now owns One Medical or Blackstone, the private equity firm with over $1 trillion in assets, are likely subject to these regulations as is Tenet Healthcare with almost $18 billion in revenues.

Health Access recommends: Further revising the regulations to capture situations in which voting power or voting control are dispersed among many shareholders with a small number or proportion having concentrated ownership or control.

Important Improvements

Health Access supports a number of important improvements in the revised regulations. Specifically, we appreciate:

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- The addition of an expedited procedure for distressed entities which are narrowly defined.
- The clarity that the Director retains the authority to conduct a market review other than a transaction review for market failures or market power.
- The addition of the full range of sexual and reproductive health care services and services for LGBTQ+ populations to the impacted services.
- The inclusion of pharmacy benefit managers, consistent with the statute.

Each of these changes is an improvement over the prior draft. We also acknowledge that other provisions, particularly in the definition section and the circumstances requiring filing, have been revised to hew more closely to the statute.

Other Problematic Provisions

- Services Offered Previously: Filing of Notice of Material Change Transactions: Section 97439 (b) (3) (F) and (H)

Section 97439 (b) (3) (D) calls for annual revenues for the prior three years but in (F) and (H) only looks at services in the prior year. In our experience with hospital closures, a series of unit closures often signals financial destabilization and leads up to the question of whether to close or sell an entire hospital. Similarly, an expansion spree often begins with a new line of business or reconfiguring an existing service line, say by moving psychiatric services from the emergency room (where all are served) to an outpatient, private pay only facility across the street from the emergency room[4].

Health Access recommends: Requiring information on prior three years for services and areas served as well as revenues.

- Geographic area: County Not Sufficient: Filing of Notice of Material Change Transactions: Sections 97439 (b) (1) and (8), (c) (7)

We are disappointed that the proposed revisions use counties rather than zip codes or other sub-county regions. Many California counties are very geographically extensive and with populations greater than the population of entire states. Outside the Bay Area, few health plans serve entire counties. Even fewer hospitals or health systems serve entire counties. Indeed, many non-profit hospitals are located in affluent areas and reviewing transactions involving these hospitals usually reveals that the hospital in question does not regard low-income areas as part of its service area.

[4] The Attorney General has oversight of transactions involving non-profit hospitals and broad authority over competitive markets but many hospital transactions are exempt from this oversight because of the parties involved. Even for those transactions involving nonprofit hospitals, looking at the broader market impacts is an area where collaboration and cooperation between HCAI and DOJ would improve the AG oversight.

California counties are not only geographically extensive but often contain barriers such as mountain ranges that result in health plans serving only a portion of the county. Whether it is the Antelope Valley in Los Angeles County, the parts of San Bernardino or Riverside Counties closer to the Colorado River, or the east side of San Diego County, geography creates barriers and health plan service areas follow these lines. Placer County, El Dorado County and Sonoma County offer other examples where those health care entities which serve the more densely populated parts of these counties often do not serve the less populated parts of these counties.

Health care markets do not respect county lines. The regulations should respect that reality or market concentration and market power will be overlooked.

Health Access recommends: Either revert to zip codes or require descriptions of service areas or other descriptions of subcounty areas served.

Filing of Notices: Overly Specific Instructions: Section 97439 (a)

In our experience, it is a mistake to include such overly specific instructions such as "an existing media account from Microsoft or Google" and the instructions for entering the portal. If these instructions would have been different twenty years ago, they are likely to be different in the foreseeable future. Nothing in the statute requires the Department to tie its own hands in this manner. We suggest moving such instructions to some sort of "technical assistance guide" or "filing manual" or some other document which can be updated without the need for revising regulations. The Department will not always have emergency regulation authority. (The last time we checked, hospitals were still required to notify the licensing agency via *telegram* when there are subsequent technologies available, such as the telephone, fax, or internet.)

Health Access recommends: Don't lock in specific technology that would not have existed twenty years ago and may not exist twenty years from now.

Prior Recommendations by Health Access

Health Access regrets that not all of our prior comments were accepted in these revisions, including lowering the threshold for review, including behavioral health in the definition of health services, requiring evidence of benefits, as well as additional provisions for public notice, public comment and public meetings. We ask that these recommendations be reconsidered or if not included in the regulations themselves, included in the procedures adopted by the Office. Our perspective as advocates on behalf of consumers who bear the brunt of the lack of affordability resulting from higher prices and the race to consolidate is quite different than that of the health care entities that anticipate being subject to market reviews.

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Additional Recommendation: Pre-Filing Questions: Section 97437

In our review of comment letters by others, we note that several commenters suggested providing additional information on pre-filing discussions. It would be helpful to all parties, including consumer advocates and other purchaser representatives, if something similar to a case summary or abstract that summarized key facts was posted. This would help to track which sorts of transactions are subject to review and which are determined not to be. It may or may not be necessary to include this idea in regulation: the Office could provide such a summary without it being required by regulation. Requiring this step by regulation would assure that future Administrations would take it.

We look forward to reviewing the final regulations and working with the Office as this important and necessary oversight of the health care market is implemented. We anticipate continuing to offer comments on developing this process further over the years to come, just as we have done for the thirty years the Attorney General has had oversight of nonprofit health facility transactions.

We thank you for your consideration of these comments.

Sincerely,

Beth Capell, Ph.D.
Policy Consultant

Anthony Wright
Executive Director

CC: Members of the Health Care Affordability Board
Attorney General Bonta, California Department of Justice
Senator Atkins, Senate President pro Tempore
Assemblymember Rivas, Speaker of the Assembly
Senator Eggman, Ph.D., MSW, Chair, Senate Health Committee
Senator Menjivar, MSW, Chair, Senate Budget Subcommittee on Health and Human Services
Assemblymember Wood, D.D.S, Chair, Assembly Health Committee
Assemblymember Weber, M.D., Chair, Assembly Budget Subcommittee on Health and Human Services
Mary Watanabe, Director, Department of Managed Health Care

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CASA
CALIFORNIA
AMBULATORY SURGERY
ASSOCIATION

October 17, 2023

Megan Brubaker
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Sent via email to: CMIR@hcai.ca.gov

RE: *REVISED* Emergency Regulations Concerning the Promotion of Competitive Health Care Markets; Health Care Affordability (Health Care Market Oversight) – CMIR

Dear Ms. Brubaker:

On behalf of the California Ambulatory Surgery Association (CASA), and our over 400 ambulatory surgery centers (ASCs), we respectfully submit these second round of written comments to the Office of Health Care Affordability (OHCA) regarding the REVISED *Emergency Regulations Concerning the Promotion of Competitive Health Care Markets; Health Care Affordability (Health Care Market Oversight) – CMIR*.

CASA is the statewide association of ASCs, and our members champion the advancement of ambulatory surgery technology and promote the efficient, safe, and effective utilization of resources that benefit our patients. CASA members are leaders in reducing costs to the health care system as we ensure patients are treated safely in outpatient settings instead of other costly alternatives.

ASCs play a major role in the overall health care delivery system and save the system and patients significant costs. For example, UC Berkeley research has shown that every procedure performed in an ASC saves the Medicare program forty (40) percent and saves Medicare beneficiaries fifty-sixty (50-60) percent in their co-payments.[1]

Article 1. Material Change Transactions and Pre-Transaction Review

§ 97435 Material Change Transactions.

This section is still overly broad and goes beyond the intent and specific authority granted to OHCA by way of SB 184 (Chapter 47, Statutes of 2022). For example, subsection (c) includes nine additional "trigger" scenarios for circumstances requiring filing.

> *(2) 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 ~~at least~~ $10 million or more or 20% or more of annual California-derived revenue at normal or stabilized levels of utilization or operation.*

Question: How does OHCA calculate a transaction annual revenue increase of 20% "or more of annual California-derived" revenue at normal or stabilized levels of utilization or operation?
Comment: This ambiguity will make it difficult for ASCs to calculate whether a transaction would trigger a filing. CASA recommends deleting the provision related to the more than likely 20% or more increase of annual California-derived revenue at normal or stabilized levels of utilization or operation.

[1] Fulton, Brent; Kim, Sue. *Study: Medicare Cost Savings Tied to ASCs.*

(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of ~~20~~25% or more of the total California assets of any health care entity in the transaction.

