CIPPA
California Independent
Physician Practice Association

August 30, 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 Regulations for Material Change Transactions and Pre-Transaction Review Process

Dear Ms. Brubaker:

The California Independent Physician Practice Association ("CIPPA") thanks the Office of Health Care Affordability ("OHCA" or "Office") for its leadership in addressing the impact that market consolidation is having on the affordability and accessibility of health care services in our State. We write to provide comments on the proposed regulations OHCA published last month[1] that, when finalized, will govern the notice and review process for "material change" transactions established under Article 8 of the Health Care Quality and Affordability Act ("HCQAA").[2]

We are deeply concerned that certain aspects of the proposed regulations will have the opposite effect of what the Legislature intended in enacting the HCQAA by undermining competition and driving even more health care services into the higher cost and rapidly consolidating hospital setting. The Legislature's stated purpose in the HCQAA is to "promote competitive health care markets."[3] The flip side of that coin is equally important—OHCA must ensure that the notice and review process does not inhibit transactions that promote competition.

We are concerned that, as framed, the Proposed Regulations will have the unintended consequence of chilling health care entities, especially medical practices that are seeking to remain independent of large hospital and health systems, from pursuing transactions that would promote competition in the health care market. The complexity of the disclosure and review process, coupled with the uncertainty of when and whether health care entities will be permitted to proceed with their transactions, will result in only the largest and most well-funded health care entities—hospital systems and vertically integrated payors—having the resources to proceed through this new regulatory process.

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[1] HCAI, Office of Health Care Affordability, DRAFT Proposed Emergency Regulation Text, Promotion of Competitive Health Care Markets; Health Care Affordability (CMIR), 22 CCR 97431 et seq. (Chap. 11.5) (July 27, 2023), *available at* chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://hcai.ca.gov/wp-content/uploads/2023/07/CMIR-Regulations-for-Workshop.pdf (last accessed Aug. 25, 2023).
[2] Cal. Health & Saf. Code § 127507 et seq. (Health Care Market Trends; role of office; applicability), added by Stats. 2022 ch. 47 (SB 184), eff. 6/30/22.
[3] HCQAA, § 127507(a).

Our comments focus on aspects of the Proposed Regulations that need to be modified to ensure that OHCA acts consistent with the text and purpose of the HCQAA and does not inadvertently harm competition in the health care market. We place in bold typeface the specific changes we ask OHCA to make to the Proposed Regulations. For ease of reference, we collect all of those recommended changes in Part IX of our comment letter (pp. 13-15).

California Independent Physician Practice Association

CIPPA's members are medical group practices from across California that provide care to hundreds of thousands of patients. The physicians in CIPPA member practices are not employed by hospitals, hospital systems, health care service plans, or health insurers. They practice in *independent* medical group practices and specialize in fields such as dermatology, gastroenterology, internal medicine, oncology, ophthalmology, orthopedic surgery, and urology. CIPPA member medical group practices provide treatment for serious injuries, conditions, and diseases, including various forms of cancer, in a lower cost, outpatient setting as compared to hospitals and health systems.

I. OHCA Is Proposing to Expand the Circumstances that Require Filing of a Notice Beyond What Is Permitted Under the HCQAA.

The Legislature decided that there are only two types of agreements or transactions for which a health care entity is obligated to provide written notice, namely those that:

> (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.[4]

The Legislature did not give OHCA the authority to subject other types of agreements or transactions to the notice requirement set forth in section 127507 of the HCQAA. In fact, the Legislature was very specific about what authority it was delegating to the Office under section 127507:

> (3) The office shall adopt regulations for proposed material changes that warrant a notification, establish appropriate fees, and consider appropriate thresholds, including, but not limited to, annual gross and net revenues and market share in a given service or region.[5]

Thus, the Legislature charged OHCA with establishing standards of materiality that will trigger a notice obligation for agreements and transactions that fall into one of the two statutorily-created categories set forth in paragraph 127507(c)(1).

[4] Cal. Health & Saf. Code § 127507(c)(1)(A) & (B).
[5] Id. § 127507(c)(3).

In subsection 97435(c) of the Proposed Regulations, OHCA has gone beyond its delegated authority by proposing to expand the types of transactions for which notice must be filed. We do not take exception with the "circumstances" that require filing of a notice set forth in paragraphs 97435(c)(1), (2), (3), (6) and (7), which establish materiality thresholds for the types of transactions set forth in 127507(c)(1)(A) & (B) of the HCQAA.[6] That was the task the Legislature delegated to OHCA.

However, other paragraphs in 97435(c) do more than set materiality thresholds; they trigger notice obligations for agreements or transactions that do not fit within the two categories the Legislature established as requiring submission of a notice to OHCA. For example, the Office proposes that a transaction requires filing of a notice if

> [t]he 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.[7]

A transaction that involves an entity taking on responsibility for negotiating or administering contracts with payers on behalf of 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."[8] If the Legislature had wanted to require health care entities to submit notices to OHCA when they entered into agreements or transactions to obtain support in negotiating or administering contracts with payers, the Legislature could have included such a category of transactions in paragraph 127507(c)(1) of the HCQAA. It did not do so. **Accordingly, OHCA should strike paragraph (5) of subsection 97435(c) when it finalizes the regulations.**

Paragraph four of subsection 97435(c) as well as subsection 97435(e) are instances in which OHCA has impermissibly rewritten a portion of the statutorily-created notice obligation. As noted above, one of the two types of agreements or transactions that trigger the filing of a notice are those that "transfer control, responsibility, or governance of a material amount of the assets or operations of the health care entity to one or more entities."[9] The statutory language is clear—a transaction that "transfers control" from the health care entity to another entity (and meets the materiality threshold) triggers a notice obligation.

OHCA rewrites this statutory language to say that one of the circumstances that requires filing of a notice is a transaction that "involves a transfer *or change in* control" of the submitting health care entity as defined in subsection (e) of 97435.[10] Subsection 97435(e) similarly rewrites the

[6] See, e.g., OHCA Proposed Reg. § 97435(c)(1), (2), (3), (6), (7).
[7] Id. § 97435(c)(5).
[8] Cal. Health & Saf. Code § 127507(c)(1)(A) & (B).
[9] Id. § 127507(c)(1)(B).
[10] OHCA Proposed Reg. § 97435(c)(4) (emphasis added).

statutory language by setting out three instances in which "a transaction will transfer *or change* control, responsibility or governance."[11]

The Legislature decided that the trigger for a notice is the *transfer of control of the health care entity to another entity*,[12] yet OHCA has decided that *changes of control internal to the health care entity*—such as the substitution or addition of a member of the governing body of the health care entity—trigger the notice requirement.[13] Not only does this exceed statutory authority, it greatly expands the scope and volume of notices that health care entities will have to submit and the Office will have to review, with no correlation to the key concern of consolidation. **OHCA should modify paragraph 97435(c)(4) and subsection 97435(e) to ensure that neither provision requires a health care entity to file a notice when the transaction involves a change of control internal to the health care entity without transferring control of a material amount of the assets or operations of the health care entity to one or more other entities.**

Paragraph nine of subsection 97435(c) of the Proposed Regulations presents a somewhat different, but equally troubling, overreach on the part of OHCA. The Office proposes that the materiality threshold is met any time "a health care entity that is 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*."[14] Respectfully, we believe it is unreasonable for OHCA to subject transactions to the onerous notice requirements based solely on the grounds that another transaction—irrespective of size—might have occurred between the parties as far back as eight, nine, or ten years. **We urge OHCA to eliminate paragraph 97435(c)(9) when it finalizes the regulations.**

II. OHCA's Inclusion of a Management Services Organization as a "Health Care Entity" that Is Subject to the Notice Obligation Violates the Plain Text of the HCQAA.

The HCQAA defines the term "health care entity" as consisting of three types of entities—"a payer, provider, or a fully integrated delivery system."[15] The statute then defines those three types of health care entity. Nowhere in the HCQAA does the statute define any of those terms to include a management services organization ("MSO"). In fact, MSOs are not mentioned anywhere in the HCQAA.

The Legislature did not grant OHCA the authority to expand or otherwise modify the definition of "health care entity" to include additional types of entities that will be subjected to the HCQAA's notice obligation. Nevertheless, OHCA added an MSO as an additional type of health care entity and justified this extra-statutory action by stating that an MSO "qualifies as a payer for the purposes of these regulations."[16] But that contradicts the plain words of the HCQAA, which

[11] Id. § 97435(e) (emphasis added).
[12] Cal. Health & Saf. Code § 127507(c)(1)(B).
[13] OHCA Proposed Reg. § 97435(e)(1) & (2).
[14] Id. § 97435(c)(9) (emphasis added).
[15] Cal. Health & Saf. Code § 127500.2(k).
[16] OHCA Proposed Reg. § 97431(g)(3).

clearly state that the term "'payer' means private and public health care payers, including all of the following":

> (1) A health care service plan or a specialized mental health care service plan, as defined in the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2) or a Medi-Cal managed care plan contracted with the State Department of Health Care Services to provide full scope benefits to a Medi-Cal enrollee pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of, Part 3 of Division 9 of the Welfare and Institutions Code.
>
> (2) A health insurer licensed to provide health insurance or specialized behavioral health-only policies, as defined in Section 106 of the Insurance Code.
>
> (3) A publicly funded health care program, including, but not limited to, Medi-Cal and Medicare.
>
> (4) A third-party administrator.
>
> (5) Any other public or private entity, other than an individual, that pays for or arranges for the purchase of health care services on behalf of employees, dependents, or retirees.[17]

This finite list of payers does not provide OHCA with the discretion to add entities not expressly identified by the Legislature.[18] OHCA acknowledges that the term "'payer' shall have the meaning set forth in subsection 127500.2(o) of the Code,"[19] and yet the Office proposes to expand that meaning—and thereby expand the types of entities that must file notices of material change transactions—by stating that MSOs qualify as payers.

OHCA's definition of "MSO" in the Proposed Regulations demonstrates that an MSO is neither a "health care entity" nor a "payer." The Office defines "MSO" as providing administrative or management services for a "health care entity" such as "provider rate negotiation."[20] By OHCA's own account, an MSO provides services to a health care entity and one of those services might be engaging in provider rate negotiation with a payer. An MSO does not "qualify" as a payer just because OHCA says it does, especially when the Legislature provided a specific definition of "payer" that does not include MSOs.

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[17] Cal. Health & Saf. Code § 127500.2(o)(1)-(5).
[18] We note that in other parts of the HCQAA, including in other statutory definitions, the Legislature chose to use the words "including, but not limited to," when setting forth a list of entities, elements, or conditions. See, e.g., Cal. Health & Saf. Code § 127500.2(a)(1), (c), (o)(3), (r), (s)(3); id. §127507(a), (c)(3); 127507.2(a)(1), (2), (4). The Legislature did not use that broader language in the definition of "payer." Id. § 127500.2(o).
[19] OHCA Proposed Reg. § 97431(n).
[20] Id. § 97431(j).

Finally, other provisions of the Proposed Regulations demonstrate that it does not make sense to state that an MSO "qualifies as a payer." In listing the types of information that a health care entity must submit to OHCA as part of the notice, the Office states that if a payer is an entity involved in the transaction, the submitter must describe with respect to the payer "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."[21] It is a non sequitur to claim an MSO qualifies as a payer or as a health care entity for purposes of the HCQAA and the statute's notice obligation.

Accordingly, OHCA should modify the proposed regulations as follows:

- **Strike paragraph 97431(g)(3) (stating that an MSO "qualifies as a payer");**
- **Strike subsection 97431(j) (defining of "management services organization");**
- **Strike paragraph 97435(d)(7) (providing meaning of "revenue" for purposes of MSOs);**
- **Remove all other references to MSOs that appear elsewhere in the Proposed Regulations, including but not limited to paragraph 97435(c)(5).**

Finalizing the regulations with MSOs treated as "payers," and, therefore, as "health care entities" that would be subjected to the HCQAA's notice obligation, contradicts the plain terms of the HCQAA and is an abuse of OHCA's discretion.

III. OHCA Should Clarify that the Proposed Regulations' Revenue Thresholds Do Not Change the Statutory Exemption Provided to Medical Groups with Less than 25 Physicians.

We ask OHCA to address a tension that exists in the Proposed Regulations between the Office's definition of "health care entity" in subsection 97431(g) and subsection 97435(b), which spells out "who must file" a written notice. Consistent with the HCQAA, the Office proposes that the term "health care entity" shall "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."[22] OHCA then includes among the health care entities that must file a notice those with annual revenue of at least $25 million or that own or control California assets of at least $25 million.[23]

The requirements of "who must file" in subsection 97435(b) of the Proposed Regulations must be read in light of—and modified by—the carve out of medical groups with less than 25 physicians set forth in paragraph 127500.2(p)(5) of the HCQAA and subsection 97431(g) of the Proposed Regulations. By way of example, a 22-physican medical group with $25 million in revenue does not have an obligation to file a notice with OHCA. **We ask the Office to clarify in the Final**

[21] Id. § 97439(b)(5)(G).
[22] Id. § 97431(g).
[23] Id. § 97435(b)(1).

Regulations that the $25 million revenue threshold only triggers a notice obligation for medical groups with 25 or more physicians.

IV. OHCA Needs to Revise its Proposed Regulations on Confidentiality to Avoid Stifling Competition in the Health Care Market.

We are concerned that the lack of confidentiality pertaining to the Material Change Transaction Review Process, particularly before the Office determines that a transaction should be placed in the cost and market impact review ("CMIR") process, will have the unintended consequence of chilling health care entities from pursuing transactions that would promote competition in the health care market. We urge OHCA to modify subsection 97439(d), entitled "Confidentiality of Documents Submitted with Notice," to comply with the text and purpose of the HCQAA.

A. The HCQAA Prohibits Information and Materials Relating to a Transaction From Being Made Publicly Available Unless and Until OHCA Decides to Conduct a Cost and Market Impact Review.

OHCA's Proposed Regulation regarding the posting of information about transactions on the Office's website violates the plain terms of the HCQAA.[24] The Legislature made clear that information and materials are not to be made public (via the OHCA website or otherwise) when a health care entity submits a notice to OHCA, but only if the Office determines to conduct a CMIR. The statute makes this clear:

> (2) Written notice pursuant to paragraph (1) shall be provided to the office at least 90 days prior to entering into the agreement or transaction. *If the conditions in paragraph (1) of subdivision (a) of Section 127507.2 apply*, the office shall make the notice of material change publicly available, including all information and materials submitted to the office for review with regard to the material change.[25]

Paragraph 127507.2(a)(1) of the HCQAA provides in relevant part:

> 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, the office shall conduct a cost and market impact review….[26]

It is clear from these two statutory provisions that information and materials about a transaction are not to be made public unless and until OHCA "advise[s] the noticing health care entity of the office's determination to conduct a cost and market impact review…."[27] However, if the Office provides the noticing health care entity with a written waiver from the CMIR, then OHCA does

[24] Id. § 97439(b).
[25] Cal. Health & Saf. Code § 127507(c)(2) (emphasis added).
[26] Id. § 127507.2(a)(1).
[27] Id. § 127507.2(a)(3)(A).

not have the authority to make public any of the information or materials that the submitting health care entity provided to the Office in connection with the transaction.[28]

We cannot overstate the harm that would arise from making the 13 categories of information and nine categories of documents included in the Proposed Regulations publicly available.[29] A health care entity's economic competitors have no business learning information (or seeing documents in redacted or un-redacted form) relating to their competitor's potential transaction, especially when that transaction might not trigger a CMIR. And yet, information about the parties to the transaction, their governance and operational structure, annual revenues, the terms of the transaction, and much more would all be made public under the regulations as proposed by OHCA.

We urge OHCA to make clear in the Final Regulations that written notices, including all information and materials submitted with the notices, are to be kept strictly confidential unless and until the Office announces that it is subjecting the transaction to a CMIR and the submitting health care entity has exhausted its rights to seek review of that decision pursuant to subsection 97441(c). To this end, this clarification needs to include OHCA modifying (i) subsection 97439(b) to ensure that information and materials are not made publicly available, and (ii) subsection 97439(d) to ensure that information and documents are not to be "treated as a public record" before the Office decides to place the transaction in the CMIR process.

B. OHCA Should Make Two Additional Changes to the Confidentiality Provisions When the Office Finalizes the Regulations.

We ask that OHCA revise paragraph 97439(d)(1) to state that a submitter need only file two versions of a notice or supporting materials if there are portions of the notice or supporting materials that are not confidential and appropriate for the Office to share publicly. We fully expect that there will be many documents and entire categories of information that are appropriately deemed confidential such that there will be no portions that would remain un-redacted. It is also possible and, in fact, likely that there will be certain agreements or transactions whose very existence needs to be kept confidential so as not to provide the health care entity's competitors with knowledge of the agreement or transaction.

We also ask OHCA to revise paragraph 97439(d)(2) to include a presumption that the public interest is served in withholding particular information or documents that the submitting health care entity identifies as being important not to disclose to the health care entity's competitors in the health care market. In light of rapid hospital consolidation, driven in large part by vertical integration through which hospitals acquire independent medical groups, a rebuttable presumption should exist that information and documents submitted by a medical group regarding a transaction that will keep the group outside of the hospital setting should be deemed confidential by the Office.

[28] Id. § 127507.2(a)(1) & § 127507.2(a)(3)(A).
[29] OHCA Proposed Reg. § 97439(b)(1)-(13) & § 97439(c)(1)-(9).

V. The Requirement that a Submitting Health Care Entity Must Describe Any Prior Transaction from the Past Ten Years Should be Removed or Modified to Avoid Creating an Undue Burden on the Parties to the Transaction.

We urge OHCA to remove or significantly modify the requirement that demands the submitting health care entity to describe "any other prior transaction" that "affected or involved the provision of health care services," involved "any of the health care entities in the proposed transaction," and occurred in the last ten years.[30] As proposed, this means that all transactions that affected or involved the provision of health care services, regardless of size, have to be described even when those transactions only involved one of the parties to the transaction and even if the prior transaction would not have required the submission of a material change transaction notice had the notice-and-review program been operational at the time. OHCA is literally requiring descriptions of all transactions affecting or involving the provision of health care services for a ten year period.

At a minimum, OHCA should modify this information request to (i) require descriptions only of transactions that involved *all* parties to the new transaction and not transactions that involved *any* party, (ii) apply only to those transactions that would have been captured by the HCQAA's notice obligation had it been in effect at the time of the prior transaction, and (iii) apply only to those transactions that occurred in the last three years. OHCA has the authority to seek additional information in the CMIR process if three years of transactions proves inadequate.

VI. OHCA Should Make Additional Changes to Clarify and Simplify the Material Change Transaction Review Process

It is critical that parties to transactions know the date from which the 90 days' advance notice begins to run. The HCQAA states that a submitting health care entity shall provide OHCA with written notice 90 days prior to "entering into the agreement or transaction."[31] We agree with OHCA that it was necessary to clarify what moment represents the "entering into the agreement or transaction." Unfortunately, OHCA's proposal in section 97435 of the Proposed Regulations will lead to more confusion. There is an easier approach that we ask OHCA to adopt.

OHCA has proposed that the 90 days be measured from the date that "any parties' respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived."[32] This creates more questions than it answers. **It would be more straightforward and would avoid confusion if OHCA modifies the Proposed Regulation as follows:**

> **For purposes of paragraph 127507(c)(2) of the Code, the phrase "entering in to the agreement or transaction" refers to the closing date of the agreement or transaction.**

[30] Id. § 97439(b)(11).
[31] Cal. Health & Saf. Code § 127507(c)(2).
[32] OHCA Proposed Reg. § 97435(a).

In addition, OHCA should modify subsection 97439(e) relating to "notification of changes." As proposed, the provision requires the submitter to notify the Office within five business days if the transaction is "amended, altered, or cancelled." **A materiality element needs to be added to subsection 97439(e) with respect to the amendment or alteration of a transaction to avoid triggering additional notice requirements for de minimis amendments or alterations of the transaction.**

VII. OHCA Needs to Modify Certain Aspects of the "Timing of Review of Notice" To Avoid Running Afoul of the Text and Purpose of the HCQAA.

We appreciate the importance of OHCA having sufficient time to review materials and make informed decisions at both stages of the Material Change Transaction Review Process—when the Office is determining whether to conduct a CMIR and when the Office is engaged in a CMIR. With that said, we are very concerned that certain aspects of the timeline that OHCA has spelled out in the Proposed Regulations will jeopardize the viability of transactions simply because the review process will take too long.

One of OHCA's proposals regarding "timing of review of notice" contradicts the plain terms of the HCQAA. The Legislature provides 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."[33] 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,"[34] the HCQAA does not provide OHCA with authority to extend this 60-day period.

Despite this limitation on OHCA's authority, the Office proposes the following with respect to the initial 60-day review period:

> 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.[35]

The Legislature did not grant OHCA the authority to extend the 60-day review period, but through this proposed regulation, if finalized, OHCA would be able to extend the 60-day period indefinitely by making a series of requests for additional information. 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. 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.**

[33] Cal. Health & Saf. Code § 127507.2(a)(3)(A).
[34] Id. § 127507.2(a)(3)(B) (emphasis added).
[35] OHCA Proposed Reg. § 97441(b)(2).

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 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.**

We also ask OHCA to clarify paragraph 97441(b)(4) in which the Office proposes that "[s]hould the scope of the transaction materially change from that outlined in the initial notice, the 60-day period may be restarted by the Office."[36] OHCA does not explain what would constitute a "material change" in the transaction.

We recommend that OHCA revise paragraph 97441(b)(4) to identify specific changes that would warrant a resetting of the 60-day clock, namely (i) an entity being added to or removed from the proposed transaction; (ii) a fundamental change in the goals of the transaction; (iii) changes in the terms of the transaction that would adversely impact the public, including but not limited to an adverse impact on quality and equity measures or reduction in access to health care services post-transaction; or (iv) modifications to the contemplated post-transaction changes that had been identified in the initial notice by the submitting health care entity pursuant to paragraph 97439(b)(12).

Finally, we urge OHCA to scale back the timeframes it has proposed for engaging in a CMIR. When adding up all of the steps in the notice-and-review process outline in the Proposed Regulations, *OHCA has given itself more than seven months—and, in some instances, an indefinite period of time—to decide whether parties can proceed with their transaction*.[37] This timeframe will stifle efforts to innovate in California. For any transaction that OHCA places into the CMIR process, the Office will already have been studying the transaction for upwards of 60 days.

OHCA should revise the timeline for completing a CMIR such that (a) a CMIR shall be completed within 45 days of the final decision by the Office to conduct a CMIR, (b) the Office is only permitted one additional 30-day period if it needs additional time to complete the CMIR, and (c) the Office should not be permitted to toll either the 45-day or 30-day period to obtain additional documents or information to complete its review. Such information and documents can be requested when the Office announces that it is going to conduct a CMIR.

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

We appreciate that OHCA included a provision in the Proposed Regulations inviting health care entities to contact the Office by email with "pre-filing questions" if the health care entities are unsure whether they must file a notice.[38] However, we do not believe that this single-sentence provision is adequate, given the significance of the Material Change Transaction Review Process and the implications for health care entities that enter the Review Process.

[36] Id. § 97441(b)(4).
[37] Id. § 97441(b)-(d) (235 days when adding up the 60 days for initial review, 90 days for CMIR, 45-day extension of CMIR at discretion of Office, 10 days for comments, 30 days to issue final report).
[38] Id. § 97437.

We encourage OHCA to look to the State of Oregon for guidance in developing a more robust pre-filing process. As OHCA knows, Oregon enacted legislation in 2021 regulating material change transactions involving health care entities. The Oregon law created a new Health Care Market Oversight ("HCMO") program within the Oregon Health Authority ("OHA")—a program similar in origin and design to what OHCA is establishing under the HCQAA.[39] Last year, OHA promulgated regulations to operationalize Oregon's Health Care Market Oversight program, which took effect on March 1, 2022.[40]

We ask OHCA to adopt two aspects of the Oregon regulatory process that would make for a more robust pre-filing process than simply stating that health care entities can email OHCA with questions:

- Oregon regulations created a process for health care entities to obtain a "Determination of Covered Transaction Status" through which entities can learn from the Agency, within 30 days of submission, whether they must submit a notice of their planned material change transaction;[41] and

- Oregon regulations established a pre-filing conference option that can be requested to determine whether the proposed material change transaction requires a health care entity to file a notice (this can either be a stand-alone process or part of the Determination of Covered Transaction Status).[42]

These aspects of the Oregon regulatory program, if adopted by OHCA, would further the purposes of the HCQAA. More specifically:

Determination of Covered Transaction Status: In keeping with California's aim of addressing market consolidation while ensuring that the State does not unintentionally undermine competition, this process would enable health care entities to learn from OHCA whether a planned transaction is subject to the notice requirement under paragraph 127507(c)(1) of the HCQAA and subsection 97435(c) of the Proposed Regulations. We suggest that any such request for a Determination of Covered Transaction Status be submitted at least 120 days prior to the effective date of the planned transaction (i.e., the closing date of the transaction). Much like the regulatory program established in Oregon, OHCA would inform the submitting party within 30 days of covered transaction status.

[39] Regulation of Material Change Transactions Involving Health Care Entities, Oregon Ch. 415 – Regulation of Health Care Entities, § 415.500 et seq.
[40] Oregon Health Authority, Health Policy and Analytics – Chapter 409, Division 70, Health Care Market Oversight Program, 409-070-0000, et seq., available at https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=6980 (last accessed April 7, 2023).
[41] Oregon Health Authority, Health Policy and Analytics – Ch. 409, Div. 70, Health Care Market Oversight Program 409-070-0042, "Optional Application for Determination of Covered Transaction Status."
[42] Oregon Health Authority, Health Policy and Analytics – Ch. 409, Div. 70, Health Care Market Oversight Program 409-070-0045, "Form and Contents of Notice of Material Change Transaction."