Question: How does OHCA calculate the other disposition of 25% or more of the "total California" assets of any health care entity in the transaction and how does OHCA define assets?
Comment: This ambiguity will make it difficult for ASCs to calculate the disposition of 25% or more of the "total California" assets to ascertain if a filing is required. CASA recommends reworking this trigger and define "assets."

(5) ~~The terms of the transaction contemplate an entity negotiating or administering contracts with payers on behalf of one or more providers and the transaction involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, management services organization, or other organization.~~
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.

Question: How does OHCA calculate the "more than likely" 20% "or more" increase in "annual California-derived revenue" at normal or stabilized levels of utilization or operation?
Comment: This ambiguity will make it nearly impossible for ASCs to calculate whether a transaction would trigger a filing. CASA recommends deleting the provision related to "the more than likely 20% or more" increase on "annual California-derived revenue at normal or stabilized levels of utilization or operation."

(8) The transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to change from a physician-owned to private equity-owned and publicly held to a privately held form of ownership.

Question: What other unlimited examples of a change of ownership are being considered by OHCA?
Comment: As written, a transaction that changes the form of ownership of a health care entity that is a party to the transaction, "including but not limited to …" is overly broad and ambiguous. Without further clarity, ASCs will be forced to trigger a filing every time an individual physician is added or deleted as an equity partner in that facility, resulting in thousands of filings annually just for the ASC industry. Medicare Certified ASCs are already required to submit a change of ownership (CHOW). CASA would recommend OHCA simply accept the CHOW.

(9) ~~A health care entity that is a party to the transaction has consummated any transaction regarding provision of health care services in California with another party to the transaction within ten years prior to the current transaction.~~
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).
(10) 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).

Question: Where does OHCA have the express authority in statute to require a "ten-year" look back on prior transactions?
Comment: This authority was not granted in SB 184 (Chapter 47, Statutes of 2022) and could be considered an underground regulation by the Office of Administrative Law (OAL). CASA recommends that subsections (9) and (10) be deleted.

§ 97439. Filing of Notices of Material Change Transactions.

(d)(2) Marked-confidential versions of stock purchase agreement(s), ~~financial documents,~~ compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office.

Question: Why are "financial documents" being deleted from those materials that shall remain confidential?
Comment: Governor Newsom just vetoed AB 616 (Rodriguez) of 2023. This legislation would have made available to the public audited financial statements of risk bearing organizations, including physician groups. In his veto message Newsom stated, *"Given the OHCA is in its initial stages of implementation, any additional requirements and associated impacts should be evaluated following full implementation of existing law. For this reason, I cannot sign this bill."* CASA recommends reverting to maintaining the confidentiality of financial documents.

§ 97441. Review of Material Change Transaction Notice; Decision to Conduct Cost and Market Impact Reviews; Findings.

(e)(5) The effect on competition for workers and the impact on the labor market.

Question: What is the rationale for this addition and what factors will OHCA consider when assessing the impact on the labor market?
Comment: CASA recommends that subsection (5) be deleted.

(e)(6) 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.

Question: As a factor for consideration in the Cost and Market Impact Review what does OCHA mean by "otherwise increase barriers to entry in any health care market?"
Comment: Such an open-ended metric of assessing whether a transaction may increase barriers to entry in any health care market is virtually impossible for ASCs. Any health care market is ill-defined and not even based on a geographic proximity to the services being delivered because of any transaction. CASA recommends that subsection (6) be deleted.

CASA would also like to remind OHCA of their overarching mission as it relates to implementing the provisions of SB 184 (Chapter 47, Statutes of 2022). Specifically, when OHCA conducts a cost and market impact review (CMIR), subsection (a)(2) of Health and Safety Code Section 127507.2 states in part:

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.

California ASCs pride themselves on reducing health care costs, increasing access to care, and doing so by providing the same high-quality care as other sites of service. It would be misguided for OHCA and detrimental to patient access to ASC services unless these regulations can be clarified and/or the provisions we recommend above be deleted. ASCs provide unique services in the overall health care delivery system and unintentionally stifling this innovation or artificially impeding growth of the ASC industry in California would be harmful to patient access at great cost to the system.

Therefore, CASA urges OHCA to strongly consider these comments to ensure ongoing access to patient encounters in the ASC setting.

Thank you for your consideration of these comments. If you have any questions or require additional information, please contact CASA Legislative Advocate Bryce Docherty at (916) 769-0573 or bdocherty@tdgstrategies.com.

Sincerely,

Elizabeth LaBouyer
Executive Director
California Ambulatory Surgery Association

October 17, 2023

Megan Brubaker
Engagement and Governance Manager
Office of Health Care Affordability
Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 1200 '
Sacramento, CA 95833
megan.brubaker@hcai.ca.gov

Re: Revised Draft Emergency Regulations on Promotion of Competitive Health Care Markets (CMIR) – SUBMITTED VIA E-MAIL

Dear Ms. Brubaker

On behalf of Sutter Health, we are pleased to provide our comments on the Office of Health Care Affordability's emergency rules pertaining to the promotion of competitive health care markets (CMIR). Thank you for allowing us the opportunity to provide additional feedback on these draft regulations that will have significant and long-term impacts on the overall health care delivery system in California, including the Sutter Health network of hospitals, physicians and ambulatory surgical centers and clinics. As you will see below, we offer specific suggestions on how these emergency regulations can be amended to more closely align with the intent of the authorizing statute while still allowing for greater detail on the nature of the Office's review.

1. We have noted several places where the revised regulation language strays from defined terms, which creates confusion and ambiguity. For example, at times the revised language uses the defined term "health care entity" but then switches to just "entity," when we believe OHCA may have meant "health care entity." [*See* Sections 97435 (c)(5), (c)(9).] It appears Section 97435(c)(9) should say, "health care entities or entities affiliated with the same 'health care entities.'). It is difficult to identify when OHCA believes it has the authority to review non-health care entity transactions. This is also the case where OHCA only defined "affiliation" or "affiliate" but then refers to "entities affiliated." [*See* Section 97435(c)(9).] We recommend that OHCA review the regulation and correct instances where non-defined terms were used in error. We also recommend that when using defined terms OHCA capitalize the term to make it clear to the reader that OHCA is referring to a defined term.

2. We appreciate that OHCA added Section 97440, Request for Expedited Review, as Sutter recommended in its August 31, 2023, Comment Letter. We believe having an expedited process when a health care entity is in severe financial distress is necessary. We do, however, recommend a few modifications to this new section, as follows:

    - This section does not include a timeframe for OHCA to notify the submitter if OHCA is denying or approving the expedited request. While the requester is to include the date by which the submitter requests OHCA complete the filing review in its entirety, it is unclear if

an approval for expedited review means OHCA agrees to the submitter's requested deadline. We recommend that Section 97440 include a requirement for OHCA to respond to the submitter within 72 hours as to whether expedited review will be granted or denied. If granted, we recommend the response specify if OHCA will be able to meet the expedited timeline requested by the submitter, and if not, state when OHCA anticipates it can complete its expedited review. Having a swift response time to the request and date certain for review completion will be imperative to the distressed party's determination as to its ability to hold off on a bankruptcy filing and continue forward with the proposed transaction.

- We concur with the recommendation of America's Physician Groups ("APG") that the definition of severe financial distress should be revised from "grave risk of immediate failure," to include, "a risk of business failure and demonstration of the likelihood of insolvency or bankruptcy within twelve months."

- We also concur with APG's recommendation that an additional criterion for expedited review should be added where the health care entity is complying with another state agency's directive to increase its provider network to meet statutory or regulatory network adequacy or timely access requirements.

3. Sutter reiterates its comment that the flat dollar thresholds proposed in Section 97435 (c)(1)-(2), of $25 million and $10 million, do not comply with the authority OHCA was granted in California Health & Safety Code Section 127507(c). In Section 127507(c)(1), as to assets, the legislature provided that a health care entity only needs to file a written notice with OHCA if the transaction disposes of, "***a material amount of its assets to one or more of the entities***." Any flat dollar amount may be immaterial when viewed in the context of the assets or operations of the actual health care entities within the transaction. We believe the only way to comply with the requirement that the transaction involve a material amount of a health care entity's assets before a filing is required is for there to be a percentage-of-assets based threshold.

4. Sutter appreciates that OHCA removed the definition and references to MSO's within the draft regulations. However, we do not believe OHCA has the authority to add the newly expanded definition of health care entity which replaced it.

   OHCA revised the definition of "Health care entity" in Section 97431(g)(3) to read as follows:

   > (3) Include any parents, affiliates, subsidiaries, or other entities that perform the functions of a health care entity and either:
   >
   > (i) control, govern or are financially responsible for the health care entity or
   >
   > (ii) 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 rates, or developing networks

   This definition is confusing and circular. For example, OHCA has defined health care entity as one that performs the functions of a health care entity. But more importantly, it is not within OHCA's authority to expand the clear and concise statutory definition of "health care entity," in

the promulgating statute. The Legislature already defined and specified the entities which are "health care entities." California Health & Safety Code Section 127500.2(k) defines "health care entity," as, "a payer, provider, or fully integrated delivery system." Section 127500.2 also individually defines "payer," "provider" and "fully integrated delivery system." The Legislature was clear as to the application of the law, yet OHCA continues to try to expand the scope of the statute application to add entities to which the Legislature did not intend these requirements apply. We recommend that OHCA limit the definition of health care entity to the exact definition set forth in California Health & Safety Code Section 127500.2 as no additional clarity is necessary as to which entities the Legislature intended within that definition.

5. Sutter continues to recommend that Section 97439(d) be revised for certain common documents to be deemed as subject to confidential treatment based on the very nature of the document, as is done when filing with other California regulatory agencies. While we appreciate that OHCA now desires information from a requestor as to whether another state or federal agency deems the filed document confidential and for what period of time, the regulation does not require OHCA to likewise deem the documents confidential and still requires the requestor set forth other lengthy justifications for confidentiality, which was likely already weighed by another agency. We recommend that if another state or federal agency has deemed a document confidential, this is the only information necessary for OHCA to match the scope and timing of the confidentiality.

6. Sutter is concerned that OHCA is requiring speculative or prospective information to be filed pursuant to Section 97439 under penalty of perjury. By its very definition an oath under penalty of perjury is a sworn declaration that ***recites facts***. Where projections, expectations, potentiality, or information about an entity which is not the submitter or under common control with the submitter is requested, a health care entity can do no more than submit based on information and belief. We recommend that OHCA clarify that data and factual statements only are submitted subject to penalty of perjury, while those items OHCA requests the submitter speculate upon be based on the submitter's information and belief and not be knowingly false.

In addition to the above recommendations, it also critical to recognize the ongoing need for additional healthcare access points and more primary care and specialty care providers in communities across Northern California. We have prioritized meeting such needs by significantly investing in graduate medical education (GME) programs to strengthen the physician pipeline. We have committed to quadrupling our GME program to eventually train 900 residents annually as part of an aggressive clinician recruiting and training strategy designed to help us serve growing communities and we are on pace to hire 650 physicians in this year alone.

Further, we recognize the landscape of healthcare is shifting and our aim is to meet patients where they are, maximizing efficiency and convenience. We are embarking on an ambulatory care center expansion model over the next several years, and plan to open care centers in multiple locations to help patients access services closer to home and outside of acute settings.

We share your view that patients deserve access to high quality and affordable care. That is why we embrace a preventive and predictive "whole-person" health approach that integrates mental health, proactive chronic disease management, care navigation support, and improved primary care and digital health access.

We look forward to continuing these important conversations and thank you for allowing us the opportunity to provide our comments and suggestions to further clarify the intent of the statute and regulatory authority of the Office. We would be happy to meet if you have any questions regarding these comments.

Sincerely,

Grace Davis
Senior Vice President & Chief External Affairs Officer
Sutter Health

Cc: Members, OHCA Board

October 17, 2023

Megan Brubaker
Office of Health Care Affordability
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Sent via email to CMIR@hcai.ca.gov

Re: Promotion of Competitive Health Care Markets; Health Care Affordability (CMIR) pre-notice public draft of proposed emergency regulations, revised October 9, 2023

Dear Ms. Brubaker:

On behalf of our nearly 50,000 physician and medical student members, the California Medical Association (CMA) thanks the Office of Health Care Affordability (OHCA) for the opportunity to comment on OHCA's pre-notice revised draft regulations: Promotion of Competitive Health Care Markets; Health Care Affordability (CMIR). The second draft of the proposed emergency regulations seeks to implement the Cost and Market Impact Review (CMIR) process established by Health and Safety Code (HSC) section 127507 *et seq*. (added by SB 184 (Stats. 2022, ch. 47, § 19)), which direct the Office to promote competitive health care markets by analyzing mergers, acquisitions, or other transactions that are likely to have "significant effects" on the health care market.

CMA appreciates the revisions OHCA made in its October 9, 2023 draft. The revisions address some of the concerns CMA identified in our August 31, 2023 comment letter, as well as the public comments we made at meetings of the OHCA Public Workshop and the Health Care Affordability Board.

We reiterate the general comments outlined in our August 31, 2023 letter, and offer the following additional comments to ensure the CMIR program is implemented in a manner consistent with the language and intention of the authorizing statutes—to promote competition, affordability, and the state's ability to meet cost targets.

I. Draft Proposed § 97431. Definitions

A. (a) Affiliation/affiliate

CMA supports clarifying the definition of "affiliation" and "affiliate" to exclude clinical trials and other training, education, and research programs. These types of affiliations are unlikely to have a significant impact on market competition or costs, and are outside the types of

transactions contemplated by HSC section 127507(a). So it is appropriate to exclude them from the definition of one of the types of transactions that may trigger a material change notice filing.

B. (g) Removal of explicit mention of MSOs from the definition of "health care entity," but with the addition of language that includes MSOs and IPAs

CMA supports deleting former paragraph (g)(3), which attempted to include management services organizations (MSOs) as a type of "payer" for purposes of the draft regulations. This revision is more consistent with the language and intent of SB 184, in which MSOs were intentionally excluded from the definitions of "payer" (HSC § 127500.2(o)) and other types of "health care entity." The revised draft also deletes the definition of MSOs in former paragraph 97431(j).

However, the addition of language in current draft subparagraph (g)(3)(ii) appears to undermine the intent of both the statute and OHCA's apparent intent in deleting the MSO provisions in the draft proposed regulations. New paragraph (g)(3), as revised, appears to be an attempt at sweeping MSOs and independent physician associations (IPAs) back into the scope of the regulations after removing explicit mentions of them from the revised draft.

MSOs serve as an administrative arm for medical groups. They do not contribute to drivers of health care costs. There is no value in subjecting transactions involving MSOs to a potentially onerous, costly, and time-consuming regulatory review process. Moreover, attempting to directly subject MSOs to CMIR not only contradicts the statutory language, it undoes the agreement made with the Administration during the final negotiations on the enabling legislative.

CMA strongly urges OHCA to delete the new language added in (g)(3)(ii) ("such as an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks"):

> (g) "Health care entity" shall:
>
> [* * *]
>
> (3) Include any parents, affiliates, subsidiaries, or other entities that perform the functions of a health care entity and either:
>
> (i) control, govern, or are financially responsible for the health care entity or
>
> (ii) 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~~; and
>
> [* * *]

C. (h) Definition of "health care services"

The definition of "health care services" in the draft regulations is so broad it is not focused on market competition and includes:

- Performance of functions to refer, arrange, or coordinate care;
- Equipment used such as durable medical equipment, diagnostic, surgical devices, or infusion; and
- Technology associated with the provision of services or telehealth, electronic health records, software, claims processing, or utilization systems.

CMA recommends removing these components from the definition as these items have nothing whatsoever to do with mergers, acquisitions or changes of control or governance of health care entities. They also do not have a clear impact on market competition or cost, particularly administrative functions such as referral and coordination of care, or tools required to meet regulatory requirements such as electronic health records and claims processing software.

D. (j) Material change transaction: Exclusions

We appreciate OHCA's attempts to narrow the definition of "material change transaction" by adding exclusions for two types of scenarios: (1) transactions in the regular course of business, and (2) transactions between existing corporate affiliates/subsidiaries or corporate restructuring.

With respect to draft proposed paragraph (j)(1), it is unclear which types of transactions the language contemplates. It would be helpful to clarify by adding a non-exhaustive, non-exclusive list of examples to provide some consistency and predictability in the sorts of transactions that would fall under this exclusion.

We also believe these two carve-outs do not go far enough to exclude the range of transactions that are not "likely to have a significant effect" on the health care market, such as plan-provider network contracts, plan-to-plan contracts, risk delegation contracts between plans and risk-bearing organizations or other delegated groups, contracts for health IT and electronic health record services, the purchase or financing of medical equipment purchases, or real estate transactions involving properties used in connection with a location where health care services are provided. Sweeping these contracts into an onerous and potentially lengthy regulatory review process will interfere with the ability of plans, providers, and healthcare facilities to comply with myriad regulatory requirements.