We believe that OHCA would need to receive the following information to evaluate covered transaction status: (i) the type of entities involved in the transaction; (ii) the nature and objectives of the proposed transaction; (iii) whether any changes in health care services are anticipated in connection with the proposed transaction; (iv) whether the proposed transaction would result in an increase in the number of physicians providing health care services through a health care entity party to the transaction; and (v) whether the proposed transaction is anticipated to eliminate or significantly reduce access to services. In order to maintain the confidentiality of proposed transactions, the documents and other information submitted by a health care entity seeking a Determination of Covered Transaction Status would not be made public and would be for OHCA-use only.

Pre-Filing Conference: As Oregon has done through regulation, we encourage OHCA to make available to health care entities the option of requesting a conference prior to filing a written notice of a proposed transaction under paragraph 127507(c)(1) of the HCQAA. This would be more substantial than merely providing health care entities with OHCA's email address in section 97437 of the Proposed Regulations. The pre-filing conference would provide the health care entity the opportunity to discuss the filing process, learn whether the proposed transaction requires the entity to file a notice, and ask questions about the particular information that would need to be submitted as part of the notice obligation in paragraph 127507(c)(1) of the HCQAA.

As part of the Final Regulations, we ask that OHCA create a more robust pre-filing process that would enable health care entities to seek a "Determination of Covered Transaction Status" and/or a pre-filing conference with the Office.

IX. Summary of Requests for Action.

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

- Strike paragraph (5) of subsection 97435(c), which requires the filing of a notice for transactions that contemplate an entity negotiating or administering contracts with payers on behalf of one or more providers.

- Modify paragraph 97435(c)(4) and subsection 97435(e) to ensure that neither provision requires a health care entity to file a notice when the transaction involves a change of control internal to the health care entity without transferring control of a material amount of the assets or operations of the health care entity to one or more other entities.

- Eliminate paragraph 97435(c)(9), which states that the materiality threshold is met any time "a health care entity that is 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."

- With respect to OHCA's proposal to include MSOs as "payers," and, therefore, "health care entities," strike paragraph 97431(g)(3) (MSO "qualifies as a payer"), strike subsection 97431(j) (definition of "management services organization"), strike paragraph 97435(d)(7) (meaning of "revenue" for purposes of MSOs), and remove other references to MSOs that appear elsewhere in the Proposed Regulations, including but not limited to paragraph § 97435(c)(5).

- Clarify that the $25 million revenue threshold only triggers a notice obligation for medical groups with 25 or more physicians.

- Clarify that written notices, including all information and materials submitted with the notices, are to be kept strictly confidential unless and until the Office announces that it is subjecting the transaction to the CMIR and the submitting health care entity has exhausted its rights to seek review of that decision pursuant to subsection 97441(c). This clarification needs to include OHCA modifying (i) subsection 97439(b) to ensure that information and materials are not made publicly available, and (ii) subsection 97439(d) to ensure that information and documents are not to be "treated as a public record" before the Office decides to place the transaction in the CMIR process.

- Revise paragraph 97439(d)(1) to state that a submitter need only file two versions of a notice or supporting materials if there are portions of the notice or supporting materials that are not confidential and appropriate for the Office to share publicly.

- Revise paragraph 97439(d)(2) to include a presumption that the public interest is served in withholding particular information or documents that the submitting health care entity identifies as being important not to disclose to the health care entity's competitors in the health care market.

- Remove the requirement that a submitting health care entity must describe any prior transaction from the past ten years or, at a minimum, modify this information request to (i) require descriptions only of transactions that involved *all* parties to the new transaction and not transactions that involved *any* party, (ii) apply only to those transactions that would have been captured by the HCQAA's notice obligation had it been in effect at the time of the prior transaction, and (iii) apply only to those transactions that occurred in the last three years.

- Clarify that for purposes of paragraph 127507(c)(2) of the Code, the phrase "entering into the agreement or transaction" refers to the closing date of the agreement or transaction.

- Add a materiality element to subsection 97439(e) with respect to the amendment or alteration of a transaction to avoid triggering additional notice requirements for de minimis amendments or alterations of the transaction.

- Strike paragraphs 97441(b)(2) & (b)(3) to avoid OHCA having the power (not permitted by the HCQAA) to toll the 60-day period for the initial review.

- Revise paragraph 97441(b)(4) to identify specific changes that would warrant a resetting of the 60-day clock for the initial review, namely (i) an entity being added to or removed from the proposed transaction; (ii) a fundamental change in the goals of the transaction; (iii) changes in the terms of the transaction that would adversely impact the public, including but not limited to an adverse impact on quality and equity measures or reduction in access to health care services post-transaction; or (iv) modifications to the contemplated post-transaction changes that had been identified in the initial notice by the submitting health care entity pursuant to paragraph 97439(b)(12).

- Revise the timeline for completing a CMIR such that (a) a CMIR shall be completed within 45 days of the final decision by the office to conduct a CMIR, (b) the Office is only permitted one additional 30-day period if it needs additional time to complete the CMIR, and (c) the Office should not be permitted to toll either the 45-day or 30-day period to obtain additional documents or information to complete its review.

- Create a more robust pre-filing process that would enable health care entities to seek a "Determination of Covered Transaction Status" and/or a pre-filing conference with the Office.

****

CIPPA appreciates OHCA's efforts to address the harmful effects of health care consolidation that undermine the quality, affordability and accessibility of health care in the State. We urge OHCA to modify the Proposed Regulations as requested above so that the Material Change Transaction Review Process does not chill or otherwise undermine the ability of independent medical group practices and other health care entities to pursue transactions that enable them to continue functioning as a lower cost, competitive counterbalance to hospitals and hospital systems.

We look forward to continuing to work with OHCA as it refines the 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

HEALTH CENTER PARTNERS
of Southern California

August 30, 2023

Megan Brubaker
Engagement and Governance Manager
Office of Health Care Affordability
megan.brubaker@hcai.ca.gov

RE: Proposed Cost and Market Impact Review (CMIR) Program Regulations

Dear Ms. Brubaker:

On behalf of Health Center Partners of Southern California (HCP), representing 17 member organizations, including 12 Federally Qualified Health Centers (FQHC), 4 Indian Health Service Organizations, and Planned Parenthood of the Pacific Southwest, collectively serving 720,000 patients each year, for 3.2 million patient visits, at 190 practice sites across five counties, and with our FQHC clinically integrated network, Integrated Health Partners (IHP), managing over 355,000 lives in a value-based accountable care model, where more than 96% of our members are enrolled in Medi-Cal managed care, I am pleased for the opportunity to comment on the proposed Cost and Market Impact Review (CMIR) Program Regulations.

I appreciate the state's efforts to control increasing health care costs, which have a profound effect on the communities we serve. I share the aim to align stakeholders and consumers throughout the state by increasing access and quality care while improving population health through a health equity lens. I support DHCS' Comprehensive Quality Strategy and Bold Goals 50x2025, and CalAIM, to transform the way care is delivered in California, and to better serve our most vulnerable populations.

I would like to support the multiple efforts and initiatives being legislated through SB184 and put forward through the Office of Health Care Affordability (OCHA) and the California Department of Health Access and Information (HCAI). However, and toward that end, I have significant concerns about the size and scope of the proposed CMIR regulations, the additional administrative burden that these regulations would put on non-profit, safety-net, primary care health centers and FQHC clinically integrated networks.

Market Concerns / Dynamics

I understand the state's desire to increase transparency and control costs. Please be advised that this downward pressure to control costs, where there is already little to no margin in Medi-Cal, comes at a time of pending legislation that would increase minimum wage and reporting requirements that would drive up costs like the new MLR requirements for delegated entities, and the State's layering in of new cost programs including CalAIM+, during a period of high inflation. In addition, workforce supply side inequities, including insufficient numbers of primary care, behavioral health, and specialty care providers for a growing underserved population, are problematic. These factors place increased demands on providers' time, often uncompensated.

HEALTH CENTER PARTNERS
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It is widely known that FQHCs have a long history of serving more complex patients, with overlapping chronic conditions. This history has included addressing patients' and families' social needs. Now known more commonly as social drivers of health, FQHCs' providers' work requires additional effort and connectivity with community-based organizations and the managed care plans. More administrative burden being proposed in this way for the sake of big data is counterproductive.

FQHC/Health Center Controlled Networks

Despite the challenges and limitations of this environment, FQHCs have been able to improve patient engagement, access, and overall care quality through utilization management, care coordination, and outreach interventions to close care gaps and ensure health equity. Through the clinically integrated network, IHP, and its population health management platform, Arcadia, providers have access to data in real time to better coordinate primary and specialty care. In this way, providers share inter-agency referrals by strategically aligning with entities that share the mission to improve care, access, and outcomes.

To emphasize this point, both Blue Shield of California Promise Health Plan and Molina Healthcare of California report that IHP is their top performing patient profile in California. (See graph below.) This has been achieved by IHPs attention to efficiencies in practice design and practice workflow that drives year-over-year performance improvement. IHP's contracts are value-based with quality performance incentives that align with state and national quality standards.

Molina 2022 IPA Rates by County	San Diego: IHP	Sacramento	Inland Empire	Imperial
Breast Cancer Screening	63%	36%	50%	48%
Controlling High Blood Pressure	62%	57%	36%	29%
Cervical Cancer Screening	61%	45%	38%	47%
Chlamydia Screening in Women - Age 16-20	63%	61%	60%	60%
Chlamydia Screening in Women - Age 21-24	68%	66%	62%	61%
Childhood Immunization Status Combo 10	43%	16%	16%	31%
Colorectal Cancer Screening	50%	23%	30%	24%
Comprehensive Diabetes Care: Hemoglobin (HbA1c<=9.0)	61%	51%	54%	56%
HbA1c Poor Control >9.0% (lower is better)	*39%*	*49%*	*47%*	*42%*
Immunizations for Adolescents - Combo 2	42%	38%	31%	29%
Lead Screening in Children	76%	45%	41%	67%
Prenatal and Postpartum Care - Postpartum	83%	73%	72%	77%
Prenatal and Postpartum Care - Prenatal	84%	82%	76%	75%
Diabetes Screen for Patients w/Schizophrenia or Bipolar - Diabetes	84%	73%	77%	85%
Well-Child Visits in the First 30 Months of Life - Age 15-30 Months	60%	58%	55%	39%
Well-Child Visits in the First 30 Months of Life - First 15 Months	48%	38%	23%	62%
Child and Adolescent Well-Care Visits - 12/17 years old	50%	53%	43%	39%
Child and Adolescent Well-Care Visits - 18-21 years old	21%	25%	21%	17%
Child and Adolescent Well-Care Visits - 3-11 years old	54%	61%	47%	51%

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of Southern California

I should point out that FQHCs are required by the Bureau of Primary Health Care (BPHC) and DHCS to demonstrate cost efficiency relative to the delivery of services they provide to all patients regardless of socio-demographic characteristics, insurance coverage, or ability to pay. HCP members are NCQA or AAAHC-certified patient-centered medical homes. In addition, I should point out that, unlike private practices, FQHC primary care services include integrated mental health, dental, and social and "enabling" (non-clinical) services to increase access and improve health outcomes, delivered in a culturally appropriate manner to a broad range of persons. FQHCs must measure and report the quality of services they provide. They are required to report on the numbers and types of staff who provide services. Due to federal and state funding requirements, FQHCs are subject to additional licensing, reporting requirements, oversight, and audits by agencies that no other provider or group in the marketplace answers to.

FQHCs' Prospective Payment System (PPS) rates are pre-determined and encounter-based, set by federal statute. FQHCs only receive PPS rates if: (1) The service is defined as an allowable encounter or set of services as defined under PPS; (2) Only one billable service is provided to a patient per day (one exception: a medical and dental visit may be provided on the same day); and, (3) A billable provider completes the service. This current PPS funding model results in slim to no margin for FQHCs. In practice, PPS creates a 'fixed income' funding model for FQHCs that cannot be modified easily to meet industry pressures or state-mandated changes. Moreover, FQHCs are financially limited due to small annually mandated Medicare Economic Index (MEI) increases (e.g., 0.8%) that do not match the pace of inflation.

Exclude FQHCs, Indian Health Centers, and their Networks from CMIR Program Regulations

FQHCs, Indian Health Centers, and their networks should not be subjected to additional reviews by OCHA that duplicate other reviews and processes. FQHCs want the opportunity to implement and expand value-based care models. This is supported by CMS and HRSA. **I request OCHA exclude FQHCs, Indian Health Centers, and their networks from the CMIR program regulations and request OCHA further promote and support primary care value-based networks by exempting FQHC-related transactions from the CMIR regulations.**

It is my understanding that what is being proposed, including managed care payer negotiations which meet the dollar threshold, would require a 90-day disclosure along with contractually proprietary information, such as anticipated revenue. This is presently protected under managed care regulations. Disclosure of this information could be used for market advancement of competing for-profit organizations, making the marketplace untenable. Confidentiality of rates and contract terms must remain the responsibility of the health care entity.

Thank you for your consideration.

Henry Tuttle
President and Chief Executive Officer

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From:	Jason Sullivan-Halpern
To:	OHCA CMIR
Cc:	Crista Barnett Nelson; Karen Jones
Subject:	Public Comment to HCAI's OHCA's proposed regulations for Assessing Market Consolidation (CMIR)
Date:	Wednesday, August 30, 2023 4:36:27 PM

Greetings,

We're emailing you to submit our written public comments to HCAI's OHCA's proposed regulations for Assessing Market Consolidation (CMIR).

The California Long-Term Care Ombudsman Association (CLTCOA), represents all 34 local Long-Term Care Ombudsman Programs (LTCOPs) across the state. Their CDA-certified staff and volunteer Ombudsman resolve resident complaints, investigate abuse and neglect reports, perform unscheduled facility visits, witness advanced health care directives, and provide other resident-centered advocacy services in long-term care (LTC). Because many issues in LTC are a result of poor business practices on the part of providers, and since long-term care is becoming increasingly unaffordable for a variety of reasons, CLTCOA has a vested interest in OHCA's ability to track the consolidation of such providers and how that impacts the overall affordability and quality of long-term care in California.

First, we note that under §97435(b) of the proposed rule, health care entities only have to report the types of transactions specified if they either: (1) have $25m+ in annual revenue; (2) have $10m+ in annual revenue or asserts AND are involved in a transaction with a health care entity with $25m+ in annual revenue; or (C) are located in or serving at least 50% of patients who reside in a health professional shortage area. However, according to HCAI's Long-Term Care Facility Financial Dataset, nearly half (43%) of all skilled nursing facilities (SNFs) have revenues under $10m annually, only 10% of SNFs have reported assets over $25m, and 73% of SNFs have reported assets under $10m. Only 33% of SNFs report that they're actual subsidiaries of other companies too. Since SNFs typically generate more profits than RCFEs, we can assume a vast majority of health care entities would be exempt from the proposed reporting requirements due to these threshold amounts being too high. In response, CLTCOA recommends that these thresholds be lowered to $5m+ in revenue/assets (rather than $10m) and $10m in assets (rather than $25m) respectively throughout the text of the proposed rule to ensure that more facilities must report transactions that have the propensity to consolidate control of the LTC industry in CA.

Second, we note that under §97435(e) of the proposed rule, "a transaction will transfer or change control, responsibility, or governance if…[it] 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" under Subsection (3). However, "administrative or operational control or governance" is not defined anywhere in the proposed rule. If "administrative or operational control or governance" includes a change in the key employees or executives of the organization, such as the CEO/ED, CFO, COO, etc., rather than the Board of Directors or Partners/Owners, then that definition

should be stated explicitly. Since the average staff turnover in a SNF is nearly 50% according to the HCAI LTC Facility Financial Dataset, such a requirement would wrap many health care entities into the reporting requirements that wouldn't otherwise meet the revenue/asset thresholds noted earlier.

Thank you in advance for your consideration. It's greatly appreciated. We hope our feedback will be incorporated into the final proposed rule by HCAI's OHCA.

Jason Sullivan-Halpern, J.D.
Association Director
California Long-Term Care Ombudsman Association
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ata ACTION
Telehealth Policy to Transform Healthcare

August 30, 2023

Megan Brubaker
Office of Health Care Affordability
Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833
CMIR@hcai.ca.gov

RE: ATA ACTION COMMENTS ON RULEMAKING TO CHAPTER 11.5 PROMOTION OF COMPETITIVE HEALTH CARE MARKETS

To the Office of Health Care Access and Information,

On behalf of ATA Action, I am writing the Office of Health Care Access and Information ("the Department") to provide comments on the proposed rulemaking to Chapter 11.5, promotion of competitive health care markets.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

ATA Action is concerned that the proposed rules will add significant and unintended administrative burdens on the safe, effective, and efficient provision of telehealth services in California. ATA Action urges the Department to consider revising the proposed rules with regard to the following recommendations.

Revise the revenue reporting threshold
ATA Action recommends that the revenue reporting threshold should be increased to avoid burdening physician practices and telehealth startups that California should be encouraging to grow. Currently, the rules would require any healthcare entity with at least $25 million in California source revenue (or $10 million in revenue and $10 million in assets) to submit a reportable transaction statement. But the Department should carefully consider the wide array of practices, telehealth entities and transactions this would capture.

The proposed rules raise particular concerns for telehealth due to the implication of the common "friendly PC" business model physician practices use to contract with telehealth managed

services organizations ("MSO"). Because these arrangements generally use a contractual restricted stock transfer agreement between the physician owned entity and the telehealth MSO, as well as an employment arrangement with practitioner-shareholders, any changes to these agreements could qualify as a transaction as defined by the proposed rules meeting the $25 million (and $10 million) thresholds.

To put these numbers into perspective, the average primary care physician generates about $1.8 million in annual revenue.[1] This means a practice of only 14 physicians would typically meet this $25 million revenue threshold, which would include close to a majority of medical practices in most regions of California.[2] While the rules do generally exclude practices of fewer than 25 physicians, these smaller practice groups will still have to be very careful to review their cost-outlier status within Cal. Health and Safety Code § 127500.2, which if applicable, would bring them within the fold of these rules anyway.

Telehealth entities would be particularly concerned with the administrative burden of this review process while seeking to enter or expand their range of services in the California market by contracting with practice groups. These rules would add to the costs related to forming these friendly PC partnerships and delay their ability to operate. Furthermore, California telehealth startups, which could easily amass $10 million in California R&D and startup assets (and are particularly sensitive to administrative cost burdens) may also lose out on critical time forming partnerships and entering certain California markets.

These low thresholds could subject many more transactions among telehealth MSOs, startups, and California primary care practices than intended to months of detailed administrative review, putting cost pressures on these practices and putting downward pressure on telehealth service adoption and development. Therefore, ATA Action recommends doubling the proposed rule's stated threshold levels to reduce the pool of entities captured by these rules.

Narrow the definition of "Health care entity"

Similarly, ATA Action recommends narrowing and clarifying the pool of providers included in the definition of Health care entity. Currently, the proposed definition of Health care entity includes "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" (§ 97431(g)(4)). It is ambiguous to what extent affiliates and subsidiaries are intended to be included for purposes of the Department's review (as well as far

[1] Press Release, *Report: Physicians Bill an Average of $3.8 Million a Year to Commercial Insurers*, AMN Healthcare (April 3, 2023), https://ir.amnhealthcare.com/news-releases/news-release-details/report-physicians-bill-average-38-million-year-commercial.

[2] *See* California Health Care Almanac, *California Physicians: A Portrait of Practice* (March 2021), page 19, https://www.chcf.org/wp-content/uploads/2021/03/PhysiciansAlmanac2021.pdf. Broadly speaking, roughly 44% of medical practices have at least 11 physicians. *See Distribution of U.S. medical practices by size in 2018*, Statista (August 27, 2020), https://www.statista.com/statistics/415971/size-of-medical-practices-in-the-us/.

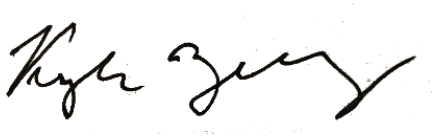
exceeds the statutory definition of the term[3]). Furthermore, this will include transactions among entities tangentially related to the substantive provision of healthcare and of which the Department will be uninterested in reviewing.

Instead, ATA Action recommends the following language change:

(4) Include 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~~ service or work with the health care entity;

Thank you for your support for telehealth. Please let us know if there is anything that we can do to assist you in your efforts to adopt practical telehealth policy in California. If you have any questions or would like to engage in additional discussion regarding the telehealth industry's perspective, please contact me at kzebley@ataaction.org.

Kind regards,



Kyle Zebley
Executive Director
ATA Action

[3] "Health care entity" means a payer, provider, or a fully integrated delivery system. Cal. Health & Saf. Code § 127500.2(k).

August 31, 2023

Department of Health Care Access and Information
Office of Health Care Affordability
Attention: Megan Brubaker
2020 West El Camino Avenue, Suite 1200
CMIR@hcai.ca.gov

Submitted electronically: CMIR@hcai.ca.gov

RE: Office of Health Care Affordability Proposed Regulations for Assessing Market Consolidation (CMIR)

Dear Ms. Brubaker,

Thank you for the opportunity to comment on the Office of Health Care Affordability Proposed Regulations for Assessing Market Consolidation (CMIR). The California Chamber of Commerce ("CalChamber") is a non-profit business association with approximately 14,000 members, both individual and corporate, representing 25% of the state's private sector and virtually every economic interest in the state of California. While CalChamber represents several of the largest corporations in California, 70% of its members have 100 or fewer employees. CalChamber acts on behalf of the business community to improve the state's economic and jobs climate by representing business on a broad range of legislative, regulatory, and legal issues.

We are concerned about the proposed regulations and the impact they will have on California's employers. As drafted, these regulations are expansive and exceed the original intent of the statute. Additionally, the proposed regulations will disrupt routine market activity in the health care sector and impede normal business functions for California's providers and patients. Furthermore, the proposed regulations layout timelines that can be extended unilaterally while simultaneously incurring investigative costs health care entities will be liable to pay but unable to control. Our concerns and suggested revisions are as follows:

Health Care Entity Definitions

Sections 97431(a) and (g) propose to expand 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 broadens the scope of entities 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" along with the definition of the related term "Affiliate" at section 97431(g). Clarifying this definition could include defining how closely the entities collaborate, or alternatively, remain consistent and utilize the statutory definition.

Sections 97431(h) and 97431(q) include overly broad definitions. The inclusivity of what constitutes a change in assets within the definition of transaction to include "sell, transfer, lease, exchange, option, encumber, convey or dispose," along with the verbiage, "or other agreements involving the provision of health care services," could be so broadly interpreted that it becomes inclusive of real estate leases of spaces where health care services are performed.

These definitions must be more specific, and their scope must be limited regarding the types of transactions they apply to. As currently written the definition will include many contracts health care providers enter into for the purpose of ensuring they can meet access standards or otherwise provide care. Additionally, some of the triggers for filing requirements depend on information about contracting counterparties that may not be known or collected by the filing entity.

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Material Change Provisions Section 97435(a)

It is unclear as to how far along a potential transaction must be before a notification must be filed. While 97435(a) makes it clear that notice must be provided at least 90 days prior to "the date any parties' respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived," it is unclear whether a binding purchase agreement must be entered before filing with OHCA. Given that any material changes in the scope of the transaction would restart the initial review period under 97441(b)(4), it is likely that parties would have to go through the substantial expense associated with negotiating and entering into a purchase agreement prior to OHCA commencing with their review.

The Proposed Rule clarifies that "entering into" a transaction or agreement occurs when parties' rights vest or when all contingencies to the agreement are met or waived. For other types of agreements, "entering into" the agreement or transaction likely takes place upon signing. The inclusion of "or" in the definition is problematic, and we suggest removing it, as it appears to include both the signing and closing of a transaction. This would subject transactions that have been signed but not closed prior to April 1, 2024 to the Proposed Rule.

Material Change Provisions Section 97435(b)

The definition of "submitter" in 97435(a) and corresponding thresholds in (b) are unclear. Specifically, the proposed regulations are ambiguous as to whether a "submitter" refers to a buyer, seller, or both. Also, Section 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 Section 97435(b)(1). Section(b)(2) can be removed, and the definition of "submitter" must be clarified regarding who it applies to.

Additionally, 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. We propose considering raising the dollar amount for the health care entity and having a percent of revenue materiality threshold for transactions.

Further, the regulations should include an exception to the notification requirement for patient continuity purposes, whereby a transaction that would allow for the continued provision of healthcare services of a health care entity that would otherwise cease providing services to the community. Acquiring and fixing such a facility to ensure ongoing operations and continuity in patient treatments oftentimes results in significant investment into a financially struggling facility. With the added financial costs and additional time needed for going through the notification process, potential mergers involving a "failing firm" would be prohibitively difficult to the point where such transactions are likely no longer worthwhile. Adding such an exemption would allow for continued access to care in communities that may already be struggling to receive adequate healthcare services.

Material Change Provisions Section 97435(c)

In Section 97435 (c)(3), the 20% disposition or transfer of assets is extremely low; the standard should be much higher. This provision could apply to the purchase of even a minority interest in any health care entity in the State of California. In fact, this provision could be interpreted to apply to the partial disposition of assets that would continue to operate following the transaction, such as the sale of medical equipment. We believe these circumstances are overly broad as written and should be subject to a minimum dollar amount.

In Section 97435(c)(8), it appears the provision indicates that no physician entity can ever change control without participating in this process. This also has the potential to subsume all the other items in (c) depending on how broadly it is read. An asset purchase essentially always involves a change in legal entity, and there is no materiality threshold related to this item.

In Section 97435 (c)(9), the language seems to attempt to prevent entities from breaking one transaction into multiple smaller transactions to undercut dollar thresholds set for filing. However, the effect is that if a health care entity consummated any transaction, not a material change transaction, within the past 10 years, with one of the same parties to the transaction, all other transactions by the health care entity with that party become a material change transaction that must be filed.