Consistent with Oregon's implementing Health Care Market Oversight Program regulations, we recommend also excluding "medical services contracts":[1]

> (j) "Material change transaction," as used in section 12507(c)(1) of the Code, shall mean a transaction (as defined in this section), which meets the requirements of section 97435(c). "Material change transaction" does not include:
>
> [* * *]
>
> (3) A medical services contract or an extension of a medical services contract. A "medical services contract" means a contract to provide health care services entered into by one or more payers, providers, fully integrated delivery systems, or other entities that provide or arrange for the provision of health care services.

II. Draft Proposed § 97435. Material Change Transactions

A. (a) Material change notice filing timeline: Transaction closing date

CMA appreciates clarifying the timeline to file a material change notice is based on the expected closing date of the transaction. This language is more precise and better understood than the "entering into" construct used in the previous draft.

B. (b) Material change notice filing: Who must file

We support the revisions made to draft subdivision (b), clarifying that a party is only required to file a notice if that party meets the entity thresholds in (b). This is a more judicious approach than imposing a notice filing requiring on all parties to a transaction when any one of them meets the thresholds in (b).

1. (b)(1)-(2) Entity materiality thresholds: Revenue and asset thresholds

We continue to have concerns, however, about the revenue and asset thresholds in (b)(1) and (b)(2). We do not believe copying the materiality thresholds of Oregon[2]—rules that have been in effect for less than year, in a state with a vastly different health care market, size, population, economy, and cost of living—is appropriate in California. California's gross domestic product is nearly 12 times that of Oregon.[3] Its total population is nearly 10 times

[1] Or. Admin. R. 409-070-0020(1)(b), (2) (2022), https://secure.sos.state.or.us/oard/view.action?ruleNumber=409-070-0020.
[2] Or. Admin. R. 409-070-0015(1) (2022), https://secure.sos.state.or.us/oard/view.action?ruleNumber=409-070-0015.
[3] U.S. Bureau of Economic Analysis, SAGDP2N Gross domestic product (GDP) by state (2022 GDP: California $3.6 trillion vs. Oregon $235 billion).

greater.[4] And California has a far more complex health care ecosystem with a substantially larger economic footprint.

Oregon is still in its first year of implementing its health care market oversight program. So there is limited data to judge how successful these thresholds have been in Oregon in capturing only the more significant health care transactions in its state, and not inundating the Oregon Health Authority with a volume of irrelevant transactions unlikely to have a negative impact on health care access or affordability. Any success Oregon's materiality thresholds may have in weeding out insignificant transactions is unlikely to occur if applied in California. Given the significant differences between the two states' health care economies, using Oregon's materiality thresholds in California is likely to capture a much greater number of transactions that are not "likely to have significant effects" on California's health care market. It is imperative to adjust these thresholds accordingly given California's substantially larger economy and higher cost of living.

To that end, we strongly recommend raising the materiality threshold in draft paragraph (b)(1) to a level that will carve out transactions between health care entities that have a smaller economic footprint, relative to the size of California's health care market.

We also recommend eliminating draft paragraph (b)(2), which would impose a filing requirement on a smaller entity when transacting with a larger entity who already triggers a filing under (b)(1). This threshold duplicates filing workload and regulatory costs which will ultimately get passed down to the market and affect the affordability of health care for consumers and purchasers. OHCA would receive any relevant information it needs to determine the need for a CMIR (and if warranted, information to conduct the CMIR) from the larger health care entity. Imposing a separate filing requirement on the other party in the transaction imposes a significant regulatory burden with very limited value in terms of new information available to OHCA.

Many of the material change notice components described by subdivision (c) of draft section 97439 call for the filing entity to provide the required information or documentation not just for the entity itself, but for all parties to the transaction. For example, paragraphs (c)(8) and (9) of draft section 97439 direct an entity that is required to file a material change notice, to submit extensive financial statements and documentation, and corporate governance documents for "all entities that are parties to the transaction." So imposing a separate filing requirement for a second, smaller entity in a transaction where one entity is already required to file will simply result in two entities submitting largely duplicate information to OHCA, doubling the cost and burden on both the entities and OHCA in the process.

[4] U.S. Census Bureau, https://www.census.gov/quickfacts/fact/table/CA,OR/INC110221 (2022 population: California 39 million vs. Oregon 4.2 million).

The breadth of the notice content requirements only underscores the need to streamline the filing process into a single consolidated filing. Accordingly, CMA recommends deleting paragraph (b)(2) of section 97435:

> (b) Who must file. [...]
>
> [* * *]
>
> ~~(2) 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 involved in a transaction with any health care entity satisfying subsection (b)(1); or~~
>
> [* * *]

Increasing the materiality thresholds will allow OHCA to focus its resources on performing meaningful reviews of the material change notices it receives by eliminating relatively insignificant transactions from its purview. This approach will also enable OHCA staff to develop and hone subject matter expertise more quickly because staff can spend more time studying transactions of larger entities.

2. (b)(3) Entities in health professional shortage areas

The revised draft deletes language that previously tied this entity trigger to whether a health care entity serves at least 50% of the patients residing in a health professional shortage area. While this revised criterion may make it easier for entities to ascertain whether they trigger the requirement under (b)(3), CMA remains concerned that this threshold may inadvertently discourage providers from establishing practices and clinics in professional shortage areas.

CMA recognizes that OHCA's intent is not to decrease access to health care or to exacerbate existing inequities, but anything that disincentivizes physicians and others from providing care in rural areas or health professional shortage areas is something that should be avoided. Accordingly, we request that you delete paragraph (b)(3) of draft § 97435.

C. (c) Circumstances requiring filing

We recommend expressly incorporating the requirements of (b) ("Who must file") in draft subdivision (c), to clarify these thresholds serve as an additional layer of criteria that must be met to trigger a material change notice:

> (c) Circumstances requiring filing. A transaction to which a health care entity who must file a written notice pursuant to subdivision (b) is a party, constitutes a material change transaction pursuant to section 127507(c)(1) of the Code if any of the circumstances in paragraphs (1) through (10) below exist.

Furthermore, as a general comment, some of the triggers in draft subdivision (c) are overly broad because they are not tied to the business of healthcare. If a health care entity that

meets one of the thresholds in draft section 97435(b) pursues side businesses unrelated to the provision of health care services, as part of a diversified business portfolio, any transactions that might generate over $10 million in annual revenue over an undefined period of time would require regulatory review—a barrier not applicable to other non-health care actors in the market. CMA urges OHCA to limit all triggers to those directly related to or stemming from the provision of health care services.

CMA also believes transactions involving the sale, acquisition, or other transfer or disposition of a health care entity or asset outside of the state of California should be exempted from the regulation. The transaction of a California entity for assets or services located outside of California should not be subject to regulatory review by OHCA. Prohibiting or interfering with such transactions raises constitutional concerns about interference with interstate commerce. Accordingly, we urge OHCA to expressly exempt transactions involving out-of-state assets or business from material change notice filing and CMIR review requirements.

1. **(c)(2)-(3), (5)-(7) California-derived revenues and California assets**

We appreciate the attempt to clarify and narrow the scope of some of the circumstance-based triggers to "California-derived" revenues. These thresholds, however, are still vague and ambiguous, especially when considering how they would apply to revenues earned from financial instruments such as stock investments, bonds, and other forms of revenue that are not generated by a physical asset or in-person services.

The scope of these triggers is also overly broad because it is not limited to revenue derived from health care services. If a health care entity seeks to acquire or invest in a side business unrelated to health care services, such as a car dealership, or real estate that is not specific to health care settings, and the acquisition or investment is expected to generate at least $10 million in "California-derived" revenues per year, the entity would be subject to a material change notice filing pursuant to draft paragraph (c)(2), even though the transaction is unlikely to have any significant impact on the health care market. This broad application would put health care entities at a regulatory disadvantage compared to non-health care entities when contemplating a business transaction unrelated to health care services. It seems inconsistent with the purpose of the CMIR authorizing statutes. Requiring filings for such transactions is unlikely to help further OHCA's mandate to research and promote competitive and lower costs in the health care market.

Furthermore, the draft provisions do not indicate over what period the specified revenue increases would have to occur to meet the threshold—whether it is limited to the immediately following 12 months, or an open-ended period. The paragraphs are notably silent on the period of time, making it unclear and difficult to determine whether a transaction meets any of these revenue increase–based triggers.

To address the above concerns, we recommend the following changes to these provisions:

- Tie all revenue thresholds to annual revenues obtained from the delivery of health care services in California. For revenue-based thresholds, eliminate the absolute dollar value thresholds and use only percentages of increased revenue.
- With respect to assets, limit the thresholds to real assets used in the provision of health care services, such as land and buildings used as sites of delivering health care services.
- Specify the time frame in which the threshold increase must be likely to occur to trigger a notice filing.
- Exclude revenues from investment products such as equities and other financial instruments that are not directly related to the provision of health care services.

2. (c)(8) Form of ownership changes

This draft paragraph is overly broad and vague. We recommend limiting this trigger to changes in the form of ownership from a physician-owned to private-equity and going-private transactions. There is no benefit to reviewing changes in the *forms* of ownership that do not significantly change the underlying owners of an entity.

> (8) The transaction changes the form of ownership of a health care entity that is a party to the transaction~~, including but not limited to change~~ from a physician owned to private equity-owned, or from a ~~and~~ publicly held to a privately held form of ownership.

3. (c)(9) & (10) Related or similar transactions over the past 10 years

Draft paragraph (c)(9) would appear to capture repeat contracts that are renewed every one or more years, such as payer-provider network contracts that are often renewed multiple times over the course of ten or more years. We recommend shortening the lookback period from ten years to five years, limiting the provision to acquisitions, and setting a minimum total transaction value threshold for the transactions that occur over the course of that period.

Draft paragraph (c)(10) is even broader, construing multiple transactions between one entity and other unrelated parties to constitute a single transaction, simply because one party has previously closed a similar transaction with another entity that provides the same or similar health care services. While this provision appears targeted at identifying market consolidation, the lack of transaction thresholds coupled with a long lookback period make this unduly broad. Under the statute, OHCA is to focus on transactions that are truly material and likely to have a significant impact on the health care market. We recommend adding a deal size threshold for past deals, as well as shortening the period from ten years to five years.

D. (d) Revenue

We reiterate the concerns raised for paragraphs (c)(2) and (c)(5)-(7) above, here for draft subdivision (d).

We also note that subdivision (d) only defines "revenue" for purposes of subdivision (b) (entity materiality thresholds). It does not apply the same definitions for purpose of subdivision (c) (transaction circumstance materiality thresholds). This leaves "revenue" undefined for one subdivision of the draft rule, suggesting the intention of applying different definitions or standards to the same term in two parts of the same rule.

The use of inconsistent definitions for the same term or concept in the same regulation is deeply concerning. OHCA should use the same definition for "revenue" throughout these regulations.

E. (e)(3) Control, responsibility, or governance

Paragraph (e)(3) defines a transfer of control, responsibility, or governance to include a transfer of 25% or more of "the administrative or operational control or governance of the management and policies" of a health care entity. CMA reiterates the concern in our August 31, 2023 comments that it is unclear what constitutes "administrative or operational control or governance." Even with the addition of "management and policies," it remains uncertain how an entity would quantify the administrative/operational control or governance that would be transferred to determine if a contemplated transaction would trigger the percentage transfer threshold and require a material change notice. We urge OHCA to eliminate this paragraph unless it can provide more clarity around how entities and OHCA would apply and test for this criterion.

III.Draft Proposed § 97439. Material Change Notice Filings

CMA reiterates its concerns with the broad and extensive list of information required as part of the material change notice filings. While this section was revised, it is no less burdensome than the original draft, including elements that are vague or call for open-ended narrative descriptions. The onerous nature of the requirements of what is supposed to be a preliminary notice, coupled with Office's infinite ability to toll the 60-day timeline to complete its review of the notice, will immediately disadvantage smaller entities in the market to the benefit of large, better-resourced entities with the means to afford the high regulatory costs to prepare these notice filings. The result will be to hinder competition by creating an insurmountable barrier to entry for smaller health care entities.

The potential costs, delays, and uncertainty around the ability of parties to execute transactions as a result of the draft regulations could thwart the primary remit of the office (reducing costs and promoting competition) by adding substantial new costs to California's health care market, increasing barriers to entry, and making transactions more difficult and costly. An overly broad scope hurts smaller and mid-sized entities contemplating a joint venture or other transaction that could otherwise improve competition. Some smaller entities may not survive as a result of the added costs and difficulty to enter into a transaction with a strategic partner. Larger health care entities are likely to benefit. These

potential impacts underscore the need to take a deliberate and measured approach in implementing the Office's cost and market impact review program.

We urge OHCA to consider drastically paring down the content of the material change notice to strike a better balance between its need to analyze market trends and transactions, and its purpose of increasing competition and curbing the growth of health care costs in the state. Alternatively, if OHCA is unwilling to alter the requirements of its material change notice filing, it must seriously consider narrowing the scope of entities and circumstances that trigger notice filings.

IV. Draft Proposed § 97440. Request for Expedited Review

The revised draft provides expedited review in the case of severe financial distress or a significant reduction in the provision of critical health care services within a geographic region. CMA supports the addition of an expedited review process.

The regulations should permit expedited review in other circumstances as well. HSC section 127501.2(a)(3)(B) allows the Office to adopt expedited timelines, as warranted, depending on the nature of the agreement or transaction. Additional circumstances where expedited review may be appropriate include instances where a transaction that triggers a material change notice filing is necessary for one or more health care entities to fulfill regulatory compliance requirements.

We also recommend revising paragraph (b)(3) to delete "immediate" in "grave risk of immediate business failure." A health care entity may be at grave risk of business failure in the short- or medium-term, but may have the ability to continue operations from some period of time before reaching the point of failure. Entities in this circumstance can start exploring transactions to prevent business failure perhaps several months in advance, because while distressed sales may occur on a timeline that is relatively fast in the health care market, they do not often happen "immediately."

To prevent pushing entities in this situation to the brink to wait for financial insolvency to become increasingly immediate before their can seek an expedited review, we recommend deleting "immediate" in (b)(3) as well as "immediately" in (d) to allow entities who are facing severe financial distress to begin exploring distressed asset sales as early as possible while still qualifying for expedited review to increase the chances of avoiding disruptions to patient care.

> (b) A submitter shall demonstrate that ~~either~~ one or more of the conditions in subsections (b)(1) ~~or~~, (2), or (3) exist to obtain expedited review:
>
> [* * *]

(3) The transaction is necessary for the health care entity to meet one or more regulatory compliance requirements.

~~(3)~~(4) As used in subsection (b)(1), "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 waiver and the transaction is necessary to ensure continued health care access in the relevant markets.

[* * *]

(d) The Office will grant or deny the request based on whether the submitter has sufficiently demonstrated conditions for expedited review exist and the transaction is ~~immediately~~ required to mitigate such conditions.

V. Draft Proposed § 97441. Review of Material Change Notice; Decision to Conduct Cost and Market Impact Review

A. (a) Office determination whether to conduct a CMIR

CMA previously raised concerns about the use of vague, discretionary language in describing when a transaction would warrant a CMIR. While the draft regulations were revised to replace one "may" with "shall" in paragraph (a)(2), all of the subparagraphs under (a)(2) retain the same language. One of the main purposes of regulations is to make a statutory requirement more specific. (Gov. C. § 11342.2.)

However, instead of making the statutory mandate of HSC section 127507.2(a)(1) more specific, this subdivision continues to provide a vague set of standards for when a transaction warrants a CMIR. The factors in paragraph (a)(2) of the draft section are drafted in such uncertain, open-ended terms, that the parties directly affected by these draft regulations would have no reasonable understanding of whether a transaction is likely to advance to CMIR. The Office's CMIR determination would be a highly subjective and arbitrary process, which invites an inconsistent application of standards and potential legal challenges over alleged abuse of discretion. The continued use of "may"—which expresses possibility, not probability, propensity, or likelihood—in many of the subparagraphs under paragraph (a)(2) makes these factors applicable to practically any transaction. Thus, the scope of transactions that could be deemed to meet "any one" of these open-ended, vague factors is boundless, and much broader than the statutory bar of transactions that are "likely" to have a "significant" impact on competition, costs, and cost targets.