Disclosure of Sensitive or Protected Documentation

The Proposed Rule outlines automatic confidentiality for certain documents, however, there are also other highly sensitive documents that would not receive such treatment. Hart-Scott-Rodino Act 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 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 requirements to disclose all transactions by either party within the last 10 years and any anticipated changes between the "submitter" (which is not clearly defined as the buyer or seller) and any other party, regardless of whether related to the proposed transaction (and regardless of whether the "other entity" is even an HCE under the regulations for purposes of future transactions) or whether the past or future transaction is occurring wholly outside of the State of California, would seem to fall outside of the purpose and limit of OHCA's statutory authority. These disclosure requirements could be particularly troublesome if applied to publicly traded companies, which have separate and potentially conflicting legal obligations regarding the disclosure of material non-public information.

Given the breadth and depth of disclosure requirements involved with a proposed transaction, we believe the confidentiality provisions of 97439(d) should be written to oblige OHCA to place stronger confidentiality protections around the competitively sensitive information that must be disclosed. OHCA should consider establishing an appeals process if it denies a confidentiality request.

Required Documentation for Market Transaction Notices Is Too Broad

The proposed regulations contain reporting and documentation requirements that are burdensome on transacting parties. Some of the requirements (for example, the requirement to file "term sheets" in addition to definitive agreements) may cause confusion at the agency level and provide no meaningful additional information. Other requirements are likely to be time consuming and resource intensive to produce. For example, the requirement to describe any health care related transactions between the parties occurring in the past ten years may require substantial efforts. Finally, 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 (for example, the FTC and DOJ's pre-merger review process) and are unlikely to provide OHCA with useful information.

Specific recommendations for section 97439(b) on the "Form and Content of Public Notice" include the following:

- (b)(7) remove entirely. There are significant reasons why other reviewing entities do not require broad narrative responses. These must be carefully crafted and can subsequently be used against the filing entity. It is also unclear why a "summary of terms" is needed when the agency will already have this information via other documentation.

- (b)(11) remove entirely for the reasons given above. In addition, this is broad and all encompassing.

- (b)(12)(B) should be eliminated.

- (b)(12)(E) should be eliminated. This can be problematic in anti-trust litigation where an entity may or may not be listed as a competitor but this could then be used in other anti-trust forums.

- (b) (13) should be eliminated. 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 might be for sale and leave.

Specific recommendations for section 97439(c) on the "Documents to be Submitted with Notice" include the following:

- (c)(1). Take out term sheets. These are non-binding and not the definitive agreements which the agency would have.

- (c)(2). Take out these contacts, it is unnecessary information.

- (c)(3). Balance sheet must be confidential, which appears is the intention in this section.

- (c)(5). The terms "certified" and "footnotes" are problematic. Smaller entities have unaudited financial statements and would not have auditor certification or GAAP footnotes.

- (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 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.

- (c)(8) and (c)(9) 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 (for example, the FTC and DOJ's pre-merger review process) and are unlikely to provide OHCA with useful information. These must be carefully crafted and can subsequently be used against the filing entity.

Section 97439(f) Reimbursement for Costs

The Proposed Rule references the statutory authority to collect any costs incurred in connection with reviews. This includes the costs of 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.

Timing of Review of Notice

The timing provisions under Section 97441 are concerning as the potential extensions and uncertainty are additional barriers that could impact health care delivery in California. 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 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.

The comprehensive list of information that must be submitted to support the application under Section 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. OHCA's broad discretion to toll timelines in the Proposed Rule should be limited or removed.

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 to provide further details regarding what must be submitted to receive a determination.

In closing, we respectfully request that these proposed regulations be reexamined and augmented in a way that reduces their potentially obstructive impact on health care market activity. Thank you for your consideration of our perspective.

Sincerely,

Preston Young
Policy Advocate

PY:ldl

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 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.

(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 under accepted, evidence-based standards.

(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;

(4) Include 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~~; and

(5) 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 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 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;

Commented [wb1]: These comments are submitted by America's Physician Groups. Contact Bill Barcellona, EVP Gov't Affairs, wbarcellona@apg.org (916) 606-6763.

Commented [wb2]: A provider cannot be determined to be in or out of compliance unless a formal, approved standard has been adopted.

Commented [wb3]: MSOs are intermediaries that supply administrative services. They are not true payers because they are not contracted or delegated by the health plan to assume the financial risk for downstream payments. Only plans and RBOs are payers in this context. Including MSOs as payers will create confusing and unnecessary duplication of data submittal and increase administrative costs in the system.

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Commented [wb4]: The definition of "affiliate" in Section 97431(a) is limited to direct control, or common control by another legal entity, and does not include "financial responsibility" or "financial control of the health care entity." This language is superfluous and creates ambiguity.

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(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) "Material change transaction" shall mean a transaction which meets the requirements of section 97435(c).

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

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

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

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

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

(q) "Transaction" includes mergers, acquisitions, affiliations, ~~or other agreements~~ involving the provision of health care services in California that involve a change 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.

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.

Commented [wb5]: The underlying statute does not include MSOs under the category of "Payer" but does include Third Party Administrators.

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Commented [wb6]: Health & Safety Code Section 12507 ©(1) requires the provision of "written notice of agreements or transactions" that include sale, transfer, lease, exchange, option, encumber, convey or otherwise dispose of assets to one or more entities, and transfer of control, responsibility, or governance of a material amount of assets or operations to one or more entities. This requirement is far narrower than the language under subsection (q) for "transactions." The definition of "transaction" as phrased here could involve the purchase of an EMR system, the lease of a piece of imaging equipment, a change in staff shifts, the application for a real property easement (change of assets) because each represents a "change of operations" under the proposed definition (q), because in each of these instances such examples could meet the materiality threshold. Such a definition is overbroad.

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) 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 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 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~~ 100 million or that owns or controls California assets of at least $~~25~~ 100 million; or

(2) A health care entity with annual revenue, as defined in subsection (d), of at least $~~10~~50 million or that owns or controls California assets of at least $~~10~~ 50million 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.

(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.

(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.

Commented [wb7]: The regulations need to include an expedited timeline as contemplated by the Legislature in Section 127507.2 for those situations that warrant it based on the nature of the agreement or transaction. OHCA has 60 days to decide if it will do a Cost & Market Impact Review, 90 days to conduct the review, can automatically extend for 45 days, and transactions cannot move forward for 60 days after the final report is issued. That's 255 days without OHCA tolling the time frame while waiting for responses, which can include waiting for responses from third parties pursuant to subpoena power.

However, these transactions can occur because health care entities are distressed and looking to avoid a disruption of care from a bankruptcy filing, so there needs to be a process to expedite both the 60 day decision timeframe and Cost & Market Impact Review timeline to avoid businesses shutting their doors and patients being left without their caregivers.

Commented [wb8]: Materiality must be defined in relation to the assets or operations of one of the health care entities. However, the draft regulations set arbitrary dollar amount triggers in Section 97435 (c)(1)-(2), of $25 million and $10 million, regardless of whether these are low dollar thresholds in relation to the assets or operations of the entities to the transaction. For two entities with billions of dollars of assets and revenue, a transaction of a market value of $25 million or increasing revenue $10 million is immaterial.

These thresholds while perhaps seemingly high to a layperson greatly underestimate the cost of standard health care operations where subleases of space for a single outpatient surgery center have a long-term value of $25 million or medical equipment contracts often have a value of $25 million or more. These thresholds are pulling in standard, ordinary operational agreements of health care entities.

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Commented [wb9]: n light of our comment lodged under subsection (a) above, APG suggests more appropriate triggers of $100 million under subsection (b)(1) and $50 million under subsection (b)(2) in the absence of any evidence of the frequency, value and volume of "transactions" between health care entities in the California market, such that this provision would be based on objective data. Further emergency regulation can be introduced once the Department gets a se ... [1]

(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 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.

~~(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 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.~~

(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.

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Commented [wb10]: This provision in subsection (5) makes the addition or deletion of a single physician in a network. This kind of transaction occurs thousands of times a year in California. This will prohibit the flexibility necessary to expand or contract networks and contribute to access issues due to the long review time contemplated under the regulations

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Commented [wb11]: The Department of Managed Health Care already reviews filings concerning the sale or change of control of its licensed entities. A review by OHCA would duplicate, and perhaps lead to conflicting outcomes. How would conflicting directives from OHCA and DMHC be reconciled?

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Commented [wb12]: The use of the phrase "from physician owned to private equity owned" is ambiguous because physician ownership is private equity ownership. Subsections 3 and 4 cover the kind of change the Department is envisioning and this provision is therefore redundant.

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Commented [wb13]: Because the current materiality thresholds contemplate acquisition of EMRs, real property leases, and other transactions that are not truly material to cost containment in the health care system, the addition of this ten year provision in subsection (9) is even more overbroad and burdensome and should be redacted.

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(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 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.~~

(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~~51% of the control of, responsibility for, or governance of a health care entity; or

(2) There is a substitution of ~~one or more~~ a majority of 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~~50% of the administrative or operational control or governance of at least one 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.

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Commented [wb14]: The financial information concerning administrative costs is covered in the existing financial filings of health plans, RBOs and facilities under other California law and OHCA has access to that information. Requiring MSOs to provide such information is duplicative, confusing and irrelevant. This provision under subsection (7) should be stricken.

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Commented [wb15]: Because this subsection e is phrased in the disjunctive, any of the three factors constitute "control, responsibility or governance." Yet, the substitution of a single member, or only 10% of the administrative or operational control or governance of an entity changes. To effect a real change in control and/or governance, at least 51% would need to change. Consider the situation in which a board member of the organization retires or passes away. This provision would trigger a filing requirement. To what practical end?

Commented [wb16]: Thank you for the clarification under subsection (f). This is an important point.

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 (excluding subsection (5), herein, using the portal on the Office's website at _*[website and registration instructions to be provided]*__. 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 of the document.

(b) Form and Contents of Public Notice. A health care entity submitting a notice ("submitter") shall 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, include a summary for each of the following categories 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 in the last year, quantity/type of services provided annually).

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

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

Commented [wb17]: Subsection (i) requires a massive amount of information to be provided, such as "quantity/type of services provided annually." This could require the submission of all claims information for an entire year. A medium-size physician organization would generate hundreds of thousands of claims in a year. Why is such information necessary and relevant ot the review of transactions, especially in the case of the addition of a single physician to the network?

(F) California licenses held by the submitter, if any, and identification of any other states where health care-related licenses are held, license type, and numbers.
(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) Primary languages used by submitter and all other health care entities in the transaction when providing services to the public and the threshold languages used when providing services to Medi-Cal beneficiaries, as determined by the Department of Health Care Services

(5) Description of all other entities involved in transaction. For each entity, describe:

(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;

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

(F) If a health care provider is involved in the transaction, include each provider type, 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), and number of patient visits by county and zip code in the year preceding the transaction;

(G) If a payer, describe 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) For all health care entities, the business addresses of any new entity(ies) that will be formed as a result of the transaction.

(6) Proposed or anticipated date of transaction closure

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

(A) The goals of the transaction;

(B) A summary of terms of the transaction;

Commented [wb18]: This section requires submission of information under penalty of perjury, but the information required in subsection (5) (A)-(H) concerning other entities to the transaction is outside the ability of a submitter to submit under penalty of perjury.

(C) A statement of why the transaction is necessary or desirable;
(D) General public impact or benefits of the transaction, including adopted 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) 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) 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) A description of current services provided and expected post-transaction impacts on health care services, which shall include, if applicable:
(A) Physical addresses where services are performed;
(B) Levels and type of health care services offered, including reproductive health care services, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services;
(C) A 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;
(E) Charity care;
(F) Community benefit programs; and
(G) Medi-Cal and Medicare.

(11) Description of any other prior transactions that:
(A) Affected or involved the provision of health care services;
(B) Involved any of the health care entities in the proposed transaction; and
(C) Occurred in the last ten years.

(12) 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.

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Commented [wb19]: To satisfy this condition, an applicant would need to refer to officially adopted quality and equity measures, since there are several sources for such metrics, and the specific standard is not referenced in this regulation. It creates an ambiguity.

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Commented [wb20]: For an independent practice association or a health plan, this would require the provision of EVERY ADDRESS of a service provider in its network. This would involve a list of hundreds, perhaps thousands of addresses. This requirement is overbroad and cumbersome.

Commented [wb21]: This provision appears to require a list of all patients identified by their language, disability status, race, gender, age and payer category. This could involve a list of tens, hundreds, perhaps millions of de-identified patients to be submitted, and is somewhat duplicative of earlier provisions under subsection (b). Suggest the provision be amended to state "A summary of..."

Commented [wb22]: Because of the breadth of scope of this regulation this could involve literally every large item purchase, single physician practice addition or deletion, expansion or contraction of services, change in lease of premises, for the past ten years. Why would such information be relevant to a filing?

(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.

Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable:

(1) 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);

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

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

(4) 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;

(5) 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;

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

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

Commented [wb23]: The confidentiality of this response in subsection 13 is IMPORTANT to the continued financial and competitive viability of submitters and should be maintained without any chance of public disclosure.

Commented [wb24]: This requirement under subsection (9) can be construed to require disclosure of attorney-client privileged consultations and should be redacted.

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(d) Confidentiality of Documents Submitted with Notice.

All of the information provided to the Office by the submitter shall be treated as confidential and shall not be deemed a public record ~~unless the submitter designates documents or information as confidential 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 agreements, financial documents, compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office. 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 that provides a reasonably detailed statement of the grounds on which confidentiality is claimed and a statement of the specific time for which confidential treatment of the information is necessary. Bases for confidentiality shall include: (1) the information is proprietary or of a confidential business nature, including trade secrets, and has been confidentially maintained by the entity and the release of which would be damaging or prejudicial to the business concern; (2) the information is such that the public interest is served in withholding the information; or (3) the information is confidential based on statute or other law.~~

~~(3) If a request for confidential treatment is granted, the submitter will be notified in writing, the information will be marked "Confidential" and kept separate from the public file. 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~~

Commented [wb25]: The filings required under this regulation include sensitive, proprietary financial and operational data. Many of the entities subject to the filing requirement are not even regulated entities under California law. The open disclosure of this sensitive information will compromise the operations of these entities. The Office should carefully consider the ramifications of this provision at the outset of implementation. Take a year to review filings and determine the propriety of public release of this information. The Office can always amend and add a disclosure provision under its power to issue emergency regulations.

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~~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.

§ 97441. Cost and Market Impact Reviews.

(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 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 under adopted standards.
(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 directly affects a general acute care or specialty hospital.
(E) If the transaction may negatively impact adopted standards of the quality of care.
(F) If the transaction between a health care entity located in this state and an out-of-state entity may increase the price of health care services 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. 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:

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Commented [wb26]: The six factors cited under subsection (a)(2) are highly subjective and could be applied in an arbitrary manner. References to standards should be incorporated under each of the six factors. The use of the phrase "may base its decision" is even further arbitrary because it implies that a decision may be based on NONE of the cited 6 factors.

Commented [wb27]: Factor (A) should be revised to state "under adopted standards" following the phrase "offer culturally competent care'" so as not to create an ambiguous or arbitrary condition of review.

Commented [wb28]: Subsection (C) should only be applied where sector or entity targets are involved. Holding an efficient organization to an overall cost target when it is in competition with an inefficient, higher cost organization is arbitrary and damaging to that organization's financial solvency.

Commented [wb29]: The requirement in subsection E should be amended to include the phrase "...under adopted standards" or else it could be applied in an arbitrary manner.

(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.

(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 may request review of the Office's determination. The request shall:
(A) Be in writing;
(B) Be signed by the submitter;
(C) Be sent to the Director with a copy to the Office;
(D) Be provided to all other submitters involved in the transaction;
(E) Set forth specifically and in full detail the grounds upon which submitter considers the determination to be in error; and
(F) State the reason(s) why the submitter 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 for good cause 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 adopted culturally competent care standards.

(2) The effect on the adopted quality of health care services to the community 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) 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) Consumer concerns including, but not limited to, verified complaints or other allegations against any health care entity that is a party to the transaction related to adopted standards for access, care, quality, equity, affordability, or coverage.

~~(7) 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

Commented [wb30]: The extension language in this section is unreasonable and arbitrary. Subsection (1) should be amended to provide a reasonable process subject to good cause, but that process should be limited to 45 days.

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Commented [wb31]: Subsection (4) should not be applied to a single organization where the target is statewide. It should only be applied within a sectoral or entity-based target, otherwise, OHCA could potentially be imposing restrictions on efficient, low-cost organizations while letting higher-cost, lower quality organizations continue to operate as they have. This creates an unequal playing field, and is manipulative of the market in a way and to the extent that the State is not qualified to judge.

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Commented [wb32]: A ten-year lookback provision is overly ambitous for the Department to invoke under subsection (5) and it should limit its review to current market conditions and their projected impacts. This provision creates onerous filing requirements that will result in voluminous filings that can't be reviewed by staff within reasonable time limits. Other states have not adopted such a broad-ranging provision.

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Commented [wb33]: Complaints must be reasonably verifiable in nature. For example, where a claim has been brought but subsequently dismissed, settled or vacated by official action, that result should be taken into account.

Commented [wb34]: The insertion of catch-all provisions throughout this regulation create an open-ended process that can be time-consuming, and injurious to the market and public access to necessary health care services. Regulations should create predictable rule sets under which the market can understand and reasonably comply. This provision should be stricken.

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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.

AMERICA'S PHYSICIAN GROUPS

Taking Responsibility for America's Health

America's Physician Groups Comments on Emergency CMIR Regulations

Submitted August 31, 2023

America's Physician Groups (APG) represents over 180 organized physician groups in California and 350 across the United States, serving more than 18 million Californians. We respectfully submit our comments in narrative form in this letter and through line comments in the attached pdf of the regulation text.

Introductory Comments:

The Office of Health Care Affordability (the Office) has been authorized to issue emergency regulations on an as-needed basis. This initial set of regulations is very broad and creates a utility model for oversight of the health care market for payers and providers. However, unlike other utility models, the provisions in this draft regulation do not contemplate the continued fragmented nature of the existing regulatory structure within California, including the Department of Insurance, the Department of Managed Health Care, the Attorney General's Office, the California Health & Human Services Agency (and sub-offices, such as CDII) and the Department of Health Care Services. The Office could take a more conservative stance and scale back the scope of regulations so that it can better judge the impact that the new rule will have on "submitters" in terms of shear volume of filings and the content of those filings. These regulations require submitters to provide endless amount of information, including:

- A ten-year lookback on prior transactions
- A broad scope of defined transactions, even down to the acquisition of a single physician practice
- The complete financials of an organization, including its ten-year financial history.
- A complete evaluation of its market environment – a time consuming and costly undertaking
- A complete listing of all its payer contracts, including submission of the documents, which involves sensitive proprietary information.
- A complete documentation of its provider network, including extensive information about all its providers, including their addresses, staffing, languages spoken and patient demographics.
- A complete documentation of the patient demographics, including age, sex, gender, disability status, distribution by zip code, even economic status, and payer relationships.
- A complete documentation of the prior 12 months of all claim's transactions for provider and payer submitters

This is a snapshot of the extent of EACH filing that would be made in a market that is orders of magnitude larger than any other existing state that undertaken cost-growth target oversight and market consolidation oversight. Indeed, these regulations far exceed the scope of any other state's work to date. We want to express the need for caution and deliberation in this process. Will OHCA have the staff (both the number and experience) necessary to examine filings that will exceed thousands of pages.

Highlighted Comments on the Overall Content and Scope of the Regulations:

Timelines for Review and Disposition: The regulations need to include an expedited timeline as contemplated by the Legislature in Health & Safety Code Section 127507.2 for those situations that warrant it based on the nature of the agreement or transaction. OHCA has 60 days to decide if it will do a Cost & Market Impact Review, 90 days to conduct the review, can automatically extend for 45 days, and transactions cannot move forward for 60 days after the final report is issued. This represents a 255-day review period without OHCA tolling the time frame while waiting for responses, which can include waiting for responses from third parties pursuant to subpoena power.

No other state has adopted such broad powers of review and disposition of transactions.

Many transactions can occur because health care entities are distressed and looking to avoid a disruption of care from a bankruptcy filing. We suggest there needs to be a process to expedite both the 60-day decision timeframe and Cost & Market Impact Review timeline to avoid businesses shutting their doors and patients being left without their caregivers. To that end we have suggested amendments to the time review provisions in the regulation in the attached pdf of the regulation text.

Scope of Transaction Review: The regulations exceed the intent of the Legislature in subjecting transactions to OHCA review which were never contemplated. California Health & Safety Code Section 12507(c)(1) provides, as follows:

> *(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.*

This language clearly requires that the transaction must be one that is material ***to one or more of the entities to the transaction***. Materiality must be defined in relation to the assets or operations of one of the health care entities. However, the draft regulations set arbitrary dollar amount triggers in Section 97435 (c)(1)-(2), of $25 million and $10 million, regardless of whether these are low dollar thresholds in relation to the assets or operations of the entities to the transaction. For two entities with billions of dollars of assets and revenue, a transaction of a market value of $25 million or increasing revenue $10 million is immaterial.

These thresholds while perhaps seemingly high to a layperson greatly underestimate the cost of standard health care operations where subleases of space for a single outpatient surgery center have a long-term value of $25 million or medical equipment contracts often have a value of $25 million or more. These thresholds are pulling in standard, ordinary operational agreements of health care entities. APG therefore suggests that the threshold triggers are amended to $100 million and $50 million, respectively, as indicated in our line-item comments to the regulation text in the attached pdf.

Reconsider the Basis for Materiality of a Transaction: The Legislature required that materiality be determined by looking at the assets & operations ***of the entities to the transaction***. We believe this can only be achieved by setting materiality based on a percentage of the assets or operations of the entities involved in the transaction, as stated in Health & Safety Code Section 97435(c)(3), although we believe 20% is too low. We request Section 97435(c)(1)-(2) be removed as criteria for determining materiality.

However, we recognize that OHCA may have wished to have a materiality floor set for transactions which involve a percentage of an entity's assets, but those assets are less than $25 million. We believe this can be accounted for by raising the percentage in Section 97453(c)(3) and including language, "[X]% or more of the assets of any health care entity in the transaction or $25 million in assets, whichever is greater."

Similarly, Section 97435(c)(5) of the proposed regulations goes beyond the authority of the statutes and scope of California Health & Safety Code Section 12507(c)(1). Section 12507(c)(1) requires that a material amount of the assets or material amount of the operations of an entity to the transaction be involved. There is no authority to make something material based simply on if it only "contemplates," or even if it involves, "negotiating and administering contracts with payers on behalf of one or more providers," as stated in Section 97435(c)(5) of the proposed regulation.

Narrowing the Scope of Involved Parties as Submitters: The California Health Care Quality and Affordability Act is also clear what entities to which it applies. Section 97435(c)(5) goes beyond that scope and attempts to give OHCA authority over other types of entities, such as "management service organizations, or other organization."

While the California Health Care Quality and Affordability Act covers Third Party Administrators (an entity which must obtain a license in California) under the definition of Payer, the Act never mentions MSOs or contemplates a wide reach to transactions with any random "other organization."

OHCA seems to be relying on the definition of Payer in California Health & Safety Code Section 127500.2(o)(5) to expand its authority to MSOs (and any other organization). Section 127002(o)(5) provides as follows:

(5) Any other public or private entity, other than an individual, that pays for or arranges for the purchase of health care services on behalf of employees, dependents, or retirees.

However, OHCA disregards that Section 127500.2(o)(5) is limited to an entity that "pays for or arranges for the purchase of health care services ***on behalf of employees, dependents, or retirees*** [emphasis added]" in order to pull in entities which merely provide administrative support services ***on behalf of Payers***. *MSOs are intermediaries that are necessary to the health care system simply because it is so regulatorily complex*. MSOs provide scale so that smaller physician organizations, plans and facilities do not have to build internal, duplicative infrastructure that would add more cost to the health care system. MSOs are not contracting parties involved in the payer-provider relationship. MSOs do not set payments or have an impact on the affordability of health care for consumers as they merely perform administrative functionality including processing claims at the rates set by those entities who are truly Payers as defined. We recommend Section 97435(c)(5) be removed.

The Ten-Year Look Back Provisions Are Onerous and Will Generate Mountains of Paper in Submitter Filings that will Consume Staff Time: Section 97435(c)(9) of the proposed regulations exceeds the authority of OHCA as set forth in California Health & Safety Code Section 12507(c)(1). It provides that one of the "Circumstances requiring filing" is that "[a] health care entity that is a party to the transaction has consummated any transaction regarding provision of health care services in California with any other party to the transaction within ten years prior to the current transaction." There is no mention of ***any*** materiality level even though Section 12507(c)(1) provides that notices of agreement only be filed if the transaction does 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.***
>
> [Bold italicized emphasis added.]

Section 97435(c)(9) of the proposed regulations allows for the mere presence of a prior health care services transaction amongst a health care entity and any other party to the transaction to pull the current transaction into a required review disregarding the limited authority provided in California Health & Safety Code Section 12507(c)(1) and regardless of whether a material amount of the assets or operations of an entity is involved.

There are several concerns with this language:

> It fails to include a materiality analysis for the current transaction, or any future transaction, as it is only the presence of two transactions amongst a health care entity and another party who is involved in both transactions which triggers a filing. The multiple transactions added together might not involve a material amount of the assets or the operation of any entity involved but will now be subject to filing. This does not meet the filing standard set in Section 12507(c)(1).

> Not only is it a look back for the last 10 years, but it also means that in any 10-year period, if you have two transactions for healthcare services amongst the same two parties, even if multiple other parties, and even if nominal funds are involved when combined, it falls within the oversight of these regulations. This does not meet the filing standard set in Section 12507(c)(1).
>
> It also makes all the information of historic transactions which were not material and not subject to be filed with OHCA subject to both reporting and a matter of public record unless confidentiality is conferred upon those documents.