CMA again urges OHCA to provide greater clarity and transparency around the standards the Office will use to decide when a CMIR is warranted, and to ensure those determinations are not made in an inconsistent and arbitrary manner.

B. (b) Timing of review of notice

CMA continues to have concerns about the limitless ability of OHCA to indefinitely toll the 60-day review timeline at any time simply by requesting additional information for the parties, regardless of whether that information is required by statute or regulation to be disclosed as part of the material change notice.

This open-ended ability to request additional information, pursuant to draft paragraph (b)(2), makes it even less clear when parties can reasonably expect a notice to be considered "complete" and the 60-day review timeline would come to an end. This is further exacerbated by the office's ability to toll the deadline indefinitely with requests for additional information, including data not required as part of the material change notice filing as described in draft section 97439.

We urge OHCA to limit its information requests to those things specifically required in the rule describing the material change notice filings, and limit the length of time for review to 30 days, consistent with Oregon's timeline for preliminary reviews of material change notices.[5]

VI. Fees

The statute directs the Office to adopt regulations that, in part, establish appropriate fees. (HSC § 127507(c)(3).) The revised draft regulations continue to remain silent on fees, with the exception of a vague reference in draft section 97439(f) to the Office's ability to "collect any costs incurred in connection with any reviews up until the first business day after the withdrawal notice is received…."

CMA reiterates its concern at the lack of transparency in proposing fees as part of the rulemaking process where OHCA establishes the standards and parameters that will dictate the Office's workload and cost recovery needs. The contemplated filing fee structure should be included in these regulations to allow for an informed discussion by the OHCA Board and stakeholders as they consider the Office's proposed approach to implementing this program.

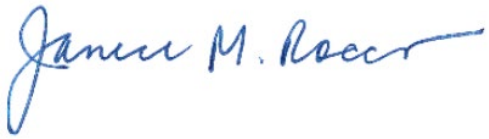
CMA appreciates OHCA's outreach to stakeholders, and its work to incorporate some of the feedback CMA and other stakeholders provided since the circulation of the first pre-notice draft proposed regulations in July 2023. OHCA's CMIR program, implemented correctly, has the potential to bring attention to certain transactional trends in the health care market that have contributed to market consolidation and decreased access and affordability. This process, however, also has the potential to hamper competition by making health care transactions too costly and onerous for small and mid-sized health care entities, like physician practice groups and clinics. It is imperative that a law enacted to promote health

[5] Or. Admin. R. 409-070-0055 (2022), https://secure.sos.state.or.us/oard/view.action?ruleNumber=409-070-0055.

care competition and contain cost growth not be implemented in a manner that directly thwarts its primary purpose.

OHCA has many years of emergency rulemaking authority to build on its implementation of the CMIR program. CMA recommends that OHCA use this time to take a measured approach.

Sincerely,



Janice Rocco
Chief of Staff
California Medical Association

Cc: Members of the Health Care Affordability Board

October 17, 2023

Vishaal Pegany, MPH, MPP
Deputy Director
Office of Health Care Affordability
2020 E. El Camino Ave.
Sacramento, CA 95833

RE: The California Health Care Quality and Affordability Act ("SB 184") and the Office of Health Care Affordability's ("OHCA's") Revised Draft Emergency Regulations

Deputy Director Pegany:

I am writing on behalf of the American Investment Council ("AIC") to discuss OHCA's revised draft emergency regulations ("Revised Regulations"), which were published on October 9, 2023.

As you know, AIC is an advocacy and resource organization established to develop and provide information about the private investment industry and its valuable contributions to the long-term growth of the U.S. economy and retirement security of American workers. We have supported and continue to support the State of California's efforts to enhance transparency through additional disclosure of health care merger & acquisition information and are grateful to OHCA for the opportunity to continue an open dialogue. We appreciate the efforts the Office has taken to consider and address many of the concerns AIC and other stakeholders in the health care community have identified: for example, that OHCA has made tremendous strides in clarifying the notification process for transacting parties, as well as taking steps to appropriately narrow the scope of affected health care entities.

We remain concerned, however, that aspects of the Revised Regulations may inadvertently expand beyond the legislature's intent and the letter of the law and could reduce productive investment and the delivery of affordable, high-quality health care services in the California health care market. To further assist OHCA in its implementation of SB 184, we respectfully offer the following comments:

I. OHCA has Clarified the Timeframe for the Submission of Notice.

OHCA's Revised Regulations expressly clarify that the phrase "entering into an agreement or transaction" refers to a transaction's *closing* date, rather than its signing date. We appreciate this important clarification, which will allow transacting parties to more easily comply with the statute.

II. Consider Limiting the Scope of "Health Care Entities" in Accordance with the Statute's Narrow Definition.

SB 184 defines the term "health care entities" to mean "payers, providers, and fully integrated delivery systems" (i.e., entities that focus on providing direct patient care).[1] The initial draft regulations expanded the legislature's intent by stating that the definition of "health care entities" includes any entities that "control, govern, or are financially responsible for a health care entity." As we have discussed, the statute states that OHCA may consider "affiliates, subsidiaries, or other entities that control, govern, or are financially responsible for the provider," but only in the context of determining whether an entity meets the definition of *"Exempted Provider"* (i.e., a health care entity *exempted* from regulation).[2] The language was aimed at guiding the Office's determination of whether an entity meets the statutory definition of a "health care entity;" its purpose was not to provide the Office with a right to regulate *non-health care entities.*

In line with SB 184's statutory definition, OHCA's Revised Regulations should aim to ensure non-health care entities are not inadvertently made subject to notice filing requirements. OHCA's Revised Regulations helpfully clarify that the definition of "health care entities" includes any "parents, affiliates, subsidiaries, or other entities that *perform the functions of a health care entity.*"[3] We appreciate this important clarification, which appears to exclude any non-health care entities with a mere tangential ownership interest in or financial responsibility for a "health care entity." Additionally, to avoid improperly broadening the statute's scope, the Revised Regulations have appropriately removed all references to Management Services Organizations ("MSOs") as meeting the definition of a "health care entity" (as a "payer").[4] Yet, the Revised Regulations seeks to *expand* the definition of "health care entity" to include "an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks."[5] We do not believe that this is intended, but this language can be read to capture MSOs, which may undercut the Office's tacit acknowledgement that MSOs fall outside the statutorily-prescribed definition of "health care entity." Importantly, limiting the Revised Regulations to exclude non-health care entities, such as MSOs, would not in any way impact a regulated health care entity's *own* responsibility for complying with SB 184's requirements.[6]

III. The Definition of "Material Change" Could Be Further Limited to Exclude Minor Transactions.

The Revised Regulations should aim to ensure that OHCA's review process is focused on significant transactions that present a likelihood of potential impact on health care costs and care in California. The Revised Regulations, however, propose a broad range of circumstances that

[1] Cal. Health & Safety Code § 127500.2(k).
[2] *See* the definition of "Exempted Provider" at §127500.29(g)(1).
[3] Proposed Emergency Regulation Revised Text § 97431(g)(3) [hereinafter "Revised Regulations"].
[4] Draft Proposed Emergency Regulation Text § 97431(g)(3).
[5] Revised Regulations § 97431(g)(3)(ii).
[6] We note that Massachusetts does not include parent companies or those related only by ownership interest or financial responsibility within the scope of its review of material health care transactions. Oregon, by contrast, regulates "the *parent* organization of, or [an] entity *closely related to*, an entity that has as a primary function the provision of health care items or services"; this is broader than Massachusetts' provision, but still more narrow than the proposed California regulations.

would trigger a notice filing, including that: (1) the transaction has a fair market value of $25 million or more; (2) the transaction will increase the annual revenue of any health care entity in the transaction by at least $10 million or 20% of the entity's normal California-derived annual revenue; (3) the transaction implicates 25% or more of the total California assets or operations of a health care entity; (4) the transaction implicates a health care entity that is joining, merging, or affiliating with another health care entity, affiliation, partnership, joint venture, or parent corporation related to the provision of health care services where any health care entity has at least $10 million in annual California-derived revenue; (5) the transaction involves a change of control of a health care entity (25% of the control or governance or the administrative or operational control, or the transfer of full or partial voting control of members of the health care entity's governing body); or (6) the health care entity has had a prior transaction related to the provision of health care services with the other transacting party or has made acquisitions of similar health care entities that provide the same or related health care services within 10 years.

We appreciate that the Revised Regulations make clear that revenue and asset calculations are limited to *California-derived* revenue and *California-based* assets. We also appreciate the steps OHCA has taken to narrow the definition of "Material Change" by raising certain reporting thresholds: capturing transactions that implicate 25%, instead of 20%, of total California assets or operations, as well as modifying the definition of a "change of control" to a change of 25%, rather than 10%, of the control or governance of a health care entity. These changes provide clarity for California health care entities, as well as private equity investors, as to what revenue and assets are used to calculate thresholds for notice requirements, and ensure that national transactions with little to no presence in California and *de minimis* transactions that are unlikely to impact the California health care market will not burden OHCA's limited resources.

However, it's important to note that the proposed triggers still maintain a remarkably wide scope. The scope set by the Revised Regulations will capture a very large swath of transactions and risks overwhelming OHCA with small transactions that are unlikely to materially impact health care delivery in the state. Although California's health care market is significantly larger than states with similar notification statutes, the Revised Regulations set a disproportionately low fair market value trigger. For example, Massachusetts defines "material change" to mean a transaction which will result in a provider organization having a *near-majority of market share* in a given service or region.[7] In Oregon, where expenditure in 2020 was roughly *one-tenth* that of California in the same year,[8] a review is triggered where one party has $25M+ in annual revenue and the other party has $10M+ in annual revenue.[9]

Moreover, the Revised Regulations continue to capture every transaction between a health care entity with a mere $10M+ in annual revenue that transacts with a health care entity of *any* size. We believe these provisions may unintentionally capture an extremely broad range of transactions engaged in by small businesses that do not present a risk of market impact.

[7] Massachusetts Gen. Laws, Ch. 6D, §13(a).
[8] The Kaiser Family Foundation produced a report comparing health care expenditures between states, which is available here.
[9] Oregon Revised Statute § 415.500(6)(a).

We also believe the Office's use of a 10-year look-back period overlooks the possibility that drastic changes occur in the market over the span of 10 years. Health care entities may decide to transact with the same parties over this period for vastly different reasons that do not impact competition in the market. In sum, the broad definition of "material change" is poised to create a significant administrative burden for both affected stakeholders and OHCA.

In light of the above, we ask that OHCA consider taking steps to further narrow the definition of "material change." We suggest that the fair market value threshold be raised to at least $50M+, and that assets and revenue thresholds be increased to $50M+ *or* 25% of the assets, operations, or revenue, of a California health care entity, whichever is greater. This will ensure that SB 184's notice requirements do not capture minor transactions. Further, we suggest OHCA limit the proposed look-back period to 5 years, as this will more accurately capture related transactions with a potential impact on the health care market.

IV. The Draft Regulations Could Expand the Expedited Review Process.

SB 184 provides OHCA with 60 days from receipt of notice of a proposed transaction to determine whether to conduct or waive a cost and market impact review and, moreover, instructs OHCA to adopt regulations "that expedite these timelines, as warranted, depending on the nature of the agreement or transaction." The Revised Regulations implement a limited expedited review process. We greatly appreciate the steps OHCA has taken to ensure that emergency transactions are not unnecessarily stalled. Forcing financially distressed health care entities to undergo a lengthy review process without providing an opportunity for expedited review threatens both the financial well-being of health care entities in dire need of capital and local patients which may entirely rely on a single local hospital for their health care needs.[10] Providing an expedited review process will help ensure that such vitally important health care entities receive the help they need.

Further, we believe SB 184 provides OHCA with expansive power to adopt expedited timelines for agreements or transactions that, by their nature, do not present a substantial likelihood of market impact. In addition to an expedited pathway for distressed health care entities, we strongly recommend OHCA adopt expedited review processes for other types of transactions.[11]

V. Shortening Proposed Timelines for the Finalization of OHCA's Preliminary and Final Reports Would Avoid Delaying Transactions.

SB 184 provides OHCA with 60 days from the notice date to determine whether or not to conduct an impact review, but the statute does not specify a time frame for the issuance of the preliminary or final reports. The initial draft regulations addressed these issues, in part, by providing a 10-day comment period between the issuance of the preliminary report and the final report, as well as a 90-day period to issue its preliminary report, *plus* an additional 30 days to issue its final report after the comment period. Factoring in the initial 60-day review period, and OHCA's ability to toll its review period for 45 days for requests for additional information, parties may be required to wait 225 days, or longer, for OHCA to complete its review. We appreciate the steps OHCA has

[10] *See, e.g.*, 3 California Hospitals Declared Bankruptcy This Year. Health Chains Could Keep Them Alive (August 14, 2023), available here.

taken thus far in its regulations to create a clear timeline, including by clarifying that notice for subject transactions is due 90 days before *closing*, which provides necessary transparency for transacting parties. However, we reiterate our concerns that these timelines are lengthy, and may delay transactions and jeopardize critical capital for important health care entities. Capital investment brings much-needed relief to at-risk hospitals, keeping facilities open and staff members employed. In particular, private equity-backed hospitals tend to be located in more rural areas and serve lower income populations where investment is most needed to stay operational. Private equity is also helping scale new solutions for these struggling hospitals.

To bring the proposed review periods in line with other states, we recommend OHCA amend the Revised Regulations to require issuance of the final report within 75 days after OHCA decides to conduct an impact review, with a right to extend the timeframe by a maximum of 45 days and toll the period for a reasonable time should parties not substantially comply with any additional requests for information. For reference, Oregon and Massachusetts require their respective regulatory agencies to issue final reports within 180 and 215 days from the date of notice.

The initial and Revised Regulations also allow OHCA to toll the time periods for its review while *any* other state or federal regulatory agencies or courts are reviewing the subject transaction. This is likely to substantially delay transactions and further threaten critical capital: under this framework, OHCA could toll its review of a transaction for months, or even years, while other agencies or courts conduct their respective reviews, i.e., OHCA could choose to start its own review only after such third-party reviews are concluded. We suggest that OHCA retain its ability to toll its own review pending other regulatory or court reviews, but only in circumstances where another agency's or court's review will extend *beyond* the maximum time that OHCA would have originally had to conduct its review.[11] This would ensure OHCA has adequate time to conduct a fulsome review and give transacting parties comfort that OHCA's full review will be completed no later than other regulatory reviews.

VI. OHCA Should Consider Establishing a Limitation on Reimbursable Costs.

In conducting its initial review and, if applicable, a cost and market impact review, SB 184 entitles OHCA to reimbursement by the transacting parties of all actual, reasonable, and direct costs incurred, including administrative costs. The Revised Regulations do not contemplate a limitation on the costs for which OHCA may seek reimbursement. AIC has long maintained that undefined reimbursable costs create an unpredictable financial and administrative burden for transacting parties, which could discourage dealmaking. Moreover, transactions between smaller parties may face disproportionately high fees in comparison to the value of the deal. We note that states with comparable health care transaction review statutes take a variety of approaches, but generally do not allow for completely uncapped cost reimbursements by the reviewing agency. For example, Oregon ensures that reimbursable costs are proportionate to the size of the parties, and are capped

[11] For example, consider a situation where a transaction is being reviewed by OHCA and the Federal Trade Commission ("FTC"). If the FTC completes its review during its initial 30-day review period, OHCA should not be allowed to toll its review, as the FTC's review did not exceed OHCA's maximum timeline. However, if the FTC instead initiates a second request and the timeline for review is estimated to take one year, OHCA should be allowed to toll its own review period beyond 225 days to the extent that it will still be able to complete its review by the time the FTC finishes its investigation.

at $100,000, while neither Massachusetts nor Washington recoups costs from transacting parties. New York does not impose a monetary cap on reimbursable costs, but limits such reimbursements to the retention of specific external professionals to aid in the agency's review of a transaction, such as actuaries. In order to bring SB 184 in line with comparable states, we recommend OHCA either consider creating a tiered structure for reimbursable costs proportionate to the size of the parties, or the size of the transaction, with a reasonable cap, or consider clarifying that any reimbursements due to the office shall be limited to the reasonable and necessary retention of specific third-party professionals for the performance of discrete tasks.

We look forward to working cooperatively with OHCA to address these concerns through the amendment of the Revised Regulations.