If the concern is that a single transaction will be broken into several smaller transactions which by themselves do not amount to a material amount of the assets or operations of an entity involved, it is unreasonable to conclude that transactions occurring over the last ten (10) years could be a circumvention of the statutory requirement to file. A different safeguard can be written into the regulation such as, stating that any related transaction with a party within the past year will be considered a single transaction when determining whether a material amount of assets or operations of any entity is involved.

We recommend that Section 97435(c)(9) of the proposed regulations be removed.

The Inclusion of "Encumbrances" and "Leases" as Triggers: We request that the regulations define "encumber" and "lease" so as to avoid potentially pulling in traditional bond financing, real estate lease transactions, and other transactions which are unrelated to consolidation, market power, venture capital activity, profit margins, and other market failures on competition, prices, access, quality, and equity as was the stated focus by the Legislature as stated in Section 127507(a).

The Treatment of Confidentiality: In our introduction to this comment letter, we cited the extensive and voluminous elements of filing requirements. Most all the information required for submittal is confidential and proprietary in nature. It is therefore simpler and more expeditious to treat each filing as confidential rather than require the submitter to itemize each document within the submittal for confidential treatment and to provide a confidentiality analysis for each document. There will be thousands of such documents in each filing. We strongly suggest that the Office spend at least a year getting familiar with the extent and content of submittal before considering the public release of information contained therein.

We therefore recommend that Section 97439(d) be amended as indicated in the attached pdf.

Change of Ownership and Control & Operational Changes: The odd sentence structure in 97435(e)(2) could be read to include a mere substitution of one or more governing body members regardless of impact to voting control. We also believe it is missing a threshold for "partial" voting control. We recommend rephrasing it and adding the same 10% threshold as set in (e)(1) and (e)(3), as follows:

> "2) There is a substitution of one or more members of the governing body of a health care entity that would transfer more than 10% voting control of the members of the governing body of a health care entity, or any other arrangement, written or oral, that would transfer

more than 10% voting control of the members of the governing body of a health care entity: or"

In our attached comments in redline to the regulation text, we suggest that the 10% thresholds be changed to a majority or 51% with respect to changes in governance and/or control within the organization, because board members often term-out, pass, or retire. These events should not trigger a filing.

Cumbersome Filing Requirements for all Entities to a Transaction: Requiring all entities to a transaction to file with the Office is not only cumbersome, duplicative, costly and time-consuming, it presents a situation in which separate staff reviewers could reach differing conclusions, and require contradictory actions of the parties. The lead entity to a transaction should file, and if the Office, during a pre-filing consultation, requires further information from another party, it can specify those requirements at the outset of the process.

Additional Redlines and Comments: APG has submitted line-by-line comments and suggested revisions to the draft regulations in the attached pdf file. This letter does not reflect all comments lodged by APG in response to this circulated draft.

Thank you for the opportunity to submit written comments and for the extensive public meeting opportunities in which to express our concerns over these regulations. APG continues to support the OHCA concept and will work collaboratively to enable the implementation of the Office. Please contact us if you need further information or clarification.

Sincerely,

William Barcellona, Esq, MHA
Executive Vice President for Government Affairs

wbarcellona@apg.org
(916) 606-6763

August 31, 2023

Megan Brubaker
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Sent via email to: CMIR@hcai.ca.gov

RE: 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 written comments to the Office of Health Care Affordability (OHCA) regarding the *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 – Section 97435 Material Change Transactions:

This section is 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 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.*

Question: How does OHCA calculate a transaction annual revenue increase of 20% 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 likely 20% increase of annual 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% or more of the assets of any health care entity in the transaction.

Question: How does OHCA calculate the other disposition of 20% or more of the 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 20% or more of the 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.

Question: How does OHCA define "management services organization" and "other organization?"
Comment: It's nearly impossible for ASCs to determine if they're an entity that would meet either definition resulting in not being able to comply with this trigger. CASA recommends reworking this trigger and defining "management services organization, or other organization."

(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.

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 subsection (9) 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

CALIFORNIA ASSOCIATION
CAHF
OF HEALTH FACILITIES

Supporting People, Health and Quality of Life

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August 31, 2023

Elizabeth Landsberg
Director
California Department of Health Care Access and Information
2020 W El Camino Ave #800
Sacramento, CA 95833

SUBJECT: Proposed Emergency Regulations: California Health Care Quality and Affordability Act

Dear Director Landsberg:

On behalf of the California Association of Health Facilities (CAHF), we thank you for the opportunity to provide comments on the draft proposed emergency regulations required by Senate Bill (SB) 184 (Chapter 47, Statutes of 2022) related to the implementation of the California Health Care Quality and Affordability Act. CAHF represents 900 skilled nursing facilities (SNFs) and 450 intermediate care facilities for the developmentally disabled (ICF/DDs).

We recognize that these regulations are required to be promulgated by Health and Safety Code section 127501.2 and subdivision (b) of 127507.2 and that the draft regulations are intended to define the requirements and the process of notice and review of material change transactions by health care entities: Who must file a notice, who is exempt from filing a notice, what the notice must contain, and what is required for a cost and market impact review (CMIR).

CAHF has significant concerns about the proposed regulations as follows:

- The proposed regulations add to (and in some cases duplicate) the many substantial financial reporting requirements specific to SNFs mandated by existing law.
- The volume of information and corporate documents required for filing Notices of Material Change Transactions will impose costly administrative burdens on both large and small SNF providers and could result in delayed or cancelled transactions that could improve access to quality SNF care in a community.

- The proposed designation of many of the documents required for the notice filing as part of the public record documents, unless the submitter undertakes an extensive redaction process, puts sensitive corporate data and information at risk.

The proposed regulations are intended to be applied for a wide range of health care entities as defined in SB 184 and while the regulations do not specifically target SNFs, when combined with existing laws that are targeted at increasing financial transparency of SNFs, the cumulative impact on SNFs results in significant additional reporting burdens on SNFs with minimal new transparency information actually being reported to the state.

There are about 1,100 licensed SNFs in California, operating just under 110,000 beds. SNFs are primarily funded by Medi-Cal, followed by Medicare and Medicare Advantage with less than 10 percent of payment from self-pay and other payors. There is little to no commercial insurance used to pay for these services. Most SNFs are investor-owned and the total annual gross revenue for all California SNFs is about $10.6 billion. Many facilities are also independently operated small businesses, with fewer than 100 licensed beds.

With the exception of a small number of self-pay patients, SNFs are contracted to accept reimbursement rates set by Medi-Cal and Medicare. In the case of Medi-Cal, SNFs receive a facility-specific daily patient rate based on audited actual costs reported by the facility and each calendar year's reimbursement rate is based on cost reports submitted three years earlier. Changes in ownership have no immediate impact on Medi-Cal reimbursement rates and since Medi-Cal reimbursement rates are facility-specific, local changes in SNF market share have a minimal impact on prices.

CAHF COMMENTS

SNFs are already reporting financial transaction information. Existing law requires SNFs to report extensive financial and corporate ownership data and limits anti-competitive transactions. California SNFs are already subject to stringent financial reporting requirements, both on a routine basis and when undergoing corporate transactions, such as changes in ownership and operations and related party transactions. Existing requirements include:

- AB 1629 SNF Medi-Cal cost reporting process which requires Medi-Cal SNF providers to provide detailed cost reports to DHCS. The cost reports are audited by DHCS for financial accuracy and allowable costs and the reports are used to develop a facility-specific Medi-Cal reimbursement rate;
- SB 650 "Corporate Transparency in Elder Care Act of 2021" which requires SNFs to prepare annual consolidated financial statements of related entities. Regulations for SB 650 implementation are in progress;

- AB 1502 "Skilled Nursing Facility Ownership and Management Reform Act of 2022", which requires SNFs to report to and seek approval from the California Department of Public Health for specified transactions relating to operating, establishing, managing, conducting, or maintaining a SNF; and
- AB 1953 requires licensees of SNFs to disclose specified information to HCAI regarding ownership or interest in a related party that provides any service to a SNF beginning in 2020.

There are also existing statutes to prevent anti-competitive transactions, such as that entities that own, operate, or manage 10 percent or more of the licensed SNFs in the state are prohibited from owning, operating, or managing additional skilled nursing facilities, unless the department in its discretion concludes that the interests of resident health and safety requires that an exception is warranted (HSC 1253.3 (g)(12)(d)).

Significant reporting and administrative burden on SNFs. The proposed regulations would likely require every specified transaction (sale, lease, transfer, etc.) between two SNF entities to be reported to the OHCA, in addition to the existing reporting requirements to other state agencies for these types of transactions. For example, in the sector, there are many scenarios where a larger company purchases a small family-owned facility and intends to continue operating the facility in the same manner as the original owner with the same reimbursement rates from Medi-Cal, Medicare, etc. Under the regulations, both the seller and the purchaser would have to undertake the submission of substantial documentation, await the OCHA determination and further delay the completion of the transaction. It is not uncommon for SNF sellers (who are often small businesses) to be in a financial position where they need to sell the facility to prevent incurring additional debt. The only type of transaction that might be excluded would be if an independent owner-operated facility purchases another independent owner-operated facility, and that transaction still might need to be reported if the facilities are located in health professional shortage area. The process in the proposed regulations would incur additional cost and delay and could be a barrier for the sale to take place.

Another common transaction occurs when an independently-operated SNF sells the land and physical building of a facility, and then continues as the operator but is now a tenant of the new owner. The care provided at the facility remains unchanged with regard to the number of licensed beds, lines of services, etc. These transactions are a mechanism for operators to obtain the necessary financing to improve the physical plant and daily operations at their facility. Under the proposed regulations, both the operator and the facility would have to report to OHCA, even if there is no actual change in service delivery or cost.

Material change submissions are unlikely to result in Cost and Market Impact Reviews (CMIR). California law governing SNF financial transactions and the state's control over cost targets for the SNF sector means that there are likely to be very few transactions that would potentially trigger CMIR. The proposed regulations state that the determination of whether to conduct a CMIR will be based on the risk of the transaction resulting in:

- A significant impact on market competition;
- The state's ability to meet cost targets; or
- Costs for purchasers and consumers.

As stated previously, there are existing laws specific to SNFs limit the ability of transactions to have a major impact on any of these factors. State law already prevents any entity from owning more than 10 percent of the facilities in the state, preventing the formation of SNF monopolies. The majority of SNF revenue flows through Medi-Cal and Medicare and ensure that the state retains control in meeting cost targets and setting prices for consumers. A significant commercial insurance benefit for SNF services does not exist.

Requiring SNFs to submit the volume of financial information required in the regulation when it is unlikely that the OHCA will find that CMIR is required will result in significant delays in completing transactions without any additional benefit for the state or consumers.

RECOMMENDATIONS

CAHF has significant concerns with the details of the proposed regulations including the low transaction value threshold triggering submissions; the inclusion of routine transactions that have no impact on the competition and are critical to efficient facility operation that may be subject to reporting and documentation submission; potential inclusion of non-CA assets in determining whether reporting is required and in the documentation requirements; and potential release of sensitive documents and trade secrets that may occur under the public information release policy. Based on the comments made at the public workshop, CAHF supports concerns voiced by other stakeholders about these issues.

Overall, we are concerned that the addition of these requirements will serve to create massive administrative burden and cost for almost no additional information of value related to creating a competitive health care marketplace.

Delay implementation of regulations for SNFs. The proposed regulations are broadly written and will require the OHCA to receive and review a high volume of financial transaction information from many health care entities that will be subject to the regulations. The OHCA will be developing and implementing new processes for intake, review, communicating with health care entities and other state agencies, as well as evaluating and improving these processes as they are developed. Recognizing that the OHCA has finite staff resources for completing these processes, we recommend that the Office prioritize health care entities and consider phasing in the application of these regulations.

Application of these reporting requirements can be delayed for SNFs because these entities already report financial information and are subject to extensive financial oversight by state and federal agencies. SB 184 grants broad rulemaking authority to the Office, including the

ability to identify exempted providers and promulgate new regulations as needed. Due to the volume of information already reported by SNFs, there is no emergent need to require the proposed level of financial transaction reporting in emergency regulations. The Office may promulgate these regulations for other health care entities for whom financial information is not already available and address whether SNFs should be carved into these requirements at a later date.

We thank you in advance for consideration of our concerns.

If you have questions or for more information, please contact Yvonne Choong at ychoong@cahf.org

Sincerely,

Craig Cornett
CEO

Cc: Megan Brubaker, Engagement and Governance Manager, OHCA

CALIFORNIA COA ORTHOPAEDIC ASSOCIATION

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August 31, 2023

To: Members, Health Care Office of Affordability Board
Staff, Office of Health Care Affordability
Megan Brubaker
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833
Via email: CMIR@hcai.ca.gov

Re: Public Comment on Proposed Regulations

Dear Chair and Members:

The California Orthopaedic Association, representing nearly 2,000 orthopedic surgeons practicing in California, appreciates the opportunity to submit comments on proposed regulations regarding Cost and Market Impact Review. We recognize that these are emergency regulations under expedited time frames, but we urge the staff and Board to make clarifying changes to ensure the regulations comport with California law.

As you well know, statute trumps regulations. California Health and Safety Code Section 127500.2 establishes definitions regarding health care affordability and 127500.2 (p) (5) specifically defines "physician organization" subject to HCAI reporting requirements as "A medical group practice, a professional medical corporation, a medical partnership, or any lawfully organized group of physicians and surgeons that provides, delivers, furnishes, or otherwise arranges for health care services and is comprised of 25 or more physicians." We urge you to clarify the triggering regulations to comport with this section of the law, so that physician groups of 24 and fewer are clearly exempt, as the statute clearly states.

We also urge further clarity and limitations regarding qualifying transactions, so thar larger groups and groups providing services in underserved areas need not provide reports on routine business transactions that have little to no market effect.

Furthermore, we suggest revisiting the requirement that multiple entitles file independent notice of a proposed transaction, which may result in unnecessary and duplicative reporting.

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Additionally, the 10 year lookback for any other transaction may be unnecessarily overbroad, providing more chaff than wheat for your staff to sort through.

Furthermore, the statute was silent as to management services organizations and California law in general does not treat MSOs as equivalent to payors. We see no justification for OCHA to do so either.

Finally, for groups who are going to merge, the 8 month (plus) time frame may prevent beneficial transactions from happening, so we urge streamlining and focusing the regulations so that staff can have access to helpful and targeted information and not have to spend months going through information that doesn't impact health care costs.

Given the complexity of these issues and the shortened time frames afforded emergency regulations, the Board may wish to hold additional meetings to review these proposed regulations. Thank you again for the opportunity to provide comments.

Sincerely,

Kim Stone

Kim Stone,
Stone Advocacy, Lobbyist for COA
kim@stoneadvocacy.com 916 798 1878

The mission of the California Orthopaedic Association is to protect patients' ability to receive timely and high-quality musculoskeletal care.

AMERICAN INVESTMENT COUNCIL

August 31, 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") Draft Emergency Regulations

Deputy Director Pegany:

I am writing on behalf of the American Investment Council ("AIC") to discuss OHCA's draft emergency regulations, which were published on July 31, 2023.

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. In California, research indicates that the private equity sector employs over 1.4 million people.[1] In 2022, private equity contributed $173 billion to 1,006 companies in California.[2] Private equity has a long history of health care investing in the U.S. and California, playing a critical role in supporting access to high-quality, affordable health care. These investments produce strong health outcomes demonstrated by the decades-long track record of innovations delivering more effective treatments that save lives and lower health care costs.

AIC has supported and continues to support the State of California's efforts to enhance transparency through additional disclosure of health care merger & acquisition information, including through the establishment of OHCA, which has an important role in promulgating regulations to implement SB 184. In that role, OHCA has already made tremendous strides by providing a clear process for transacting parties to request confidential treatment of information submitted to the Office for its review; this aspect of the draft emergency regulations will ensure fair treatment of the transacting parties and incentivize parties to readily assist with OHCA's review. We are concerned, however, that aspects of OHCA's proposed draft emergency regulations may cause confusion and, therefore, undermine the ability of covered parties to

[1] *See* Economic Contribution of the US Private Equity Sector in 2020 (May 2021), available here.
[2] *See* New Report on Top States & Districts with Private Equity Investment (Mar. 20, 2023), available here.

comply with the regulations. Further, there are other aspects of OHCA's proposed draft emergency regulations that could inadvertently reduce productive investment, which may ultimately undercut the state's goals. Where the regulations cause compliance time and costs to escalate, this may cause parties to terminate the proposed transaction. To assist OHCA in its implementation of SB 184, and to ensure that the regulations do not inadvertently hinder productive investment activity and the delivery of affordable, high-quality health care services in the California health care market, we respectfully offer the following recommendations:

I. The Timeframe for the Submission of Notice Should be Further Clarified.

Parties required to submit notice under SB 184 must do so at least 90 days before "entering into an agreement or transaction."[3] We understand that OHCA's draft emergency regulations were intended to 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. To better facilitate the Office's intention, we propose OHCA further revise the definition as follows:

> "a health care entity who meets any threshold in subsection (b) … shall provide the Office with at least 90 day's advance notice of the transactions that will be entered into on or after April 1, 2024… [T]he phrase 'entering into the agreement or transaction' refers to the *closing* date of the transaction (not the signing), when *all* parties' respective rights have vested in a binding agreement *and* the contingencies to the agreement are met or waived."

As we have previously discussed with the Office, requiring the notice to be filed 90 days before the signing of a transaction is unworkable for most transactions and transaction parties and may inadvertently chill investment in the California health care market. By making clear that the notice is tied to *closing*, OHCA will protect access to critical capital for the California market.

II. The Scope of "Health Care Entities" Should Be Appropriately Limited to Exclude MSOs and Entities with A Mere Financial Interest in Health Care Entities.

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).[4] Additionally, the statute makes reference to the regulation of "pharmacy benefit managers."[5] In line with the narrow statutory definition, OHCA's draft emergency regulations should appropriately limit the types of entities subject to notice filing requirements. However, the regulations appear instead to *expand* the statutory definition of "health care entities" by including references to (i) management services organizations ("MSOs"), and (ii) *non-healthcare entities* that have an ownership interest in a health care entity.

A. MSOs. A "payer" is defined at §127500.29(o) of the statute as public or private health care payer entities, such as: (1) health care service plans or specialized mental health

[3] Cal. Health & Safety Code § 127507(c)(2).
[4] Cal. Health & Safety Code § 127500.2(k).
[5] Cal. Health & Safety Code §§ 127500.5(i); 127501(c)(12); 127507(a).

care service plans, as defined in the Knox-Keene Health Care Service Act of 1975, or Medi-Cal managed care plans; (2) health insurers licensed to provide health insurance or specialized behavioral health-only policies; (3) publicly funded health care programs, such as Medi-Cal and Medicare; (4) third-party administrators; or (5) other public or private entities that pay for or arrange for the purchase of health care services on behalf of their employees, dependents, or retirees. California has long ensured that payers, including risk-bearing entities and third-party administrators, are appropriately regulated by state agencies, including the California Department of Health Insurance ("DHI") and the Department of Managed Health Care ("DMHC"). Such payers are subject to a broad range of requirements for state licensure, including capital requirements. MSOs, by contrast provide only non-clinical management and administrative services to health care entities and do not fall under the regulatory purview of the DHI or DMHC; thus, MSOs do not meet SB 184's definition of "payer." Therefore, to avoid improperly broadening the statute's scope, we recommend OHCA remove the reference to MSOs as meeting the definition of a regulated payer entity.

B. Non-Healthcare Entities. The regulations expand the legislature's intent by stating that the definition of "health care entities" shall include any entities that "control, govern, or are financially responsible for a health care entity." This definition appears to capture *non-healthcare entities* that have a mere ownership interest in a regulated health care entity. 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).[6] We do not believe the language was intended to apply to the Office's determination of whether an entity meets the statutory definition of a "health care entity," nor do we believe it was intended to provide the Office with a right to regulate non-healthcare entities. The inclusion of entities that have a mere ownership interest in a health care entity will impose a significant regulatory burden on businesses, both inside and outside of California, that do not meet the intended criteria for regulation under SB 184, and OHCA risks being overwhelmed by reviewing an inordinate number of transactions with no relation to the California health care market. To remedy this issue, we recommend OHCA amend the regulations to expressly provide that no tangentially-related company (e.g., a technology vendor or a private equity fund) will be deemed a "health care entity" merely by virtue of its ownership interest in, or financial responsibility for, a "health care entity." This change would appropriately prevent the inadvertent capture of non-healthcare entities and preserve OHCA's limited resources, but, importantly, would not in any way impact a regulated health care entity's *own* responsibility for complying with SB 184's requirements.[7]

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[6] *See* the definition of "Exempted Provider" at §127500.29(g)(1).

[7] 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.

III. The Definition of "Material Change" Should Be Appropriately Limited to Exclude Minor Transactions.

The draft emergency regulations should 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. Setting clear thresholds would allow transacting parties to easily determine whether a contemplated transaction would incur regulatory scrutiny. The draft emergency regulations, however, propose an extremely broad range of circumstances that 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 annual revenue; (3) the transaction implicates ***20% or more of the 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 revenue;*** (5) the transaction involves a ***change of control*** of a health care entity (***10%*** 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 within ***10 years***.

We appreciate the steps OHCA has taken to make clear that revenue calculations are limited to *California-derived* revenue: requiring a clear nexus to California's health care market provides consistency for California health care entities, as well as private equity investors, without unintentionally delaying national transactions that present a *de minimis* impact on California or raising other legal issues. However, this nexus to California is not similarly attached to calculations of a health care entity's *assets* or *operations*. This raises concerns about how OHCA may handle deals involving multi-state or national health care companies if they have operations in California. Moreover, the proposed triggers are *extraordinarily* broad. We understand the need for thorough oversight, but the scope set by the regulations captures an incredibly large swath of transactions and risks overwhelming OHCA with small transactions that are unlikely to materially impact health care delivery in the state. For reference, 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.[8] In Oregon, a review is triggered where one party has $25M+ in annual revenue and the other party has $10M+ in annual revenue[9]—these thresholds appear appropriate for Oregon given that Oregon's state health expenditure in 2020 was approximately $42.8 billion, roughly one-tenth that of California in the same year.[10] In 2022, the Oregon Health Authority reported only 6 transaction filings, suggesting the scope of regulatory review was limited to transactions that presented a material impact on the Oregon health care market.[11]

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[8] Massachusetts Gen. Laws, Ch. 6D, §13(a).

[9] Oregon Revised Statute § 415.500(6)(a).

[10] The Kaiser Family Foundation produced a report comparing health care expenditures between states, which is available here.

[11] The 2022 Oregon Health Authority report available here.

California's health care market is significantly larger than its neighboring states: it services nearly 40 million people, with a reported 2020 health care spend of $410.9 billion.[12] Given the size of the California health care market, a fair market transaction value of $25 million is exceedingly low and will capture a substantial number of transactions with little to no impact on the overall health care market. The regulations' focus on revenue is also misplaced, as it could incentivize health care entities to lower their revenue projections; further, the regulations will capture every transaction between an entity with $10M+ in annual revenue that acquires a company of *any* size. Similarly, the regulations' definition of change of control—a mere *10%* of control or governance—will capture all sorts of transactions that simply have no impact on the day-to-day operations of the health care entity. Finally, using a 10-year look-back period is excessive; markets change drastically in the span of 10 years and health care entities may decide to transact with the same parties for vastly different reasons that do not reflect poorly on the state of competition in the market. In sum, the overly-broad definition of "material change" is poised to create a tremendous administrative burden for both affected stakeholders and OHCA.

In light of the above, we recommend that OHCA limit the definition of "material change" to a transaction with a fair market value of $50M+, or that impacts 50% of the assets, operations, or revenue, of a California health care entity. This will ensure that SB 184's notice requirements do not capture minor transactions that are unlikely to meaningfully impact the California health care market. Further, we recommend that OHCA limit these determinations, as it did with revenue, to the California-based assets or operations of a health care entity. This will align OHCA's approach with other California agencies tasked with reviewing health care agencies and ensure that OHCA's review does not unintentionally delay national transactions with a limited impact, if any, on the California health care market.

IV. The Draft Regulations Should Provide an 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 draft emergency regulations do *not*, however, contemplate an expedited review process. Forcing financially-distressed health care entities to undergo a lengthy review process without providing an opportunity for expedited review threatens not only the financial well-being of health care entities in dire need of capital, but also the local patients which may entirely rely on a single local hospital for their health care needs.[13] To alleviate this issue, we recommend that OHCA amend its draft emergency regulations to adopt an expedited review process. Providing for expedited review in cases of emergency would streamline the review process and facilitate the movement of critical capital, particularly in circumstances where the provision of health care services is at imminent risk and the transaction will protect consumer interests or preserve the entity's solvency. For reference, Oregon has adopted an expedited review process for "Emergency and Exempt Transactions" for this very circumstance: "the [Oregon Health] Authority, for good cause shown, may exempt an otherwise covered transaction from

[12] *See* the Kaiser Family Foundation report, *supra* note 3.

[13] *See, e.g.*, 3 California Hospitals Declared Bankruptcy This Year. Health Chains Could Keep Them Alive (August 14, 2023), available here.

review if the Authority finds that: … [t]he transaction is urgently needed to protect the interest of consumers and to preserve the solvency of an entity."[14]

V. Shortening Proposed Timelines for the Finalization of OHCA's Preliminary and Final Reports Would Avoid Unnecessarily Delaying Transactions.

As previously noted, 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. Under this framework, OHCA has an indefinite time frame to deliver its reports; additionally, the statute does not expressly provide a reasonable comment period for the parties, and the public, to respond to OHCA's preliminary report before its issuance of the final report. The draft emergency regulations successfully address these issues, in part, by providing a 10-day comment period between the issuance of the preliminary report and the final report. However, the regulations provide OHCA with a 90-day period to issue its preliminary report, *plus* an additional 30 days to issue its final report after the comment period. In other words, 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 (which does not appear to have any limitations), parties may be forced to wait 225 days, or longer, for OHCA to complete its review, which may unreasonably delay transactions and jeopardize critical capital for important health care entities. To bring the proposed review periods in line with other states, we recommend OHCA 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 a right to 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 regulatory agencies to issue final reports within 180 and 215 days from the date of notice, respectively.

VI. The Draft Regulations Should Establish 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 draft emergency regulations do not contemplate a limitation on the costs for which OHCA may seek reimbursement. 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 recommend OHCA create a cap on reimbursable costs, and we propose $75,000 as the cap. This amount should be more than sufficient to support OHCA's actual and reasonable costs while providing a measure of predictability for transacting parties. We note that Oregon ensures that reimbursable costs are proportionate to the size of the parties and are capped at $100,000, while Massachusetts does not recoup costs from transacting parties, funding its reviews through appropriations.

[14] The Oregon Health Authority's administrative rules are available here.

VII. The Draft Regulations Provide Appropriate Confidentiality Protections.

Parties to a transaction often exchange highly confidential information that, if disclosed, could cause severe and irreparable harm to their business. Under SB 184, if OHCA determines that a cost and market impact review is necessary, OHCA must make both the parties' initial notice and the Office's preliminary and final reports public. However, the notice and reports will likely contain highly sensitive information about the parties, the public disclosure of which could irreparably harm the businesses and otherwise jeopardize the transaction. The draft emergency regulations have successfully addressed this important issue by allowing parties to submit requests for confidential treatment of information contained within the initial notice and the Office's preliminary and final reports. We believe OHCA's approach will minimize disclosure-related harm while still promoting public transparency as contemplated by the legislature.

We look forward to working cooperatively with OHCA to address these concerns through the amendment of the draft emergency 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

California Nurses Association
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OUR PATIENTS. OUR UNION. OUR VOICE.

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August 31, 2023

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

Dear Chair Ghaly, Director Landsberg, Deputy Direct 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 its Proposed Emergency Regulatory Action on Cost and Market Impact Review (CMIR). CNA strongly supports OHCA's development of CMIR regulations on an emergency basis to implement its authority to review market failures or market power within the health care sector in California.

As bedside RNs, CNA members are alarmed by market trends in the health care sector that weaken nurses' ability to advocate for their patients and that exacerbate problems with health care access and affordability. CNA is acutely concerned with the growth of monopoly and monopsony power of health care entities in our state and across the country. Increasing conglomeration across the health care sector through vertical and horizontal integration of health care services and employer labor market dominance harms both patients and health care workers. For RNs and other health care workers, monopsony power of employers not only depresses wages but also dilutes the power of workers to advocate for better working conditions and safe patient care. In other words, anticompetitive behavior in the health care sector through market consolidation is a threat to the health and safety of patients, nurses, and other health care workers.

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

1. **As a factor in determining whether to conduct a CMIR under § 97441(a)(2), OHCA should expressly include labor market impacts, such as employer concentration, potential impacts on health care worker wages and benefits, safe staffing levels, and other working conditions, and a health care entity's past labor practices.**

We understand and appreciate that OHCA intends to evaluate negative labor market impacts as part of its CMIR. However, there is no clear indication in the current draft emergency rule that labor market impacts could be a factor in OHCA's determination to initiate a CMIR or as a factor evaluated in the CMIR itself. To clarify OHCA's intent to evaluate labor market impacts in the CMIR process, CNA urges OHCA to expressly list labor market impact in § 97441(a)(2) as a factor for determining whether to conduct a CMIR.

The emergency rule should further detail that labor market review include an analysis of whether labor market concentration or monopsony will have negative impacts on health care workers, including unsafe staffing levels, unsafe occupational safety and health conditions, job loss, exploitative employment terms, or other negative impacts on health care worker wages or benefits. Moreover, a labor market review should include a review of a health care entity's past labor practices such as past post-transaction changes in staffing or reductions in force, past health care worker wage or benefits reductions, and past complaints of or citations for violations of state or federal worker protection laws, including unfair labor practice charges under labor law, state and federal antidiscrimination law, wage and hour law, and whistleblower complaints. Accordingly, CNA proposes the inclusion of new subparagraphs to § 97441(a)(2) and we have included proposed language in Appendix below.

Including express language on analyzing the labor market impact of transactions would be consistent with the Federal Trade Commission (FTC) and the U.S. Department of Justice (U.S. DOJ) update to federal merger guidelines.[1] These federal antimonopoly and antitrust regulators are also evaluating whether a transaction would harm or lessen competition for workers and have drafted merger guidelines that expressly state that the FTC and U.S. DOJ will analyze the impact of a merger on workers and labor market competition.

Health care employer concentration has a substantial negative effect on labor market competition because dominant employers in highly concentrated labor markets have more power to exploit the health care workforce. Employer concentration and monopsony power enables health care employers to lower labor standards, depress wages, maintain unsafe staffing levels, force health care workers into coercive employment contract terms, and otherwise treat nurses and other health care workers poorly.

Importantly, because registered nurses and the health care workforce are the backbone of our health care system, the potential impact of labor market competition on health care worker staffing levels should be a critical component of OHCA's CMIR determinations. Employer concentration in the health care labor market can lead to reduction in employment rates within a

[1] Federal Trade Commission and the U.S. Department of Justice. Jul. 2023. "Draft Merger Guidelines U.S. Department of Justice and the Federal Trade Commission." https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf.

labor market. Generally, market concentration results in lower staffing levels and reduced hiring. A 2021 study by Marinescu et al. in France found a 10% increase in labor concentration is associated with 3.2% fewer new hires.[2] For hospitals, increased market competition is associated with increased RN staffing levels.[3]

Market concentration in the health care sector also enables dominant employers to pursue polices of unsafe and understaffing nurses. However, cuts in health care worker staffing, particularly registered nurses, place patients in danger. Decades of research demonstrates that increases in patient assignments for registered nurses endanger patients is linked to poorer health outcomes of patients.[4] Ultimately, because the health care labor market is elastic (unlike the demand for health care), nurses are driven away from bedside nursing and sometimes the profession altogether when employers devalue their lives through intentional policies of understaffing, failing occupational health and safety precautions, and other unfair wages and poor working conditions.[5]

In short, it is important for OHCA to evaluate the potential impact of labor market competition on health care worker staffing levels and working conditions for health care workers because hyper-concentrated employers have sufficient market power to exploit our health care workforce, which ultimately harms patient care.

2. Like the FTC and U.S. DOJ's proposed updated merger guidelines, OHCA's emergency rules should clearly allow for CMIR review under § 97441(a)(2) solely based on labor market impact.

CNA further urges OHCA to clearly indicate that labor market impact can provide a stand-alone basis for OHCA to initiate a CMIR. Adding labor market impact as a factor listed under § 97441(a)(2) would address this issue. As this change would be consistent with the FTC and U.S. DOJ's draft update to their merger guidelines, OHCA should clarify that labor market impact can provide the sole basis for CMIR. The FTC and U.S. DOJ's draft merger guideline states:

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[2] Marinescu et al. 2021. "Wages, Hires, and Labor Market Concentration," *J Econ Behav & Org.* 184(C), 506-605. *See also* Wasser D. Jan 2022. "Literature Review: Monopsony, Employer Consolidation, and Health Care Labor Markets." *Cent for Econ and Pol'y Res.* https://www.cepr.net/report/literature-review-monopsony-employer-consolidation-and-health-care-labor-markets/.

[3] *See* Shin et al. 2020. "The Impact of Market Conditions on RN Staffing in Hospitals: Using Resource Dependence Theory and Information Uncertainty Perspective." *Risk Manag Healthcare Pol'y.* 13, 2103-14. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7568637/.

[4] Decades of studies have shown that low nurse staffing levels in acute care settings—where there are few nurses to take care of high patient workloads—is associated with increased medical complications and missed patient care. Summaries of leading literature on staffing ratios and patient safety can be found in several National Nurses United publications. *See* National Nurses United. 2018. "RN Staffing Ratios: A Necessary Solution to the Patient Safety Crisis in U.S. Hospitals." https://www.nationalnursesunited.org/sites/default/files/nnu/graphics/documents/NNU_Ratios_White_Paper.pdf.

[5] *See* National Nurses United. Dec 2021. "Protecting Our Front Line: Ending the Shortage of Good Nursing Jobs and the Industry-created Unsafe Staffing Crisis." National Nurses United. https://www.nationalnursesunited.org/sites/default/files/nnu/documents/1121_StaffingCrisis_ProtectingOurFrontLine_Report_FINAL.pdf.

> The Agencies will consider whether workers face a risk that the merger may substantially lessen competition for their labor. Where a merger between employers may substantially lessen competition for workers, that reduction in labor market competition may lower wages or slow wage growth, worsen benefits or working conditions, or result in other degradations of workplace quality. When assessing the degree to which the merging firms compete for labor, any one or more of these effects may demonstrate that substantial competition exists between the merging firms.[6]

As described below, CNA also urges that OHCA clarify that labor market impact, and all other factors listed in § 97441(a)(2), can provide the basis for OHCA's decision to conduct a CMIR regardless of whether the factor is tied to a material change transaction.

3. As a factor in determining whether to conduct a CMIR under § 97441(a)(2), OHCA should expressly include the risks of health care service reductions, closures, or shifts, and a health care entity's past practices of service reductions, closures, or shifts.

CNA appreciates and supports OHCA's inclusion of "the availability or accessibility of health care services" in § 97441(a)(2)(A) as a factor in determining whether to conduct a CMIR. We further urge OHCA to clarify that § 97441(a)(2)(A) includes the risks of health care service reductions, closures, or shifts in the location, availability or acuity level of service, particularly higher acuity services. CNA proposes the inclusion of a new subparagraph to § 97441(a)(2) and we have included proposed language in Appendix.

An important consideration for OHCA in its CMIR is analyzing the risk that a health care entity may close facilities, reduce, or eliminate needed health care services, or otherwise engage in shifts or downgrades in the location, availability, or acuity level of services. Following a hospital acquisition, it is often the stated objective of the new owner to search for efficiencies and then eliminate redundancies in its operation.[7] After a merger or acquisition, health care firms frequently reduce or eliminate key health care services, such as maternal care, surgical care, and mental health access, or in some cases end inpatient care all together despite the need for such acute care facilities in that health care services area.[8]

An analysis of national hospital merger and acquisition data shows a concerning pattern of hospitals being closed after the deal concludes. Of the 2,782 hospitals that have been involved in a merger or acquisition from 1994 through May 2022,[9] at least 409 were closed following the

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[6] *See supra* note 1, at 26 (citations omitted).

[7] Deloitte Center for Health Solutions, Healthcare Financial Management Association. 2017. "Hospital M&A: When Done Well, M&A Can Achieve Valuable Outcomes." https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-hospital-mergers-and-acquisitions.pdf.

[8] Henke et al. Oct 2021. "Access To Obstetric, Behavioral Health, And Surgical Inpatient Services After Hospital Mergers in Rural Areas." *Health Affairs* 40(10). https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00160.

[9] Hospital transaction data based on CNA's analysis of Irving Levin Associates LLC Healthcare Deals database (accessed on Mar. 14, 2022), as well as hospital news sources and public disclosures. The Irving Levin Associates LLC Healthcare Deals database is available at https://prohc.levinassociates.com/.

deal.[10] Roughly translating this data, one hospital has closed for every seven hospital mergers or acquisitions since 1994.

Hospital and health services closures, reductions, and shifts can have profoundly negative impacts on the health and economic status of the communities they occur in and should be a top concern for OHCA in the CMIR process. There are several post-merger trends in the health care sector that have harmed patients and workers which OHCA should analyze in its CMIR determinations. These trends include:

- Cuts in health care services or closed facilities post-acquisition (e.g., conversion of full-service acute care hospitals into freestanding emergency departments).
- Cuts in hospital capacity (e.g., decreased the number of hospital beds or closed hospital services) after a vertical merger or acquisition with a physician group, home care company, telehealth company, or other non-acute care health care service firm.
- Policies encouraging practitioners to shift patient care to newly acquired health care facilities with an inappropriate level or intensity of care, particularly lower levels of care (e.g., shifts in acute care from a hospital to outpatient settings after a vertical merger or acquisition between a hospital and physician group, skilled nursing facility, home care company, or other health service firm).
- Increased use of "just-in-time" lean staffing models and short-staffing models, which can result in decreased availability and capacity of facilities to provide care.
- High charge-to-cost ratios in highly concentrated health care markets[11] and post-acquisition price or fee increases, which can lead to decreased access to care as health care prices become unaffordable for patients and payers.

4. The market failure or market power factors for conducting a CMIR under § 97441(a)(2) should be clarified to ensure that OHCA can conduct a CMIR without being tied to a transaction.

Our understanding is that OHCA's authority to conduct a CMIR based on "market failure or market power" need not be linked to a noticed material change transaction. Accordingly, OHCA should clarify that the factors, listed in § 97441(a)(2), that OHCA will use to determine whether to conduct a CMIR do not have to be linked to a material change transaction.

[10] Hospital closure figures were compiled by CNA in March 2022 based on the American Hospital Association Annual Survey Database (https://www.ahadata.com/aha-annual-survey-database), U.S. Department of Health and Human Services hospital closure reports, newspaper reports and various state hospital associations. Please contact CNA for a full list of sources.

[11] Higher average charge-to-cost ratios are strongly associated with hospitals that are affiliated with health care systems, but it should be noted that there is a large amount of variation in chare-to-cost levels among systems. *See* National Nurses United. Nov. 2020. "Fleecing Patients: Hospitals Charge Patients More Than Four Times the Cost of Care." https://www.nationalnursesunited.org/sites/default/files/nnu/graphics/documents/1120_CostChargeRatios_Report_FINAL_PP.pdf.

The current draft language in § 97441(a)(2) confusingly prefaces each factor with the phrase "[i]f the transaction[.]", which could be misconstrued to limit OHCA's market failure-based or market power-based CMIR to impacts that are a directly linked to a merger, acquisition, or other market transaction. Moreover, by including the reference to "transactions" in § 97441(a)(2), OHCA may inadvertently be creating an additional burden of proving a causal and temporal link between a transaction and the factor listed. Market failures and the impact of market power may not be felt by patients, workers, or health care entities until years after the closing of a transaction.

For these reasons, we encourage OHCA to add language throughout § 97441(a)(2) to clarify that the factors apply to all market failures or market power impacts or remove the reference to "transactions". To this end, CNA suggests adding the phrase "the market failure, or market power" after each reference to "the transaction" in subparagraphs (A) to (E) of § 97441(a)(2). CNA's proposed amendments to 97441(a)(2) are available in their entirety in Appendix.

5. **As a factor considered in a CMIR under § 97441(e), OHCA should expressly include the negative effect on labor markets, including employer concentration, potential impacts on health care worker wages and benefits, safe staffing levels, and other working conditions, and a health care entity's past labor practices.**

For the same reasons described above in Comment #1, CNA urges OHCA to expressly list negative labor market impacts as a factor under § 97441(e) that OHCA evaluates in a CMIR. To reiterate, we appreciate that OHCA intends on analyzing the labor market impacts of health care transactions. This intention to review labor market impacts should be clear in the draft emergency CMIR rule. To clarify OHCA's intent to evaluate labor market review, CNA urges OHCA to expressly include labor market impacts in its list of factors examined when conducting a CMIR. Accordingly, CNA proposes the inclusion of new subparagraphs in § 97441(e), and we have included proposed language in Appendix.

6. **OHCA should clarify that the "availability and access" factor considered in a CMIR under § 97441(e)(1) includes the risk of health care service reductions, closures, or shifts, and a health care entity's past practices of service reductions, closures, or shifts.**

For the same reasons described above in Comment #3, CNA urges OHCA to expressly list the risk of service reductions, closures, or shifts as factors under § 97441(e)(1) that OHCA evaluates in a CMIR. To reiterate, we appreciate that OHCA intends on analyzing the effect on the availability or accessibility of health care services to the community affected by the transaction. It remains important to clarify in the emergency rule that the "availability and access" factor includes a review of potential service closures, reductions, or shifts in the location, availability, or acuity level of services. CNA proposes the inclusion of additional language in § 97441(e)(1) and a new subparagraph in this section and have included proposed language in the Appendix.

7. As a factor considered in a CMIR under § 97441(e), OHCA should expressly include 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.

While recognizing that OHCA intends that a CMIR will analyze the "availability and accessibility" of health care services under § 97441(e)(1), CNA urges OHCA to also clarify that a CMIR will evaluate 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. CNA proposes the inclusion of additional language in § 97441(e), and we have included proposed language in Appendix.

California's patients have long identified financial and administrative barriers to care in our fragmented system of health insurance—such as copayments, deductibles, premiums, lack of coverage, and limited choice of doctor—as leading problems in our health care system. These community concerns were reflected in the 2021 survey of low-income Californian's experiences with our health care system that was prepared for the Healthy California for All Commission.[12] Low-income Californians reported that "costs of services/expensive (co-pay, deductible, premiums, etc.)" as the leading reason why they are "dissatisfied" with their current health insurance (27%). Other leading reasons for dissatisfaction with their current health insurance was that all services/treatments were not covered (26%) and limited choice of doctor (16%).

As health care providers and other health care entities more frequently enter into risk-sharing and risk-bearing arrangements, it remains important for the CMIR to specifically evaluate how health care transactions and market power can result in harm to patients through insurance barriers to care. Insurance barriers to care can be both financial barriers to care (e.g., premiums, deductibles, copayments, coinsurance, etc.) or administrative barriers to care (e.g., narrow networks, prior authorization, step therapy, etc.). Additionally, although surprise billing and medical debt collection often occurs after a health care service is provided, these and other related billing and collection behaviors can result in patients forgoing ongoing or future care to avoid additional financial penalties.

In short, OHCA should clearly include in the factors analyzed in CMIRs the effect of financial and administrative barriers to care on patients.

8. It is important that OHCA monitors out-of-state transactions by health care entities in California under § 97411(a)(2)(F) and serial or patterns of transactions under § 97441(e)(5).

CNA strongly agrees with and supports OHCA's inclusion of out-of-state transactions in and serial or patterns of transactions in its CMIR notice and review process. In recent years, there

[12] See "Community Voices: Priorities and Preference of Californians with Low Incomes for Health Care Reform." Prepared for the Healthy California for All Commission. Oct. 2021. https://www.chhs.ca.gov/wp-content/uploads/2021/10/Final-Report-Community-Voices-Priorities-and-Preferences-of-Californians-with-Low-Incomes-for-Health-Care-Reform-October-2021.pdf.

has been increasing vertical, horizontal, and cross-market conglomeration within the health care sector. These kinds of unprecedented consolidation of market power among health care corporations across state lines have the potential to harm patients, payers, and health care workers. A number of academic studies have found price increases following "cross-market" mergers in the 7-17% range.[13] The potential for harm is particularly true as firms outside of the health care sector, including technology firms based in California, are increasingly seeking to acquire health care entities.

As mentioned by commentors at the CMIR regulatory workshop on August 15, 2023, there is a pressing need for OHCA to review out-of-state transactions by California health care entities. This need is underscored by the announced acquisition of Geisinger Health System, a Pennsylvania-based health care system, by Risant Health, an organization created by Kaiser Foundation Hospitals, a California-based hospital system. OHCA's review of out-of-state transactions is additionally important because Kaiser Foundation Hospitals also announced that the Geisinger acquisition is the first of many acquisitions of large health systems across the country and that it created Risant Health for the purposes of placing future health system acquisitions into Risant Health.[14] The proposed Kaiser-Geisinger transaction exemplifies the growing vertical and cross-market conglomeration in the health care sector. Geisinger Health System includes hospitals and other health care facilities, health insurance plans, a multi-specialty medical group, and a school of medicine. OHCA must be vigilant in reviewing the growing national reach of California health care entities to ensure that California's patients and workers are not negatively impacted through price increases, service cuts, job loss, or other changes in health care delivery that result from cross-market market consolidation.

In cross-state transactions that involve California entities, it is important for OHCA to review the financial condition of the out-of-state entity because potential market failures or financial shortfalls of the out of state entity may indirectly result in price increases, service cuts, staffing cuts, or shifts to dangerous health care outsourcing or workforce gigification models in California. In the case of the Risant Health, it remains unclear whether Kaiser's California members or California taxpayers will subsidize the Geisinger acquisition, which includes $2 to $5 billion of promised investments by Kaiser Foundation Hospitals into Risant Health and Geisinger Health, or future acquisitions.[15] This should be a major concern for OHCA in transactions like the Kaiser-Geisinger merger where significant financial investments in the out-

[13] *See, e.g.,* Leemore D et al. 2019. "The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry." *RAND J of Econ* 50(2). https://www.people.fas.harvard.edu/~robinlee/papers/PriceEffects.pdf (finding a 7 to 10% price increase at hospitals involved in cross-market transactions, relative to hospitals that were not between 1996 and 2012).

Lewis MS, Pflum KE. 2017. "Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions." *RAND J of Econ* 48(3). https://onlinelibrary.wiley.com/doi/abs/10.1111/1756-2171.12186 (finding that prices at the independent hospitals that were acquired by out-of-market systems between 2000 and 2010 increased by as much as 17% relative to the standalone hospitals that were not acquired).

[14] See Caroline Hudson. Aug 29, 2023. "Risant Health could reshape healthcare: Geisinger CEO." *Modern Health Care.* https://www.modernhealthcare.com/mergers-acquisitions/risant-health-value-based-care-geisinger-jaewon-ryu.

[15] See Kaiser Foundation Health Plan, Inc. and Subsidiaries and Kaiser Foundation Hospitals and Subsidiaries. Combined Financial Statements and Additional Information (For the six months ended June 30, 2023 and 2022) (Unaudited).

of-state entity has been assured by an entity that provides a large share of health care services in California. In that same vein, as large California health care entities like Kaiser Foundation Hospitals seek out-of-state transactions, it is important that OHCA review what state and local California tax breaks the entity is receiving and whether California taxpayers are or should be receiving any benefits.

CNA also agrees that it is equally important that OHCA monitor smaller serial or patterns of transactions that may not be subject to OHCA material change notice. Health care entities should not be able to avoid OHCA material change notice and CMIR by breaking up transactions into smaller agreements that do not trigger notice or review.

It is important for OHCA to monitor whether larger health care entities have engaged in patterns of acquisition of smaller or community clinics within a health care market. In some areas of the country, health care firms have engaged in a pattern of acquiring small competitors and then closing those facilities or parts of those facilities.[16] For example, it is unfortunately a routine strategy of some health care firms to increase their market power by purchasing a full-service acute care facility and then closing all or some of the acquired firm's non-emergency services, often converting the acquired full services acute care facility into a free-standing emergency room.[17] Patients are then forced to travel long distances for non-emergency care, frequently provided by another facility owned by the acquiring firm. In other words, a health care firm can eliminate its competition in acute care services by buying a competing hospital and turning it into a freestanding emergency room. Freestanding emergency rooms often do not provide the same level of care as hospital-based emergency rooms, but regularly charge hospital emergency room prices for their services.[18]

9. OHCA should further specify the information that health care entities must report as part of a CMIR, including 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.

To evaluate labor market effects and the effects on staffing, prices, and location and availability of services, OHCA should clarify its emergency rule to include additional requirements on reporting by health care entities as part of CMIR. Specifically, CNA urges OHCA to maintain or add the following reporting requirements in §§ 97439(b)(10), (11), or (12) of the CMIR material change notice. CNA proposes additions to §§ 97439(b)(10), (11), or (12), which are included in Appendix below.

[16] For examples of this acquire and close behavior, please see National Nurses United's comments to the Federal Trade Commission's 2022 Request for Information on Merger Enforcement. See National Nurses United. Apr. 27, 2022. "Comment Submitted by National Nurses United." *Regulations.gov*, Docket ID FTC-2022-0003, Comment ID FTC-2022-0003-1831. https://www.regulations.gov/comment/FTC-2022-0003-1831.

[17] *Ibid.*

[18] *See, e.g.*, Byrne E. June 3, 2019. "Texas has more than 200 freestanding ERs. Lawmakers just passed bills to combat patient confusion and price gouging." *Texas Tribune*. https://www.texastribune.org/2019/06/03/freestanding-emergency-centers-bills-legislature/

- **Labor market impact reporting:** The health care entity should be required to report and provide a summary of its historical and expected post-transaction impact on the labor market, including employer concentration, unsafe staffing levels, unsafe occupational safety and health conditions, job loss, exploitative employment contract terms, or other negative impacts on health care worker wages or benefits.
- **Reporting on service reductions, closures, or shifts:** The health care entity should be required to report and provide a summary of its historical and expected post-transaction service reductions, closures, or other shifts in the location, availability, or acuity level of health care services.
- **Financial and administrative barriers to care reporting:** should be required to report and provide a summary of its historical and expected post-transaction impact on premiums, deductibles, provider network, prior authorization, out-of-pocket costs to patients, surprise billing, and other financial and administrative barriers to care for patients.

10. In § 97441(f)(2), OHCA should add provisions on public posting of CMIR reports and allow for OHCA to hold public hearings and receive verbal public comment on CMIRs.

To ensure effective public participation in the CMIR process, OHCA should include a provision in § 97441(f)(2) of the emergency rule that clearly states that OHCA shall publicly post on its website completed factual findings and preliminary reports upon completion of a CMIR. Additionally, while we appreciate that OHCA's emergency rule allows the public to submit written comments in response to the findings in the preliminary CMIR report, OHCA should also add language to § 97441(f)(2) that clearly requires OHCA to take additional measures to ensure public participation in the CMIR process. Specifically, OHCA should include language that permits OHCA to hold public hearings or workshops to take verbal public comment on the factual findings and preliminary reports of a CMIR and public comment on the CMIR.