Sincerely,

Dillon Iwu
Director of Government Affairs
American Investment Council

cc: The Honorable Gavin Newsom, Governor, State of California
The Honorable Jim Wood, Chair, Assembly Health Committee
The Honorable Marie Waldron, Vice Chair, Assembly Health Committee
The Honorable Susan Talamantes Eggman, Chair, Senate Health Committee
The Honorable Janet Nguyen, Vice-Chair, Senate Health Committee
The Honorable Phillip Ting, Chair, Assembly Budget Committee
The Honorable Vince Fong, Vice-Chair, Assembly Budget Committee
The Honorable Nancy Skinner, Chair, Senate Budget & Fiscal Review Committee
The Honorable Roger Niello, Vice-Chair, Senate Budget & Fiscal Review Committee
The Honorable Akilah Weber, Chair, Assembly Budget Sub Committee #1, Health and Human Services Committee
The Honorable Caroline Menjivar, Chair, Senate Budget & Fiscal Review Sub Committee #3, Health and Human Services
Richard Figueroa, Deputy Cabinet Secretary, Office of the Governor
Rosielyn Pulmano, Chief Consultant, Assembly Health Committee
Gino Folchi, Consultant, Assembly Republican Caucus
Melanie Moreno, Staff Director, Senate Health Committee
Joe Parra, Consultant, Senate Republican Caucus
Andrea Margolis, Consultant, Assembly Budget Committee
Eric Dietz, Consultant, Assembly Republican Caucus
Elisa Wynne, Staff Director, Senate Budget & Fiscal Review Committee
Anthony Archie, Senate Republican Caucus

Purchaser Business Group on Health

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October 17, 2023

Health and Human Services Secretary Mark Ghaly, M.D.
Director Elizabeth Landsberg, Health Care Access and Information Department (HCAI)
Deputy Director Vishaal Pegany, Office of Health Care Affordability (OHCA), HCAI
Megan Brubaker, CMIR, Office of Health Care Affordability
2020 W. El Camino, Ste. 1200
Sacramento, CA

Re: Draft Revised Cost and Market Impact Review Regulations

Dear Dr. Ghaly, Ms. Landsberg, Mr. Pegany, and Ms. Brubaker,

I am writing on behalf of the Purchaser Business Group on Health to express strong support for the Cost and Market Impact Review (CMIR) program. **We endorse the core elements of the draft revised CMIR regulations, and we have several recommendations to strengthen the program consistent with the intent of the enabling legislation.**

The Purchaser Business Group on Health is a nonprofit coalition representing nearly 40 private employers and public entities across the U.S. that collectively spend $350 billion annually purchasing health care services for more than 21 million Americans and their families. PBGH has a 30-year track record of incubating new, disruptive operational programs in partnership with large employers and other health care purchasers.

Circumstances Requiring Filing: Lookback Period (p. 5)
We are concerned that the revised draft defines the types of historical transactions too narrowly. The transactions subject to filing are limited to "similar transaction(s), in the last ten years, with a health care entity that provides the same or related health care services." This appears to exclude transactions between health plans (or other non-provider entities) and hospitals or physician groups, as well as those between hospitals and physician groups. As a result, the Director would not be able to assess these transactions, many of which have resulted in higher prices and reduced access to critical services. *We recommend that the limits on the types of historical transactions requiring filing be removed.*

Change of Control Thresholds (p. 7)
It is important for the CMIR program to include all relevant entities and transactions, while minimizing the burden on small entity transactions that do not have a significant effect on affordability, quality, access, and equity. The draft revised regulations would raise the change of control threshold from a transfer of 10 percent of voting power to 25 percent. We are concerned that this would exclude transactions that would have a potentially

significant impact on affordability, quality, access, and equity. *We recommend that the 10 percent threshold in the original proposed regulations be retained.*

Confidentiality (p. 13)
There appears to be contradictory guidance on whether contract rates are considered confidential. One section says that "marked-confidential" documents – including those regarding contract rates -- are deemed confidential, but the next section says that the submitter must make a statement that the information has been confidentially maintained. It is likely that many of an entity's internal documents on contract rates are "marked-confidential", but we also know that federal regulations require the publication of contract rates, at least for hospitals and health plans, so these data have not been "confidentially maintained". *The regulations should be clarified by stating that information is confidential only if it has been confidentially maintained and is not otherwise publicly available*.

Other Elements
We support the following proposed revisions to the regulations:

- Filing exemptions for entities in a health professional shortage area (p. 4). We strongly support limiting the exemptions to areas with shortages in mental health and primary care.
- Serial acquisitions in the 10-year lookback period (p. 5). We appreciate the clarification that "related transactions will constitute a single transaction for purposes of determining the revenue thresholds".
- Decision to conduct cost and market impact reviews (p. 15). We applaud the explicit inclusion of serial transactions as well as vertical and cross-market mergers.
- Market failure and market power (p. 18). We appreciate the addition of this section to ensure that the CMIR process includes reviews for market failure or market power and is not limited to transactions.

Thank you for the opportunity to offer comments on the draft revised CMIR regulations, and please contact us if you have any questions or need additional information.

Sincerely,

William E. Kramer
Senior Advisor for Health Policy

From: Joan Allen <jallen@seiu-uhw.org>
Sent: Tuesday, October 17, 2023 5:11 PM
To: Brubaker, Megan@HCAI <Megan.Brubaker@hcai.ca.gov>
Subject: RE: Revised CMIR draft regulations- Comments requested by 10/17

Good afternoon Megan,
Thank you for the additional opportunity to comment on the CMIR regs. Please see my comments below:

Labor market considerations
I appreciate the inclusion of labor market considerations among the factors determining whether OHCA will conduct a CMIR as well as including it as a factor of consideration in the actual CMIR. That is a critical factor for ensuring that our health care system is resilient into the future.

I would encourage OHCA to go one step further and mirror the labor market disclosure requirements proposed by the FTC in their current update of pre-merger disclosure requirements. Recognizing that entities engaged in an affiliation may have previously competed for labor, the FTC is proposing collecting basic data on the largest employee classifications of each entity in a transaction as well as information about geographic areas where entities in a transaction have substantial overlap of employees.

Additionally, the proposed FTC regulations include a new section on Worker and Workplace Safety Information on the grounds that *"If a firm has a history of labor law violations, it may be indicative of a concentrated labor market where workers do not have the ability to easily find another job."* Specifically, the draft regulations would require entities to provide the following information:

Proposed FTC Regulations Require Reporting Worker and Workplace Safety Information

- Identify any penalties or findings issued against the filing person by the U.S. Department of Labor's Wage and Hour Division (WHD), the National Labor Relations Board (NLRB), or the Occupational Safety and Health Administration (OSHA) in the last five years and/or any pending WHD, NLRB, or OSHA matters.
- For each identified penalty or finding, provide (1) the decision or issuance date, (2) the case number, (3) the JD number (for NLRB only), and (4) a description of the penalty and/or finding. (source)

Confidentiality of submitted documents
I applaud the change from the previous draft to remove the broad category of "financial documents" from the types of documents for which a submitting entity can presume confidentiality under section 97439(d)(2) without following the justification process outlined at 97439(d)(3)(i-iv).

I would encourage OHCA to similarly submit contract rates, stock purchase agreements, and compensation documents to the 97439(d)(3)(i-iv) justification process rather than presuming confidentiality. In many cases, those documents

would eventually be made public through other legal requirements – such as federal requirements that make contracted rates public or existing state and federal financial disclosures. However, the tight timelines of the CMIR process mean that, in many cases, that information would only be available from other sources after the CMIR process has concluded.

The justification process as outlined at 97439(d)(3)(i-iv) is a reasonable step for entities to take in order to ensure that only the minimum necessary information is being withheld from the public. Additionally, requiring these types of documents to go through the justification process would mean that if OHCA determines the information should be granted confidential status, the public will at least have access to the justification provided and OHCA's response granting confidentiality.

Out-of-state transactions

I appreciate that the draft regulations specifically envision CMIR oversight of transaction between entities in California and those outside California. To strengthen the language at 97441(a)(2)(I), I recommend adding the reference to price increases back in to the language:

> (I) If the transaction between a health care entity located in this state and an out-of-state entity may negatively impact affordability, quality, **increase the price of health care services in California** 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.

I would also request that the requirement to identify other states currently served by the submitter be added back into the language. That requirement was struck in the updated draft at 97439(b)(3), but that information is important to help understand the full picture of a submitter's business interests. Particularly when companies may use many subsidiaries it can be difficult to trace the true parent company, and knowing in which other states a submitter operates would give at least some understanding of what out-of-state companies are seeking to enter California's health care market.

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