11. OHCA should lower the patient revenue and asset thresholds for material change notice in § 97435(b)(1) & (2).

CNA supports lowering the patient revenue and asset threshold for material change notice in § 97435(b)(1) & (2). Reviewing HCAI's 2021-2022 annual financial data for hospitals, a significant number of hospitals would not meet the $25 million or $10 million revenue or asset thresholds.[19] There were 68 hospitals that had less than $25 million in net patient revenue and 40 with less than $10 million in net patient revenue. There were 51 hospitals with less than $25 million in total assets and 51 hospitals with less than $10 million in total assets. OHCA's draft patient revenue and asset thresholds also may inadvertently leave out from material change notice requirements some hospitals and health care entities that are a part of larger health care

[19] CNA analyzed data from Department of Health Care Access and Information. "Hospital Annual Financial Data – Selected Data & Pivot Tables, 2021-2022 FY Hospital Annual Selected File." California Health and Human Services Agency. https://data.chhs.ca.gov/dataset/hospital-annual-financial-data-selected-data-pivot-tables.

systems. Because some larger health care systems may use holding companies for assets, a single hospital or facility may not have reportable assets over $10 million or $25 million. For example, while it is not clear from reviewing HCAI annual financial data why precisely this is the case, there were over 30 hospitals that are Kaiser Foundation Hospitals that reported zero net assets for fiscal year 2021-2022.

Additionally, the dual $25 million and $10 million asset and revenue thresholds could be simplified to use only the lower $10 million asset and revenue threshold.

12. In § 97435, OHCA should use total annual revenue rather than net patient revenue and should clarify the definition of California asset.

To ensure that a number of large hospitals and health care facilities are not inadvertently left out of material change notice requirements, OHCA should use total annual revenue thresholds, including non-operating revenue, for CMIR material change notice rather than net patient revenue.

Additionally, it is unclear how OHCA defines ownership or control of California assets. As discussed in Comment #11, some hospitals and health care entities are a part of larger health care systems that use holding companies for assets. This leads to individual hospitals or health care facilities reporting zero net assets to HCAI in their annual financial data. Reviewing HCAI's 2021-2022 annual financial data for hospitals, over 30 hospitals that are Kaiser Foundation Hospitals and 14 other hospitals reported zero net assets for fiscal year 2021-2022. OHCA should clarify that a health care facility's control of California assets for the purposes of the CMIR rule would include assets owned by a holding company but operated by the health care entity.

13. CNA supports the inclusion of the § 97435(b)(3) material notice requirements for health care entities located in or serving health professional shortage areas.

To appropriately monitor for negative impacts of market consolidation and market power on rural and underserved communities, CNA strongly supports the CMIR emergency rule's inclusion of a notice filing requirement if a transaction involves a health care entity that serves a health professional shortage area.

It is precisely because of the interest of large investors, particularly for-profit health care systems, large health systems, and private equity firms, in small and rural health care facilities that OHCA should include, not exclude transactions involving health professional shortage from material change notice requirements. Large investors may be interested in acquiring health care facilities that serve rural or underserved areas because they may be able obtain a market advantage over competitor prices and payer mixes or because they may be able to close a competitor altogether.

First, CNA is greatly concerned about the trend of private equity and large health care systems buying small competitor hospitals and clinics in rural and underserved areas and

subsequently closing or reducing important services at hospitals and clinics. The acquire and close tactic by large health care systems appears to be growing throughout the country.[20] Health care entities should notify OHCA of transactions involving these critical health care providers so that OHCA can review the risk of post-transaction health care service closures or reductions.

Additionally, CNA is concerned about market-dominant health systems leveraging their market power to manipulate their own and competitor payer mixes to the dominant health system's advantage. In the CMIR process, OHCA should be monitoring whether a transaction may result in a health system gaining leverage through increased market dominance to demand favorable contract terms with commercial payers.[21] Exacerbating existing issues of access and affordability of care in health professional shortage areas, firms that dominate a market can cherry pick patients who have insurance plans that will pay higher prices for health care services while leaving patients without health insurance or who are enrolled in public health care programs to public or critical access facilities. In turn, loss of private payers in a critical access hospital or public health care facility's payer mix and attendant financial loss may make these facilities more susceptible to closing or being acquired by the dominant health care operator in the market. Because health care facilities serving rural and underserved areas are particularly vulnerable to changes in payer mix as a result of market consolidation, OHCA must ensure that it is notified when large health systems enter in a transaction with entities that provide services in health professional shortage areas.

14. CNA supports the inclusion of management service organizations and independent physician associations as health care entities in § 97431(g).

Finally, CNA supports the inclusion of management service organizations (MSOs) and independent physician associations (IPAs) as health care entities subject to the material change notice and CMIR requirements. The increasing use of risk-bearing arrangements by providers and vertical integration of providers through managed care arrangements makes the market behavior of MSOs and IPAs, which manage the administrative functions and structures of risk-bearing entities, increasingly important. As risk-bearing entities consolidate in the market, the opportunity to increase financial and insurance barriers and to leverage favorable insurance market arrangements between providers and the risk-bearing entities serviced by MSOs and IPAs also grows. In other words, even though their decision-making is based on financial risk and not based on the clinical judgement, MSOs, and IPAs function as gatekeepers to care and should be regulated as health care entities subject to material change notice requirements and CMIR under the emergency CMIR rule.

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[20] *See supra* note 16.

[21] Some examples of contracts between large health systems and commercial insurers that can alter payer mixes of health care facilities serving rural and underserved communities include agreements where private insurance provider networks include all facilities owned and operated by a health system ("all-or-nothing" agreements), clauses that require insurers to place all system facilities in the most favorable tier ("anti-tiering" clauses), and contracts that prohibits an insurer from steering patients to other health systems ("anti-steering" clauses). See also Gudiksen K et al. 2021 "Mitigating the Price Impacts of Health Care Provider Consolidation." *Issue Brief*, Milbank Memorial Fund. https://www.milbank.org/wp-content/uploads/2021/09/Mitigating-the-Price-Impacts-of-Health-Care-Provider-Consolidation_2.pdf.

CNA again appreciates the opportunity to provide OHCA with comments on the draft CMIR emergency rules. If you have any questions, please contact Carmen Comsti at (510) 206-6083 or ccomsti@calnurses.org.

Sincerely,

Puneet Maharaj
Director of Government Relations
California Nurses Association/National Nurses United

Appendix

CNA's Proposed Amendments to the CMIR Emergency Regulations

Proposed amendments to § 97441(a)(2) with additions underlined and deletions with strikethrough:

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

(A) If the transaction, the market failure, or market power 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, the market failure, or market power 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, the market failure, or market power may lessen competition or tend to create a monopoly in any geographic service areas impacted by the transaction.

(D) If the transaction, the market failure, or market power directly affects a general acute care or specialty hospital.

(E) If the transaction, the market failure, or market power may negatively impact the quality of care.

(F) If the transaction between a health care entity located in this state and out-of-state entity may increase the price of health care services or limit access to health care services in California.

(G) If the transaction, the market failure, or market power may result in a negative labor market impact, including employer concentration, unsafe staffing levels, unsafe occupational safety and health conditions, job loss, exploitative employment contract terms, or other negative impacts on health care worker wages or benefits.

(I) If the transaction, the market failure, or market power may result in health care service reductions, closures, or other shifts in the location, availability, or acuity level of health care services.

(H) The health care entity's history of any of the factors described in subparagraphs (A) to (H).

Proposed amendments to § 97441(e) with additions underlined and deletions with strikethrough:

(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 and the risk of health care service reductions, closures, or other shifts in the location, availability, or acuity level of health care services.

(2) The effect on the quality of health care services to the community 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) 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) 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) The negative effect on the labor market and health care workers, including employer concentration, unsafe staffing levels, unsafe occupational safety and health conditions, potential job loss, exploitative employment contract terms, or other negative impacts on health care worker wages or benefits.

(8) The effect on premiums, deductibles, provider network, prior authorization, out-of-pocket costs to patients, surprise billing, and other financial and administrative barriers to care for patients.

(9) The health care entity's history of any of the factors described in paragraphs (1) to (8), including, but not limited to, citations, complaints or other allegations against any health care entity that is party to the transactions for violations of local, state, or federal worker protection, consumer protection, or antitrust law.

~~(7)~~ (10) Any other factors the Office determines to be in the public interest.

Proposed amendments to §§ 97439(b)(10), (11), and (12) with additions underlined and deletions with strikethrough:

(10) A description of current services provided and expected post-transaction impacts on health care services, which shall include, if applicable:

(A) Physical addresses where services are performed;

(B) Levels and type of health care services offered, including reproductive health care services, labor and delivery services, pediatric services, behavioral health services, cardiac services, ~~and~~ emergency services, and potential service reductions, closures, or other shifts in the location, availability, or acuity level of health care services;

(C) 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;

(E) Charity care;

(F) Community benefit programs; and

(G) Medi-Cal and Medicare.

a summary of its historical and expected post-transaction.

(11) Description of any other prior transactions that:

(A) Affected or involved the provision of health care services, including service reductions, closures, or other shifts in the location, availability, or acuity level of health care services;

(B) Involved any of the health care entities in the proposed transaction; and

(C) Occurred in the last ten years.

(12) 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, labor market concentration, any prior transaction that had a labor market impact, and any labor or employment violation or complaint within the past ten years.

(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.

(F) Billing and insurance administration policies, including any expected post-transaction changes to, as applicable, premiums, deductibles, provider network, prior authorization policies, out-of-pocket consumer costs, or out-of-network billing policies, and including any consumer 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 within the past ten years.

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August 31, 2023

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BY EMAIL

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Re: **Proposed Rules for the Office of Health Care Affordability Review of Material Change Transactions**

Dear Ms. Brubaker:

Ropes & Gray LLP ("Ropes & Gray") is a leading global law firm with offices in New York, Boston, Chicago, San Francisco, Washington, D.C., Silicon Valley, Los Angeles, London, Hong Kong, Shanghai, Tokyo and Seoul. We represent interests across a broad spectrum of industries and businesses and—most relevant to the review of material change transactions by the Office of Health Care Affordability's ("OHCA")—have market-leading positions in mergers & acquisitions, private equity, health care and life sciences. Given this expertise and based on our experience representing clients with businesses in the State of California, Ropes & Gray appreciates the opportunity to provide written comments on the proposed rules promulgated by OHCA, as set forth in the proposed regulations issued on July 28, 2023 (the "Proposed Rule").

We commend OHCA for its efforts to issue regulations that clarify open questions in the underlying material change transaction statute, and for its willingness to solicit public feedback on the draft standards. We write to raise several, critical outstanding issues regarding the standards contained in, or omitted from, the Proposed Rule that, without further clarity, create ambiguity and could result in OHCA's review of transactions that exceed the intended legislative scope. We offer these comments in the spirit of contributing to the creation of commercially reasonable standards that will support the Health Care Quality and Affordability Act's aim to promote transparency for the California community and support statewide priorities related to health equity, cost, access and quality, but without stifling interstate commerce or the ability for California to attract investment in the health care industry.

Please find below our specific questions and recommendations in response to the Proposed Rule.

1. **Transactions Exempted from Review (22 CCR § 97435 (referencing Cal. Health & Saf. Code § 127507(d)))**
    a. Subdivision (d) of Cal. Health & Saf. Code § 127507 enumerates exemptions from the OHCA review process for certain agreements or transactions already subject to review by the Department of Managed Health Care ("DMHC"), the Commissioner of the Department of Insurance ("CDI"), the California Attorney General ("AG"), or county transactions for continued access. The Proposed Rule references such exemptions in 22 CCR § 97435, but provides no further clarification.
        i. While enumerated statutory exemptions may be written narrowly to apply only to certain subsets of transactions subject to DMHC, CDI, or AG purview, our understanding from OHCA guidance materials is that "[n]otices are not required" more broadly for *any* "transactions subject to DMHC, CDI, or AG review."[1] We agree with such intent, as duplicative review by multiple state agencies would be an inefficient use of resources, and could create unnecessary burden for parties to a transaction.
        ii. We suggest clarifying the Proposed Rule to align with such intent, and to avoid duplicative review processes by state agencies.
            1. For example, if a third party administrator that otherwise qualifies as a "health care entity" per Cal. Health & Saf. Code § 127500.2(k) consummates a transaction subject to CDI's change of ownership process, this transaction should be exempt from OHCA review as it is already undergoing review by CDI.
            2. Furthermore, we understand that there are several pending California bills, including a bill that would impose additional review by the AG for certain health care entities (AB 1091) and a bill that would expand DMHC's review authority (AB 1092). In light of such pending bills, it is even more vital that OHCA's Proposed Rule establish clear exemptions to avoid duplicative layers of review.
        iii. We recommend that OHCA clarify that *any* transaction that already undergoes review by a separate state agency is exempted from OHCA's review process per Cal. Health & Saf. Code § 127507(d).
            1. In particular, please elaborate and expand on the enumerated exemptions. For example, Cal. Health & Saf. Code § 127507(d)(3) should be expanded to include, in addition to counties, agreements or transactions where a government entity is undergoing such a transaction, where

[1] *See* June 2023 OHCA Board Meeting Presentation, page 38. *See also* August 2023 OHCA Board Meeting Presentation, page 15.

"government entity" includes hospital districts, cities, counties, and other governmental entities.

2. **Cost and Market Impact Review Referrals (22 CCR § 97441; Cal. Health & Saf. Code § 127507.2(a)(1))**
    a. Pursuant to Cal. Health & Saf. Code § 127507.2(a)(1), OHCA may conduct a Cost and Market Impact Review ("CMIR") if DMHC, CDI or the AG refer a transaction or agreement to OHCA. The Proposed Rule does not provide further clarification regarding the referral process from other reviewing authorities.
        i. The CMIR process, as set forth in Cal. Health & Saf. Code § 127507.2(a) and 22 CCR § 97441(d) of the Proposed Rule, is extremely lengthy (90- to 135-day review period after OHCA's determination to conduct a CMIR; a 10-day public comment period from issuance of a preliminary report; a 30-day period from close of the comment period for OHCA to issue a final report; and a 60-day waiting period for a transaction or agreement to occur after issuance of a final report). We note also that the Proposed Rule grants OHCA broad discretion to toll such review period at various points throughout the process. As such, the CMIR process may delay transactions over six months; and, for all practical purposes, there are no actual timeframes or deadlines with which OHCA must act.
        ii. The uncertainty and delay caused by initiation of a CMIR may adversely impact transactions – especially those that are already undergoing separate review processes by other state authorities. Accordingly, we urge OHCA to: i) clarify in the Proposed Rule under what specific circumstances a transaction or agreement may be referred to OHCA for a CMIR by DMHC, CDI or the AG; and ii) establish a more reasonable timeline for CMIRs. For example, the timeline for review (at the very latest) should tie to the date the reviewing authority referred the transaction to OHCA.

3. **Documents to be Submitted with Notice (22 CCR § 97439(c))**
    a. Under 22 CCR § 97439(c) of the Proposed Rule, entities submitting a notice must upload: all current agreements and term sheets related to the transaction; contact information for parties; balance sheets; organizational charts; certified financial statements; organizational documents; HSR filings; any documentation related to mitigation of any potential adverse impacts of the transaction; and any analytic support for and/or documents supporting the submitter's responses to answers provided.
        i. While we appreciate OHCA's desire to have as much information about the parties and the transaction as possible to inform the review process, we believe that this vast volume of paperwork will be overly burdensome for parties to a transaction. We urge OHCA to tailor its requests, and, at minimum, remove requirements for the parties to the transaction to produce pro forma balance sheets (22 CCR § 97439(c)(3)),

financial statements (22 CCR § 97439(c)(5)) and organizational documents (22 CCR § 97439(c)(6)).

ii. We also ask OHCA to consider the intersection of the production requirements with the Hart-Scott-Rodino ("HSR") filing process. Under 22 CCR § 97439(c)(7) of the Proposed Rule, an applicant that has filed an HSR notice must submit a copy of such notice and any attachments thereto to OHCA. We note that many of the documents requested may be duplicative of an HSR filing, and as such it would be unnecessary to ask parties to provide these documents twice. Additionally, under proposed changes to the HSR notification process announced in July 2023, transacting parties who file an HSR notification will be required to submit substantially more information and documents in connection with the proposed transaction, past transactions, labor market competition, products and services, as well as draft and final transaction documents and ordinary course documents from a large number of document custodians. We urge OHCA to consider how such future changes in the HSR review process are likely to impact the documentation requested in the OHCA review process, and in particular account for how the HSR filing could satisfy certain aspects of the information required under Section 97439.

4. Confidentiality (22 CCR § 97439(d))

a. 22 CCR § 97439(d) of the Proposed Rule treats all information provided to OHCA in connection with a notice submission, including the required attachments as part of the public record, unless designated as confidential. Marked-confidential versions of stock purchase agreements, financial documents, compensation documents, contract rates, and unredacted resumes are automatically deemed confidential. If an entity submitting a notice would like to claim confidentiality with regards to the contents of the notice itself or other documents not specifically mentioned above, it must submit a detailed redaction log to OHCA and request confidentiality.

i. We share concerns with other commenters from the Public Workshop on August 15, 2023 that the regulations as currently drafted could be damaging to health care entities. While certain documents specified above are automatically considered confidential, given the breadth of documents required by 22 CCR § 97439(c) of the Proposed Rule, there are still many important and highly sensitive documents that would not receive such treatment. Documents that are not currently deemed as automatically confidential under the Proposed Rule include HSR filings, certain transactional documents (e.g., affiliation agreements), organizational charts, or private corporate governance documents such as partnership agreements.

1. First, we note that, in particular, HSR filings are treated as confidential by the federal government. As such, these documents should be automatically confidential in the OHCA review process and entities submitting a notice should not have to submit a corresponding redaction

log. We urge OHCA to consider the fact that many entities captured by its review process are private health care entities. Requiring these entities to disclose sensitive information without the guaranty of confidentiality would be unreasonably burdensome and inconsistent with the confidential treatment of HSR filings under federal law.

2. Second, the Proposed Rule provides that "stock purchase agreements" may be marked confidential and automatically deemed so by OHCA; we ask OHCA to clarify whether asset purchase agreements, merger agreements or other types of purchase agreements would be treated similarly.
3. Third, in the event that OHCA denies a confidentiality request, we ask OHCA to clarify: (a) whether OHCA will be required to explain the rationale behind such denial; and (b) if there is an appeal or withdrawal process for such denial.

a. We understand from OHCA's presentation at the Public Workshop on August 15, 2023 that only the notice of material change would be immediately posted to the OHCA website, and that supporting documentation would only be published if the transaction is subjected to a CMIR. Please confirm this understanding is correct, and if so, please clarify this in the regulations.

5. Reimbursement for Costs (Cal. Health & Saf. Code § 127507.4)

a. Under Cal. Health & Saf. Code § 127507.4, OHCA may consult with other state agencies or contract with consultants or experts in its transaction review. Expert contract costs must be "reasonable and necessary," and OHCA can seek reimbursement from the health care entity subject to review for these costs. The Proposed Rule, under 22 CCR § 97439(f), notes that a submitter may withdraw notice by submitting a request to OHCA any time between submission of the notice and issuance of a final report, and that OHCA will remain entitled to collect any costs incurred in connection with any reviews up until the first business day after withdrawal notice is received.
    i. We ask OHCA to clarify what constitutes "reasonable and necessary" and to consider imposing an explicit limit of $75,000 on the amount that health care entities are required to reimburse OHCA.

6. Affiliates (22 CCR § 97431(g)(3); 22 CCR § 97431(a))

a. Per 22 CCR § 97431(g)(3) of the Proposed Rule, the definition of "health care entity" includes any affiliates, subsidiaries, or other entities that control, govern, or are financially responsible for a health care entity or that are subject to the control, governance, or financial control of a health care entity. This expansive definition inherently creates ambiguity for potential filers.
    i. Specifically, we believe that including affiliates, subsidiaries or other entities that have control over a health care entity within the definition of "health care entity"

is overly broad and should be removed from the definition. The Health Care Quality and Affordability Act posits that health care entities only include payors, providers, and fully integrated delivery systems, none of which capture a broader set of affiliates or subsidiaries, but rather simply apply to health care entities directly.

b. Furthermore, under 22 CCR § 97431(a), "affiliate" is defined as 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.
    i. We ask OHCA to clarify the meaning of "*collaborate* for the provision of health care services."

7. Management Services Organizations (§ 97431(g)(3))

a. Per 22 CCR § 97431(g)(3) of the Proposed Rule, the definition of "health care entity" includes "a management services organization, which qualifies as a 'payer'" pursuant to Cal. Health & Saf. Code § 127500.2(o).
    i. If OHCA is interpreting all MSOs to be "payers" for purposes of the regulations:
        1. please explain OHCA's rationale and the practical effect under the Proposed Rule behind designating MSOs as "payers";
        2. note that including MSOs as "payers" appears to run contrary to statutory intent, because the statutory definition of "payer" per Cal. Health & Saf. Code § 127500.2(o) does not capture the vast majority of MSOs; and
        3. consider clarifying that the definition only includes those MSOs that directly enter into contracts with payors, as opposed to MSOs that simply provide administrative services related to payor arrangements.
    ii. An alternative interpretation of this definition is that an entity must qualify as a payer, under the statutory definition of such term, to be considered a management services organization. In other words, only management services organizations that are also considered payers are subject to review. This interpretation would be more limited and would address several comments received during the Public Workshop on August 15, 2023.
    iii. Additionally, please clarify the definition of management services organizations under 22 CCR § 97431(j) of the Proposed Rule. In particular, please confirm what constitutes "other services and support" and consider the deletion of such phrase, to prevent unintentionally broadening the scope of entities to which the law applies.

8. Revenue Thresholds for Health Care Entities (22 CCR § 97435(b))

a. 22 CCR § 97435(b) of the Proposed Rule clarifies the revenue thresholds that subject health care entities to a filing requirement.
    i. While we appreciate OHCA's efforts to impose materiality thresholds on health care entities subject to review, we believe that the enumerated thresholds in the

Proposed Rule are too low based on market conditions, both locally and nationally. Accordingly, we ask OHCA to consider requiring that both the health care entity *and* another party to the transaction have annual revenue exceeding $25 million.

9. "Material Change" Thresholds (22 CCR § 97435)

a. 22 CCR § 97435 of the Proposed Rule outlines the materiality thresholds that trigger notice and review requirements.

i. Under 22 CCR § 97435(c)(3), a transaction is considered a material change if it involves the transfer of 20% or more of a health care entity's assets. A health care entity might make minor divestitures or sales of assets in the ordinary course. Such minor transactions are unlikely to affect the health care quality or price of health care delivered to California residents, and imposing significant transaction review delays on such sales could jeopardize health care entity solvency. We urge OHCA to consider increasing this percentage to 75%, which reflects a focus on material transactions affecting health care entities, and aligns with the definition of "substantially all" assets under California nonprofit law. *See* Cal. Code Regs. tit. 11 328.1.

ii. Under 22 CCR § 97435(c)(5), a transaction is considered a material change if the terms of the transaction contemplate an entity "negotiating or administering contracts with payers… and the transaction involves an affiliation, partnership, joint venture, accountable care organization, parent corporation, management services organization, or other organization." This definition is quite broad, as almost any management services agreement would be included if it involves a form of affiliation (even if the affiliation were existing and the management services agreement is simply a re-negotiation). We urge OHCA to consider narrowing this provision by deleting "negotiating or", which would be consistent with New York law. Please also clarify why accountable care organizations are being brought in specifically here, and whether the proposed rule is intended to involve transactions with accountable care organizations negotiating commercial payor contracts and transactions involving Medicare Shared Savings Program accountable care organizations.

iii. Under 22 CCR § 97435(c)(7), a transaction is considered a material change if it involves a health care entity merging or affiliating with another health care entity, affiliation, partnership, joint venture or parent corporation, where any health care entity has at least $10 million in annual revenue. We ask that OHCA consider increasing such threshold to at least $25 million in annual revenue. Additionally, we note that for purposes of this subsection, a clinical affiliation does not include a collaboration on clinical trials or graduate medical education programs. However, "clinical affiliation" is not used in this section. Please clarify.

iv. Under 22 CCR § 97435(c)(8), a transaction is considered a material change if the transaction changes the form of ownership of a health care entity that is a party to the transaction, including but not limited to a change from a physician-owned to private equity-owned and publicly held to a privately held form of ownership. Please (i) clarify whether a physician entity can ever change control without being subject to the review process, and (ii) consider adding a materiality qualifier.

v. Under 22 CCR § 97435(c)(9), a transaction is considered a material change if 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. Please clarify what transactions OHCA intends to capture here and what exemptions apply.

10. "Control" Definition (22 CCR § 97435(e))

a. 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.

i. Please consider the distinction between equity ownership and governance. We agree that a change in governance should require a change in board or manager control; however, with respect to a change in equity ownership, we ask that you consider increasing this percentage to greater than 50%. As drafted, the 10% threshold is an extremely low and could capture ordinary course activities of health care entities related to governance and operations. Further, we suggest clarifying how a percentage of administrative control would be calculated.

ii. Moreover, given the current cash flow issues facing many businesses, it is common to issue minority equity interests in exchange for capital to meet immediate operational needs. This type of transaction may no longer be feasible with a reasonable time frame if it is subject to burdensome review processes.

11. "Revenue" Definition (22 CCR § 97435(d))

a. The Proposed Rule, under 22 CCR § 97435(d), defines revenue to mean the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years.

i. We believe that the nexus to "California-derived" revenue is helpful in ensuring that the OHCA law does not violate principles of interstate commerce and capture transactions outside of the state's borders.

ii. However, we urge OHCA to consider whether "revenue" is defined too broadly, because the Proposed Rule contemplates aggregating revenue of all "affiliates." If there are multiple California entities at issue in a national platform, the thresholds could be easily triggered, even if no single entity has a significant

California presence. Moreover, the limitations on the definition of "affiliate" are unclear – please clarify whether a holding company that owns multiple independent businesses would have to aggregate the revenue of all businesses, for example.

12. "Transaction" Definition (22 CCR § 97431(q))

a. The Proposed Rule clarifies that "transaction" includes "mergers, acquisitions, affiliations, or other agreements involving the provision of health care services in California that involve a change 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," in 22 CCR § 97431(q).
    i. We urge OHCA to consider whether this definition is too broad, as it includes both indirect and direct changes to ownership, and does not specify how far up the chain of ownership to which "indirect" changes apply.
    ii. Please also clarify what is considered to constitute "other agreements involving the provision of health care services." For example, please clarify whether the lease of a medical building or a debt issuance would be considered a "transaction."

13. Pre-Filing Questions (22 CCR § 97437)

a. Thank you for clarifying that health care entities that are unsure if they must file a notice may email OHCA.
    i. Please provide further detail regarding the process for answering pre-filing questions, including the timeframe in which OHCA will respond to entities (e.g., within ten days), the information that should be provided for such determination, and the confidentiality of such request.

14. Corporate Restructuring Exemption (22 CCR § 97435(f))

a. Under 22 CCR § 97435(f) of the Proposed Rule, a transaction is not a material change transaction if a health care entity already controls, is controlled by, or is under common control with "all other parties to the transaction" such as a corporate restructuring.
    i. Please confirm that a corporate restructuring involving the formation of a new entity, such as a holding company, within the same organizational structure, would fall under such exemption (rather than under 22 CCR § 97435(c)(6) of the Proposed Rule).

15. Emergency Exemption

a. We urge OHCA to consider exempting emergency transactions from the full review process.
    i. For example, Oregon may exempt a transaction from review if "there is an emergency situation, including but not limited to a public health emergency,

which immediately threatens health care services; and the transaction is urgently needed to protect the interest of consumers and to preserve the solvency of the entity other than a domestic health insurer." OAR 409-070-0022(1).

ii. Given the potential length of time associated with review, distressed entities may not be able to survive for the entirety of the review process. An emergency exemption is vital to ensure that these entities can consummate transactions to keep them solvent and providing health care services in the state.

iii. Consider adding a specific review timeline for the emergency exemption process (*e.g.*, 30-60 days).

* * * * *

We thank you once again for the opportunity to provide comments to OHCA's Proposed Rule for material change transactions. We value OHCA's willingness to consider our input, and we look forward to continued collaboration.

Very truly yours,

Timothy M. McCrystal
Ropes & Gray, LLP

August 31, 2023

Secretary Mark Ghaly, M.D., CA Health & Human Services Agency
Director Elizabeth Landsberg, Department of Health Care Access & Information (HCAI)
Deputy Director Vishaal Pegany, Office of Health Care Affordability (OHCA), HCAI
Megan Brubaker, Cost and Market Impact Review, OHCA, HCAI
2020 W. El Camino, Ste. 1200
Sacramento, CA

Re: Proposed Cost and Market Impact Review Regulations

Dear Dr. Ghaly, Ms. Landsberg, Mr. Pegany, and Ms. Brubaker,

Our organizations support strong oversight of the health care market, including oversight of market failures and market power, as well as proposed transactions. We offer the following comments to strengthen the proposed emergency regulations on cost and market impact reviews and to close gaps in those regulations.

1. Lower thresholds for transactions aligned with the OHCA Act and Attorney General review:
    a. A threshold of $6 million in assets or revenue for the acquiring entity and $3 million in assets or revenue for the entity being acquired
    b. Clarity that revenue applies to total revenue from all sources, not net patient revenue
2. Clarity that market reviews include reviews for market failure or market power as demonstrated by the repeated testimony from Monterey County and are not limited to transactions.
3. Clarity that information is not eligible to be designated confidential unless it is not otherwise publicly available.
4. Inclusion of the full range of health care services:
    a. Addition of behavioral health services in health care services
    b. The full range of reproductive health services, including all forms of contraception and abortion in affected services
    c. The full range of LGBTQ services, including gender-affirming care, which was omitted in the current draft
5. Inclusion of IPAs and Management Service Organizations as health care entities.
6. Expected labor market impacts, including direct health care labor market impacts and indirect impacts on wages and benefit costs for all consumers.
7. Requirement that any statements about the potential benefits of a transaction include evidence, if any, such as peer-reviewed studies of similar transactions or post-merger impacts as well as measurable impacts post-transaction for future monitoring.

8. Fees on the health care entity or entities subject to review equal to “all actual, reasonable, and direct costs”, consistent with the Act.
9. Public notice, public comment, public meetings
    a. Public notice of a determination not to conduct a transaction review
    b. Clarity that public comment will be accepted during the period after a transaction is noticed and prior to the preliminary report
    c. Addition of public meetings for significant transactions or upon request of stakeholders

These changes would further strengthen and provide clarity to the proposed regulations as well as being consistent with the OHCA Act and other state law.

HEALTH ACCESS CALIFORNIA

August 31, 2023

Elizabeth Landsberg, Director
Department of Health Care Access and Information

Vishaal Pegany, Deputy Director
Department of Health Care Access and Information
Office of Health Care Affordability

Sheila Tatayon, Assistant Deputy Director
Department of Health Care Access and Information
Office of Health Care Affordability, Health System Compliance
2020 W. El Camino, Ste. 1200
Sacramento, CA

Attn: Megan Brubaker

Re: CMIR Regulations

Dear Ms. Landsberg, Mr. Pegany and Ms. Tatayon:

Health Access, the statewide health care consumer advocacy coalition committed to quality, affordable health care for all Californians offers comments on the proposed regulations on "Cost and Market Impact Reviews."

Health Access appreciates the opportunity for comment on these proposed emergency regulations. We also recognize that these are initial regulations that may be further revised and improved in future years. In that spirit, in some instances we may recommend consideration of further action in the future. In other instances, corrections and clarifications are needed now.

If enacted as proposed, the regulations would provide important and necessary oversight of a broad range of mergers and other transactions in health care, transactions which have real impact on cost, quality, equity and value of that care for Californians. The Act does not allow the Office to approve, deny or approve with conditions but only to refer to other agencies for appropriate action.

Many of the proposed regulations are consistent with the Act and contain many commendable provisions to clarify and implement that law. Unfortunately, some provisions of the proposed regulations are contrary to the statute, prohibit the implementation of statutory provisions, or contain other omissions and lack of clarity for stakeholders.

The timelines proposed in the initial regulations appear to us to provide the OHCA staff sufficient time to carefully review the market implications of large and complex transactions with various cross-market impacts: some but not all of the transactions reviewed will be large and complex and will require such time. Also, the provision in the Act on the Office being entitled to reimbursement for "all actual, reasonable, and direct costs" incurred in the review[1] is similar to provisions in the law governing review of transactions by both the Attorney General and the Department of Managed Health Care. Health Access would oppose capping the reimbursement or otherwise limiting the time, resources or ability of the Office to undertake the market reviews required under the Act.

Health Access has worked on merger oversight for over thirty years, dating back to the earliest days of oversight by California Attorneys General of non-profit hospital transactions. Many of those transactions involve a single hospital and are much less complex than some of the transactions encompassed in the OHCA statute and the proposed regulations.

Major Points: Summary

- The proposed regulation literally precludes reviews for market failures and other instances of market power absent a noticed transaction. This must be corrected.
- The proposed thresholds for transactions should be lower to be consistent with the Act on the size of physician groups and to align with the thresholds used by the Attorney General in hospital transactions. The definition of revenue and assets are unduly narrow and should be revised.
- Documents submitted with the notice should be considered confidential only if information is not otherwise public.
- The definition of health care services should include the full range of behavioral health services described in SB 855 and AB 988
- The definition of health care services should include the full range of reproductive services, including those provided in outpatient settings. It should also include gender-affirming care and other LGBTQ care.

- Assertions about benefits of transactions should include supporting evidence, if any, as well as measurable impacts that can be evaluated post-transaction for impacts.
- Public notice, public comment and public meetings should be clarified and enhanced.
- Coordination with other departments: consistent with the enabling statute, some transactions are in the purview of other departments. Greater clarity on this would be helpful.
- As already noted, we support a sufficient timeline to allow review of complex transactions and recovery of actual and necessary costs to the Office of the review, consistent with the Act.

Major Points: Discussion

Health Access takes note of the extensive work involved in developing the proposed regulations and supports much of what is proposed. These major points identify key provisions that prevent implementation of the statute or that constitute major omissions. In the next section, we will provide further comment on important points, both good and problematic.

- Reviews for "market power and other market failure" Section 97441

Section 97441 (a) (1) p. 12 states "in determining whether to conduct a cost and market impact review based on a market failure or market power," the "Office will consider the factors in (a) (2)." Section (a) (2) states "the Office may base its decision on any one or more of the following factors". But every one of the factors in (a) (2) relate to transactions. Indeed, each of the subsections under (a) (2) (A), (B), (C), (D) (E) and (F) begins with "If the transaction may." Not one of the factors in (a) (2) relates to market failure or market power that has already occurred. Read literally Section 97441 (a) would preclude the implementation of the statutory provisions for "cost and market impact reviews based on a market failure or market power" and limit such reviews only to transactions. This is directly contrary to both the statute and to what has been represented as the intent of the staff. This must be corrected. We propose two possible approaches to do so.

Section 97441 (e) (1) and (2) on "factors considered in a CMIR" are similarly limited solely to transactions. Section (3) read literally could also be limited to transactions because it says "The effect of lessening competition or tending to create a

monopoly" and does not take into account situations in which a functional monopoly already exists or competition has been lessened by prior transactions.

Taken together, these provisions would prevent the Office from conducting a review of *existing* market failures or market power and limit its role exclusively to review of transactions. As cited in the Notice,

> *Pursuant to Health and Safety Code section 127501(c)(12), the Office of Health Care Affordability within the Department of Health Care Access and Information shall:*
>
> > *Review and evaluate consolidation, market power, and other market failures through cost and market impact reviews of mergers, acquisitions, or corporate affiliations involving health care service plans, health insurers, hospitals, physician organizations, pharmacy benefit managers, and other health care entities.*

Our strong preference is the creation of a new section to reflect the Department's authority to conduct market reviews for market failure and market power similar to Section 97441 for transactions and then editing Section 97441 to narrow it to transactions. Examples of market failures and market power are not limited to geographic regions. For example, Envision Healthcare and other privately held staffing services are increasing costs through using market power.

However, if creating a new section on market reviews for market failures is not possible at this time because of time limits, the Department could choose to come back to this topic later and make a smaller drafting change:

> Section 97441 (a) Office Determination Whether to Conduct Cost and Market Impact Reviews
>
> > (1) In determining whether to conduct a cost and market impact review based on a market failure or market power *in the absence of a specific transaction, the Office may base its decision to initiate a review on any of the following: the lack of the availability or accessibility of health care services; lack of affordability for payers, purchasers or consumers; lack of competition in a geographic area; or the presence of high-cost outliers.*
> >
> > *(2)* 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 competition, 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) (3).
> >
> > ~~(2)~~ *(3)* The Office may base its decision to conduct a cost and market impact review on any one or more of the following factors:

No changes proposed for (A), (B), (D), (E), or (F).

We propose that (C) be amended as follows:

(C) If the transaction may lessen competition or tend to create a monopoly in any geographic service areas, *market segments, or types of care or service* impacted by the transaction.

For example, in the Oakland-Berkeley area, Sutter has a monopoly of the non-Kaiser commercial market. Similarly, some large specialty groups have functional monopolies of particular types of physician care.

- Material Change Transactions. Section 97435

Health Access seeks thresholds for material change transactions that are proposed in Section 97435 (b), (c), (d), and (e).

(b) Who must file?

The draft regulations propose a threshold of $25 million in annual revenue or $25 million in assets for one entity in the transaction and $10 million in revenue or assets for the other entity. While these thresholds may be modeled on the thresholds used in other states, the law in other states about which entities to which such a review applies is different than California law. The OHCA Act and other California law has different and more expansive thresholds than the thresholds in other states.

The proposed thresholds of $25 million and $10 million are far in excess of the $3 million threshold used by the Attorney General for hospital transactions. It is also far in excess of the threshold in the OHCA statute of 25 or more physicians, particularly if the revenue or assets of a physician organization is separate from a medical services organization as the regulations appear to intend. The average salary for physicians in California is $230,000 according to the federal Bureau of Labor Statistics[2]. At that rate, a threshold of $6 million would be more consistent with the underlying statute. We also note that under Section 127507 (b) if a transaction involves an exempted provider, then the obligation to file rests with the acquiring or affiliating entity, not the exempted provider. This should be clarified in the regulations.

We propose the following thresholds for (b):

(1) Annual revenue or assets of $6 million

(2) For an entity involved in a transaction with an entity in (b) (1), annual revenue or assets of $ 3 million (consistent with the existing California DOJ standard)

We also propose broadening (b) (3): the concept of serving at least half of the patients is good but should not be limited to health professions shortage areas:

(3) A health care entity located in a health professions shortage area or serving at least 50% of the patients or providing at least 50% of a particular service in a geographic area, defined in the same manner as health professions shortage areas.

At the Health Care Affordability Board, there was extensive discussion about the equity impacts of focusing reviews on health professions shortage areas precisely because these are areas in need of greater health care investment. Our solution to that concern is to broaden the standard of review so it applies to any geographic area where a health care entity is serving 50% of the patients or providing at least 50% of a service. We propose using the same definition of geographic area as is used for health professions shortage areas[3].

We also note that Section 97435 (b) (1) and (b) (2) apply to either entity engaged in the transaction, that should be clarified. The existing language creates two different dollar thresholds without being clear about which applies to which entity. Finally, we note that the statute expressly exempts "exempted providers" from being required to file: in that instance, it is only the acquiring entity which must file. Consistent with the statute, that should be corrected as well.

(b) Who must file. A health care entity shall provide written notice of a transaction with the Office if the transaction involves any parties listed in (b) (1) through (b) (3) under any one or more 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 *$6 (six)* million or that owns or control California assets of at least *$6 (six)* million; or

(2) A health care entity with annual revenue, as defined in subsection (d), of at least *$3 (three)* million or that owns or controls California assets of at *$3 (three)* million and is involved with any health care entity satisfying (b)

(1) *and that is not an exempted provider*;

(3) A health care entity ~~located in or~~ serving at least 50% of the patients in a geographic area *or providing at least 50% of a particular service in a geographic area, defined in the same manner as health professions shortage areas*.

(c) Circumstances requiring filing:

For (1), (2), (6) and (7) we propose parallel changes in the thresholds of $6 million and $3 million rather than $25 million and $10 million as proposed.

We also propose a threshold of 10% of revenue or assets rather than 20% for (2) and (3). Depending on the structure of ownership or control, even 10% may be sufficient to create effective control.

For (8), it is unduly narrow as drafted. While we appreciate that a change to private equity-owned from physician-owned is important, other changes of ownership or control should also be captured. For example, in some instances a privately held entity becomes publicly held. In other instances, a health system may acquire a physician-owned 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 a private equity-owned and publicly held to a privately held form or ownership *or from a privately held to publicly held form of ownership.*

We strongly support (9) with its emphasis on cumulation over ten years. We have time and again observed serial transactions where the initial transaction may be small but the cumulative impact is great. This has occurred with physician organizations, including those associated with Optum which is owned by United Healthcare. Other transactions such as those involving 99-year leases of district hospitals had a similar cumulative impact.

(d) Revenue:

We support the definition of revenue as the "total average annual California-derived revenue for received for all health care services by affiliates over the most recent three years".

We suggest a small revision to this sentence to read:

> For purposes of this section, revenue means total average annual California-derived revenue for received for all health care services by affiliates, *subsidiaries, and other related entities* over the most recent three years, *including revenue from any of the following* ~~as follows:~~

While the definition of revenue for hospitals reaches for the most convenient source of information, we note that health systems now extend far beyond the four walls of the licensed facility and include a variety of outpatient and other settings, including labs, imaging and more. The definition of revenue needs to be broad to capture all of these; greater clarity on this would be helpful.

For both hospitals and nursing homes, net patient revenue is a subset of total revenue and often is not a good measure of financial capacity. Many health facilities and health systems have substantial investments and reserves that produce income. Using net patient revenue and excluding other income creates a threshold that will exclude dozens of hospitals and nursing homes. A better measure would be total revenue[4].

(e) Control, responsibility or governance.

We ask that as in 97435 (f), section (e) be amended to refer to a transfer of control, responsibility or governance that "directly or indirectly" transfers or changes control, responsibility or governance.

(f) should be amended to provide greater clarity. Although (b) (1) references the relevant part of the statute by stating that a health care entity "shall file a notice" "unless exempted" under Section 127507 (d)(1) through (4), we are encountering instances of confusion about duplicate review. Greater clarity would be helpful. We suggest revising (f) as follows:

> (f) *Transactions Not Subject to Filing Requirements*
> (1) A transaction is not a material change transaction (no other change)
> *(2) The requirement to provide notice of a material change does not apply to agreement subject to review by the Department of Managed Health Care, the Department of Insurance, the Attorney General, or a county, consistent with by subdivisions (d) (1) through (4) of section 127507 of the Code.*

- Confidentiality: Section 97439 (d): Confidentiality of Documents Submitted with the Notice:

First, we commend the inclusion of the statement that "all of the information provided to the Office shall be treated as public record unless" the entity requests that it be treated as confidential and the Office accepts that designation.

We also commend the provision in (d) (2) that information may be withheld if the information is proprietary or of a confidential business nature, the public interest is served in withholding the information and other law or statute makes the information confidential. We appreciate the inclusion of the language that recognizes that information is not confidential if it has not been confidentially maintained.

Unfortunately, (d) (2) has an omission that should be corrected: it should be amended to require that any information that an entity asserts is confidential must not be "otherwise available to the public". Information is not confidential if federal or state law or regulations require it to be made public.

Numerous examples of this occur. For instance, an acquiring entity may disclose to investors in investor calls explanations of the probable benefits of a transaction to shareholders or other investors such as cutting staff, eliminating services lines, or terminating existing payer contracts in order to increase reimbursement rates. If such information has been disclosed, it has not been "confidentially maintained." Similarly, some information is required to be disclosed by state law and regulations or federal law and rules. For example, contracted rates for hospitals as well as negotiated rates paid by health plans/insurers to physician organizations is required to be publicly disclosed by federal rules, but various entities frequently assert that such information is confidential. Within the last month, health care entities have asserted that such information should not be made public in the context of HCAI discussions of the Health Payments Database even though the federal rules already require that it be made public. Similarly, audited financial statements for health plans and hospitals are already publicly available and should not be treated as confidential information. Federal rules also require other disclosures to investors.

The specific changes we seek are in Section 97439 (d) (2):

> Bases for confidentiality shall include: (1) the information is proprietary or of a confidential business nature, including trade secrets, and has been confidentially maintained by the entity *or is not otherwise public*; (2) the information is such that the public interest is served in withholding the

information; or (3) the information is confidential based on statute or other law.

- Reproductive services: Section 97439 (b) (10): Content of public notice

Health Access appreciates that the proposed regulations require the public notice to include information on reproductive services. We ask that this be clarified to include the full range of reproductive services because of the ethical and religious directives that govern some health care systems. For example, the ethical and religious directives for Adventists limit the range of abortion services. Similarly, health systems with a Catholic mission may have ethical and religious directives regarding not only abortion services but also contraception and other services. This is particularly important because most contraception and abortion care is done in a doctor's office or on an outpatient basis, not within the four walls of the hospital. If the ethical and religious directives of a health system would limit the full range of reproductive services in an outpatient setting or doctor's office, that should be part of the transaction review.

The specific change we seek to Section 97439 (b) (10) would read:

> Levels and types of health care services, including *the full range of* reproductive services, *care for the LGBTQ community including gender-affirming care,* labor and delivery services, pediatric services, behavioral health services, cardiac services, emergency services, *and any other services currently provided.*

- LGBTQ care: including gender-affirming care. Section 97439 (b) (10).

There is no mention, anywhere, of services for the LGBTQ community, including gender-affirming care. Again, most of these services are provided on an outpatient basis. Any limitation on these or other services is an area of public concern. Some religious or ethical directives limits such care in the hospital setting and may limit such care in doctors' offices or other outpatient settings. Health Access regards this an oversight that needs to be corrected.

- Definition of Health Care Services: 97431 (h): Behavioral Health

The definition of health care services is comprehensive for physical health but to be consistent with the state law governing health plans and insurers, it should be broadened to include the care and services for behavioral health included in SB

855, C. 151 of 2020 as well as AB 988, C. 747 of 2022 and AB 118, C. 42 of 2023, a subsequent trailer bill that clarified AB 988.

- Notice of the Material Change Transaction: Possible Benefits: 97439 (b) (7) and (c) (9)

Consistent with the statute, the regulations in 97439 (b) (7) (C) through (F) ask for the need for the transaction, impacts of the proposed transaction, and mitigation of any potential adverse impacts. In (c) (9), the regulations ask for any "analytic" support for the narrative. The requirement for analytic support should apply clearly to (b) (7) and (b) (10) and perhaps other provisions as well. Peer-reviewed studies demonstrating of similar transactions or analyses of similar transactions by the appropriate review body in another state should be provided to the extent available. Analytic support does not consist of promises and unsubstantiated assertions by those proposing the transaction. Rather, it should consist of independent analyses, clear commitments and measurable outcomes.

Assertions of benefits should be bolstered by analyses of likely post-transaction outcomes, including measurable impacts on competition, quality, equity and cost. Some of the proponents of transactions have listed possible benefits of transactions: we offer an accompanying list of potential measures of possible benefits and mitigations for negative impacts:

- Increased access and quality: If access is going to improve, for what services and for which populations? If quality will improve, what measurable outcomes will improve? Also, what will the impact on equity be?
- Lifeline to distressed hospitals: If a transaction is a "lifeline" to a "distressed" hospital, will services be maintained and will investment be sufficient and appropriate to create a reconfigured facility that serves the needs of the community?
- Economies of scale create efficiencies: Often these are code words for layoffs and reductions in less profitable services. What are the expected impacts of "efficiencies"? What happens to the care communities rely on?
- "Clinical integration and care coordination" will improve: Will quality and equity measurably increase? What will be the indicators? How long will it take to result in better care?
- "Ability to accept risk": Existing California law is clear: If an entity accepts a significant amount of risk, licensure is required as a fundamental consumer protection against financial insolvency. Risk means reserves sufficient to prevent provider insolvency that would deprive consumers of access.

- "Growth and innovation" in health care: Does this translate into higher costs for consumers and other purchasers? Or true innovation that improves quality while reducing costs?
- One proponent of transactions said the intent was to "ensure affordability": Will it improve affordability for consumers and purchasers? Or increase costs to consumers and purchasers?

Post-transaction market reviews: If a transaction is expected to improve or preserve access and availability, that should be documented consistent with (b) (10) and should be evaluated with a post-transaction market review at five years and ten years. Similarly, if costs are expected to decline while measurable quality and equity improve, the description of benefits should allow measurement post-transaction. If a transaction will improve competition, how will it do that? What are the expected labor market impacts? Whatever benefits are listed should be subject to post-transaction verification.

The specific changes we seek to 97439 Filing of Notices of Material Change Transactions are as follows:

(7) Description of the transaction, which shall include the following:
(A) no change
(B) no change
(C) A statement of why the transaction is necessary or desirable, *including any analytic support such as peer-reviewed studies or analyses of similar transactions reviewed in California or other states*
(D) General public impact or benefits of the transaction, *including measurable improvements in* quality and equity measures and impacts *and impacts on availability and accessibility of care and services.*
(E) Narrative description of the expected competitive impacts of the transaction *including any increase in competition in the geographic area or services*
(F) Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public, *including measurable outcomes in terms of cost, competitiveness, quality and equity.*

- Public notice, Public Comments, Public Meeting

OHCA market reviews will provide the public, including policymakers and stakeholders, a comprehensive understanding of changes in the market. To ensure that transaction reviews are subject to appropriate public scrutiny rather than

occurring in the dark of night, public notice, public comments and public discussion are important.

Public notice: what does the public know and when do we know it? 97439 (a) should provide clarity that when the advance notice of the material change notice is filed, the material change notice will be made public. 97441 on the determination of the Office to conduct a market review: either way the fact of the determination to review or to waive review should be made public. So should any re-review.

The specific changes we seek are as follows:

Section 97435 (a) *Upon receipt of the advance notice, the Office shall make public the fact of the advance notice and the parties to the proposed transaction. The Office shall accept public comment on whether to conduct a cost and market impact review during the review period.*

Section 97441 (a) (3) is added to read:
When the Office has determined whether or not to conduct a cost and market impact review, the Office shall make public the fact of the determination or the waiver of such a review.

Section 97441 (c) (6) is added to read:
The determination of the Director, either upholding the original determination or substituting an amended determination, shall be made public.

Public comment: Public comment may inform the Office of potential consequences or impacts identified by the community or other stakeholders. 97441: the regulations should provide clarity that Office will accept public comment at three critical points in the Office's review: during the preliminary review of the material change notice, during the entire 90-day period in which the Office is conducting a market review and once the preliminary review is made public.

The specific changes we seek to 97441 are as follows:

97441 (d) (4) is added to read: *Once the Office has determined to conduct a cost and market impact review, the Office shall accept public comment that may inform that review.*

97441 (f) (2) is amended to read: Within *15 (fifteen)* 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. *This period may be extended by another 15 days at the discretion of the Director.*

Public meeting: The law does not require a public meeting but it also does not prohibit it. The regulations would be improved by adding a provision that allows the Office to hold a public meeting either when someone petitions the Office to do so or when it is a significant or major transaction. If the regulations do not provide for a public meeting, comment will occur during other public meetings such as the Health Care Affordability Board or the Advisory Committee, no matter what other urgent work is scheduled in such venues. Other forums, such as legislative oversight hearings, may also be sought out. This can be anticipated and disruption avoided if the Office pro-actively schedules public meetings on significant or major transactions.

Section 97441 (g) is added to read:
(g) At any time during the consideration of the material change notice, including the advance notice, the determination to conduct a cost and market impact review, the period when the cost and market impact review is developed, or upon the preliminary report, the Office may hold a public meeting to receive public comment on the transaction. This meeting may be held concurrent with a meeting of the Health Care Affordability Board.

Coordination with Other State Agencies:

We have already recommended that Section 97435 (b) and (f) be amended to provide greater clarity as follows:

(f) *Transactions Not Subject to Filing Requirements*
(1) A transaction is not a material change transaction (no other change)
(2) The requirement to provide notice of a material change does not apply to agreement subject to review by the Department of Managed Health Care, the Department of Insurance, the Attorney General, or a county, consistent with by subdivisions (d) (1) through (4) of section 127507 of the Code.

We also recommend that a provision be added, in an appropriate section, restating the provision of the Act in Section 127507.2 (d) (2) that

"the office may refer its findings, including the totality of the documents gathered and data analysis performed, to the Attorney General for further review"

While not technically necessary to include since the power is already granted by the Act, sometimes restating the law is helpful to provide clarity to all parties.

Other Important Comments

Definition of Health Care Entity: 97431 (g) (4)

We support the language in (4) that a "health care entity"

> shall include 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.

This would be strengthened by inserting "directly or indirectly" as the start of each clause to read:

> shall include any affiliates, subsidiaries or other entities that *directly or indirectly* control, govern, or are financially responsible for the health care entity or that are *directly or indirectly* subject to the control, governance, or financial control of the health care entity.

Inclusion of Management Services Organizations: 97431 (j) and elsewhere

Health Access supports the inclusion of management services organizations or MSOs. These entities are an important part of the health care delivery system in California, as important as pharmacy benefit managers. Management services organizations may set clinical guidelines and take other actions that affect the cost of delivering care[5]. If a management services organization is a "captive" MSO that serves one medical group but becomes an "independent" MSO serving multiple medical groups or conversely, a number of medical groups merge so that control of an "independent" MSO changes, this is important market information. Investments in MSOs by entities not traditionally in the health care field may also be an important development affecting costs and competition. We also note that under 97435 (f) if an MSO is a "captive" MSO and a transaction does not change its relationship with the physician organization, then it is "not a material change transaction".

Definition of Physician Organization: 97431 (o)

The OHCA Act in Health and Safety Code Section 127500.2 (p) defines a physician organization as any lawfully organized group of physicians with 25 or more

physicians. The law includes independent practice associations or IPAs despite repeated requests by some parties to exclude such entities. Excluding IPAs would violate the letter and the spirit of the law.

Definition of Transaction: 97431 (q)

We note that the enabling statute in 127507 includes the following:

> the office shall promote competitive health care markets by examining mergers, acquisitions, corporate affiliations, or other transactions that entail a **material change to** ownership, **operations**, or governance structure involving health care service plans, health insurers, hospitals or hospital systems, physician organizations, providers, pharmacy benefit managers, and other health care entities. (Emphasis added)

The definition of transaction that some have characterized as overly broad is consistent with the plain statutory language. We also note that the Attorney General has addressed the issue of ordinary course of business in the regulations governing non-profit health facility transactions and there may be language in those regulations that is helpful here.

Filing on Notices of Material Change Transactions: 97439

97439 (b) (8) should also include reviews of transactions involving any of the parties to the transactions conducted in other states with review of health care entity transactions and the results of those results.

97439 (b) (12) (E) asks about competition within 20 miles of any physical facility offering comparable patient services. To align with the standards in the Knox-Keene Act since 1975, this should be amended to read “15 miles or 30 minutes”.

Conclusion

Thank you for your consideration of these comments. We recognize the important work that the Office of Health Care Affordability is doing in releasing these proposed emergency regulations to begin the process of cost and market impact reviews. For your convenience, we have provided an appendix listing our changes to the proposed language in the order that the regulation is proposed.

Sincerely,

Anthony Wright
Executive Director

Beth Capell, Ph.D.
Policy Consultant

CC: Members of the Health Care Affordability Board
Attorney General Rob Bonta, California Department of Justice
Toni G. Atkins, Senate President Pro Tempore
Robert Rivas, Speaker of the Assembly
Susan Eggman, Chair, Senate Health Committee
Caroline Menjivar, Chair, Senate Budget Subcommittee on Health and Human Services
Jim Wood, D.D.S, Chair, Assembly Health Committee
Akilah Weber, M.D., Chair, Assembly Budget Subcommittee on Health and Human Services
Mary Watanabe, Director, Department of Managed Health Care

Appendix: Recommended amendments in same order as proposed regulations:

Section 97431. Definitions.

Definition of Health Care Entity: 97431 (g) (4)

shall include any affiliates, subsidiaries or other entities that *directly or indirectly* control, govern, or are financially responsible for the health care entity or that are *directly or indirectly* subject to the control, governance, or financial control of the health care entity.

Definition of Health Care Services: 97431 (h): Behavioral Health: please add those services described in SB 855 (C. 151 of 2020) and AB 988 (C. 747 of 2022), as amended by the recent trailer bill, AB 118, C. 42 of 2023.

Section 97435. Material Change Transactions.

(a) Add as last sentence: *Upon receipt of the advance notice, the Office shall make public the fact of the advance notice and the parties to the proposed transaction. The Office shall accept public comment on whether to conduct a cost and market impact review during the review period.*

(b) Who must file. A health care entity shall provide written notice of a transaction with the Office if the transaction involves any parties listed in (b) (1) through (b) (3) under any one or more 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 *$6 (six)* million or that owns or control California assets of at least *$6 (six)* million; or

(2) A health care entity with annual revenue, as defined in subsection (d), of at least *$3 (three)* million or that owns or controls California assets of at *$3 (three)* million and is involved with any health care entity satisfying (b) (1) *and that is not an exempted provider*;

(3) A health care entity ~~located in or~~ serving at least 50% of the patients in a geographic area *or providing at least 50% of a particular service in a geographic area, defined in the same manner as health professions shortage areas*.

(c) Circumstances requiring filing.

(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 a private equity-owned and publicly held to a privately

held form or ownership *or from a privately held to publicly held form of ownership.*

(d) Revenue. For purposes of this section, revenue means total average annual California-derived revenue for received for all health care services by affiliates, *subsidiaries, and other related entities* over the most recent three years, *including revenue from any of the following* ~~as follows:~~

(1) no change

(2) no change

(3) For hospitals, *total revenue* ~~net patient revenue~~ as reported to the Department

(4) For long-term care facilities, *total revenue* ~~net patient revenue~~ as reported to the Department

(5) no change

(6) For other providers and provider organizations, *total revenue* ~~net patient revenue~~

(7) no change

(e) Control, responsibility or governance.

(f) *Transactions Not Subject to Filing Requirements*

(1) A transaction is not a material change transaction if (no other change)

(2) The requirement to provide notice of a material change does not apply to agreement subject to review by the Department of Managed Health Care, the Department of Insurance, the Attorney General, or a county, consistent with by subdivisions (d)(1) through (4) of section 127507 of the Code.

Section 97439 Filing of Notices of Material Change Transactions are as follows:

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

(A) no change

(B) no change

(C) A statement of why the transaction is necessary or desirable, *including any analytic support such as peer-reviewed studies or analyses of similar transactions reviewed in California or other states*

(D) General public impact or benefits of the transaction, *including measurable improvements in* quality and equity measures and impacts *and impacts on availability and accessibility of care and services.*

(E) Narrative description of the expected competitive impacts of the transaction *including any increase in competition in the geographic area or services*

(F) Description of any actions or activities to mitigate any potential adverse impacts of the transaction on the public, *including measurable outcomes in terms of cost, competitiveness, quality and equity.*

(8) Please add: *reviews of transactions involving any of the parties to the transactions conducted in other states with review of health care entity transactions and the results of those reviews*.

(b) (10) A description of the current services provided and expected post-transaction impacts on health care services, which shall include, if applicable:

(A) No change

(B) Levels and types of health care services, including *the full range of* reproductive services, *care for the LGBTQ community including gender-affirming care,* labor and delivery services, pediatric services, behavioral health services, cardiac services, emergency services, *and any other services currently provided.*

(b) (12) (E) asks about competition within 20 miles of any physical facility offering comparable patient services. To align with the standards in the Knox-Keene Act since 1975, this should be amended to read "15 miles or 30 minutes".

(d) Confidentiality of Documents Submitted with Notice:

(1) No change.

(2) Bases for confidentiality shall include: (1) the information is proprietary or of a confidential business nature, including trade secrets, and has been confidentially maintained by the entity *or is not otherwise public*; (2) the information is such that the public interest is served in withholding the information; or (3) the information is confidential based on statute or other law.

Section 97441 Cost and Market Impact Reviews

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

(1) In determining whether to conduct a cost and market impact based on a market failure or market power *in the absence of a specific transaction, the Office may base its decision on any of the following: the lack of the availability or*

accessibility of health care services; lack of affordability for payers, purchasers or consumers; lack of competition in a geographic area; or the presence of high cost outliers.

(2) 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 competition, 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) (3).

~~(2)~~ *(3)* The Office may base its decision to conduct a cost and market impact review on any one or more of the following factors:

No changes proposed to (A), (B), (D) (E) and (F).

(C) If the transaction may lessen competition or tend to create a monopoly in any geographic service areas, *market segments, or types of care or service* impacted by the transaction.

(4) is added to read: *When the Office has determined whether or not to conduct a cost and market impact review, the Office shall make public the fact of the determination or the waiver of such a review.*

(c) (6) is added to read: *The determination of the Director, either upholding the original determination or substituting an amended determination, shall be made public.*

(d) (4) is added to read: *Once the Office has determined to conduct a cost and market impact review, the Office shall accept public comment that may inform that review.*

(f) (2) is amended to read: Within *15 (fifteen)* 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. *This period may be extended by another 15 days at the discretion of the Director.*

(g) is added to read: *(g) At any time during the consideration of the material change notice, including the advance notice, the determination to conduct a cost and market impact review, the period when the cost and market impact review is developed, or upon the preliminary report, the Office may hold a public meeting to receive public comment on the transaction. This meeting may be held concurrent with a meeting of the Health Care Affordability Board.*

UNIVERSITY OF CALIFORNIA HEALTH

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August 31, 2023

Elizabeth Landsberg
Director, Department of Health Care Access and Information
2020 West El Camino Avenue, Suite 1200
Sacramento, CA 95833

Via Email to: CMIR@hcai.ca.gov

Re: Promotion of Competitive Health Care Markets Cost and Market Impact Review Emergency Regulations

Dear Director Landsberg:

University of California (UC) Health appreciates the opportunity to comment on the Department of Health Care Access and Information (HCAI), Office of Health Care Affordability (OHCA) proposed emergency rulemaking entitled, *Promotion of Competitive Health Care Markets Cost and Market Impact Review* (CMIR). UC Health is supportive of OHCA's charge to further the public interest in ensuring that all Californians receive health care that is accessible, affordable, equitable, high-quality, and universal.

Background

Guided by its tripartite mission of teaching, research, and public service, UC has a bold vision: to improve the health and well-being of all people living in California now and in the future by better educating and training the inclusive workforce of tomorrow; delivering exceptional care; and discovering life-changing treatments and cures. UC Health operates the nation's largest health sciences education program which includes six academic health centers and twenty health professional schools (medicine, nursing, pharmacy, optometry, dentistry, veterinary medicine, and public health), enrolling approximately 15,000 health sciences students, trainees, and residents. More than 70 percent of our students build their careers in California after graduating from our health professional schools. We treat the most challenging and complex cases and provide tertiary and quaternary care to patients across the state including half of all organ transplants and one-fourth of extensive burn care in California.

All of UC's hospitals are ranked among the best in California and our medical schools and health professional schools are nationally ranked in their respective areas. Our general acute care hospitals include four children's hospital campuses, three American Burn Association verified Regional Burn Centers, three Level I Trauma Centers, three Level I or Level II Pediatric Trauma Centers and five Transplant Centers. UC Health is also home to five National Cancer Institute-designated Comprehensive Cancer Centers that provide access to cutting edge care and clinical trials not available elsewhere.

UC Health's patient care mission is carried out through our local academic health centers comprised of hospitals, comprehensive network of clinics, and other clinical service locations throughout California integrated with our world-class schools of medicine. UC Health's teaching, clinical care, and research functions are complemented by affiliations and partnerships with a variety of entities including government agencies, other colleges and universities, community clinics, community hospitals, and other health care organizations. These affiliations are critical for:

- Delivering UC's public service mission to care for all the people of California, including the most vulnerable and patients in underserved areas of the state.
- Providing access to care in areas that are otherwise underserved for all types of health services.
- Increasing access to specialized services on-site that are often otherwise not available at community-based institutions.
- Providing access to hospital services for UC employees, retirees, and students in California communities where other options are not available.
- Fulfilling the educational mission of our academic health centers, especially at UC Riverside's community-based medical school, with a mission to improve the health of all the people of California, and principally, to serve inland Southern California by training a diverse workforce of physicians and by developing innovative research and health care delivery programs that will improve the health of the medically underserved in the region.

Comments on Proposed Regulations

We offer the following comments to assist OHCA in finalizing regulations to facilitate the CMIR process and urge the scope of the proposed regulations be refined to focus on transactions most likely to affect costs and market impact and ensure consistency with the enabling statute. UC Health supports many of the comments made by the California Hospital Association (CHA) and we underscore the following issues of importance to UC Health:

1. **Focus on the Most Impactful Transactions**
   The CMIR process should focus on transactions likely to have a risk of a significant impact on market competition, the state's ability to meet cost targets, or affordability for consumers and purchasers. As such, the proposed regulations should be drafted to avoid inadvertently bringing in a large variety of routine business transactions required to operate a health system. Taking a focused approach would ensure OHCA is not inundated with notices for immaterial activities and allow OHCA to devote its limited resources on transactions of significance.

2. **Clarify Entities Subject to Proposed Regulations**
   UC Health agrees with CHA's request to clarify the entities subject to the CMIR process. The statute defines "health care entity" in Health & Safety Code (HSC) Section 127500.2(k) as *"a payer, provider, or a fully integrated delivery system"*. The proposed regulations go beyond the statutory definition in Section 97431(g) by adding additional entities to this definition (in Section 97431(g)(2) through (4)), which additions should be deleted.

3. **Exempt Ordinary Business Transactions**
   UC Health is concerned that broadly defining "transaction" in Section 97431(q) to include "other agreements," coupled with the wide range of transactions that are proposed to be "material change transactions," (e.g., Section 97435(c)(7) (transaction where any health care entity has at least $10 million in annual revenue)) would result in health care entities being required to file notices for a large number of routine agreements that are necessary to operate an academic health center and that do not involve a transfer of material assets or control of a health care entity.

   UC health centers have professional services agreements where UC clinicians provide services at other health care organizations including public and community hospitals, federally qualified

health centers, and local medical groups. The presence of UC clinicians in these settings improves the quality of care delivered; increases access to services that are often not otherwise available in those facilities; and presents patients with options and connections to UC clinicians when the care they need is not available where they are being seen.

In addition, UC clinicians serve as medical directors for certain types of services at other facilities, which means that UC clinicians are responsible for oversight of the quality of care of those services at those facilities. These agreements provide another important mechanism whereby UC expertise is provided to patients at locations outside of the UC Health system, particularly in rural and underserved areas that would otherwise not have access to those services. UC does not believe that any of these types of agreements would qualify as "material change" transactions, but as outlined below, requests that OHCA clarify its proposed regulations to expressly exempt professional services, medical direction, and other routine services agreements, as well as training affiliation agreements.

4. **Align Circumstances that Require Filing with Statute's Materiality Requirements**
The proposed regulation delineates the circumstances that trigger the filing of a notice in subdivision (c) of Section 97435. However, many of the circumstances described do not align with the governing statute in Health and Safety Code Section 127507(c)(1), which requires notice only when a health care entity transfers "a material amount of its assets to one or more entities" or control, responsibility, or governance of "a material amount of the assets or operations to one or more entities." Paragraphs (c)(2), (c)(6), (c)(7), (c)(9) of the regulations do not align with the governing statute and UC Health recommends the regulations be revised to conform with the statute's materiality requirements.

Paragraphs (c)(2), (c)(6) and (c)(7) should be revised to: (1) specify that a *transfer* of assets or control must occur, (2) specify a threshold to determine a material amount of assets or control was transferred, and (3) in paragraph (c)(7) only, delete the word "joining" from the sentence to avoid ambiguity. Paragraph (c)(9) should be revised to shorten the timeframe in which past transactions are used to determine whether a proposed transaction should be filed and specify that the past transactions resulted in the transfer of a material amount of assets.

Furthermore, the regulations should exempt ordinary business transactions that do not result in a transfer of material assets or control of a health care entity, like exemptions adopted by the Federal Trade Commission and the California Attorney General.

5. **Revise Definition of Affiliation to Exclude Graduate Medical Education, Health Professions Training Programs, Clinical Trials, Other Research**
UC Health requests the proposed regulation exclude graduate medical education, health sciences training programs, clinical trials, and other research from the definition of affiliation in Section 97431(a) because they do not involve material change in control or material change in assets.

UC Health includes twenty health professional schools in medicine, nursing, pharmacy, optometry, dentistry, veterinary medicine, and public health. In keeping with the public service mission of the University, and to enhance our educational mission, UC's health professional schools are responsible for educating and preparing health care providers to serve every member of our community. Many types of clinical training sites are required to provide patient experiences for our students and trainees that represent the diversity of California and that are necessary to prepare them for future practice. Across the University's health sciences instructional system, our students, residents, and trainees have experiences in UC-owned and operated ambulatory and hospital settings and in other settings, including public hospitals, Veterans Administration facilities, primary care clinics, community hospitals and community sites across the state. Training partnerships are especially critical for UC Riverside's community-based School of Medicine and

for UCSF Fresno, which carries out its training and patient care through a network of affiliated partners. UC Health does not believe that the Legislature intended to include those types of training agreements in this regulatory framework.

UC's research efforts in health occur at academic health centers, health professional schools and UC campuses. Faculty, students, trainees, and staff at all our campuses conduct government, industry, and private-sponsored research to improve the health and wellness of the people of California and beyond. UC Health researchers are running more than 4,600 clinical trials investigating treatments for more than 2,400 health conditions. Many research endeavors involve partnerships that should not be subject to CMIR's notice, filing and review processes. Therefore, we recommend the following amendment:

> Recommended Amendment
> 97431 (a) "Affiliation or "affiliate" refers to situation in which an entity controls, is controlled by, or is under common control with another legal entity to collaborate on the provision of health care services. **For purposes of this Article, a clinical affiliation or affiliate does not include a collaboration on clinical trials, other research, graduate medical education, or health sciences training programs**.

6. **Length of CMIR Review Process Poses Concerns for Affiliations to Provide Needed Care**
The proposed timeline for completion of a full CMIR process will take a minimum of 250 days to complete. As a public institution governed by The Regents of the University of California, UC Health is required to seek approval from The Regents on many transactions that would also then be subject to the CMIR process. UC Health is therefore especially concerned about the additional time, costs, and uncertainty that the CMIR process will add to these endeavors. UC Health affiliates with other institutions so our academic health centers can improve quality of care and expand care options for all Californians, including those living in underserved areas of the state. Many UC hospitals operate at capacity and regrettably must turn away patients seeking care due to space limitations. Affiliations with lower-cost facilities that care for lower-acuity patients help preserve the limited capacity at UC facilities that is needed to treat patients who truly need UC's expertise and specialized services while facilitating access to care by UC providers in facilities located closer to where patients live. Timing is a critical component to any transaction and can influence the risks to and potential feasibility of a transaction altogether. We urge OHCA to swiftly evaluate transactions and align its timeline with that of the Attorney General's review of nonprofit health facility transactions (within 90-days of receipt of the notice and one additional 45-day extension).

UC Health respectfully submits these comments and recommendations to assist the Office of Health Care Affordability's efforts to implement the Cost and Market Review process, which should focus on transactions most likely to affect costs and market impact and exclude routine operational activities, health sciences training, clinical trials, and other research. We appreciate your consideration of UC Health's unique role as California's public academic health system and our tripartite mission of teaching, research, and public service to the people of California.

Sincerely,

Tam M. Ma
Associate Vice President
Health Policy and Regulatory Affairs

August 31, 2023

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

Sent via email: *CMIR@hcai.ca.gov*

SUBJECT: CHA Comments on the 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 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. However, we have significant substantive concerns about the regulations as drafted.

The recent closure of Madera Community Hospital shows what can happen when state regulatory processes come into conflict with the needed speedy resolution of collaborations to save a provider in severe financial distress. As the office finalizes its draft regulations on the cost and market impact review (CMIR) process, we urge it to consider the potential ramifications of asserting overbroad authority to review even small and routine transactions; the expense, time, and uncertainty the process adds for these basic market activities; and the potential for overly burdensome regulations to ultimately undermine the enabling statute's foundational goals of improving access to high-quality, equitable, and affordable care.

We recommend that the office reconsider its current approach of seeking maximal noticing, information submission, and timeline authority at the outset to one that focuses on the key areas of concern. 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. This is followed by our detailed comments, analysis, and requested revisions.

Executive Summary

CHA has significant concerns with the CMIR regulations as currently drafted. We ask for a large 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.

Focus on the Most Impactful Transactions. As drafted, the regulations establish noticing and materiality requirements that would capture an enormous array of basic market and operations activities that extend far beyond what was intended by the authorizing legislation. We urge the office to substantially narrow the draft regulations to focus its efforts on transactions likely to have significant effects on the health care market, prevent the office from being overwhelmed by notices and information from filing entities, and 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.

- **Exempt Transactions in the Ordinary Course of Business.** Due to its overly broad definition of a "transaction," the current draft regulations would require 90-day notice for changes in operations above a given dollar threshold. For many providers, this would include routine transactions such as 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. Mandating advance notice and subjecting health care entities to a costly and slow review process for the hundreds or thousands of such transactions that they conduct annually is neither what the Legislature intended nor what would be conducive to a functioning health care delivery system. The regulations must be revised to categorically exempt transactions in the ordinary course of business from the definition of a transaction, or enumerate an expansive list of transactions explicitly exempted from office oversight under the CMIR process.
- **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 paragraph of subdivision (c) must:
  (1) Include a *transfer* of assets or control, and
  (2) Include a threshold dollar amount of assets and/or threshold measure of control *that is being transferred*

  As described later, several of the conditions requiring notice of a material change under the regulations fail to comply with this statutory imperative. These include the conditions requiring notice for transactions that raise revenues by $10 million (even for entities making tens of billions of dollars annually), affiliations where an entity has $10 million in annual revenue, and transactions among parties that have previously consummated another transaction.
- **Establish Reasonable Asset Transfer Materiality Thresholds Pegged to Inflation**. The $25 million threshold in Section 97435(c)(1) 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.
- **Conform With Generally Accepted Definition of "Control."** The draft regulations define a change in control as a transaction that transfers more than 10% of the control of a health care entity. This threshold is far too low. A person or corporation with a 10% interest in a health care entity does not, under any scenario, have control over 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. Under the current draft regulations, the full CMIR process would take a minimum of 250 days — 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. To prevent the discouragement of constructive collaborations, prolonged uncertainty surrounding the outcome of a proposed transaction, and inadvertently raising health care costs, we urge the office to expedite and clarify its timelines for the CMIR process. 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, simplify the reference date for "closing" a transaction, create an expedited review process for urgent transactions, 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 ask the office to include in revised regulations a provision that will 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 proposed regulations are 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 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 will be delayed by 250 or more days. Moreover, the automatic inclusion of any transaction involving a general acute care or specialty hospital shows a preconceived and undeserved bias by the office against hospitals and hospital transactions. We strongly encourage the office to clarify the criteria via regulation to identify when a CMIR will be required and, in doing so, conform with statute.

Reasonable Information Submission Requirements for Parties to a Transaction. Overly expansive 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, in identifying the information parties to a transaction must submit prior to and during the CMIR process, the office must seek to gather the minimum kinds and amounts of information necessary to fulfill its statutory prerogatives. 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.

Protect Sensitive Non-Public Information Provided to the Office. Health care entities maintain large amounts of data to fulfill their patients' clinical needs, manage their finances and operations, and compete in the health care marketplace. Protecting the confidentiality of these data is critical. 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 and contact information for individuals other than the designated public contact be deemed confidential. In addition, we request that the office establish a process to inform the submitter if it denies a confidentiality request and provide an opportunity for the submitter to appeal the denial before the office makes the information public.

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 current draft regulations do the opposite, and instead, capture a vast array of transactions and operational activities that a health care entity undertakes on a routine basis. Finalizing the rule in its current form risks seriously impeding basic market activities by and among health care entities and would overburden the office with notices for activities outside of the scope of what is intended under state statute.

Under statute, a transaction must meet three definitional requirements to trigger a mandatory notice to the office:

1. It must involve a "health care entity" as defined in Section 97431(g)
2. Meet the definition of a "transaction" in Section 97431(q)
3. Entail a "material change" as defined in Section 97435

As described below, all three definitions are overly broad, and in combination lead to a scope of oversight stretching far beyond statutory intent.

Clarify Who Counts as a Health Care Entity and an Affiliate. The office's governing statutory authority already defines "health care entity" 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 their statutory authority in Section 97431(g) by adding to this definition (in Section 97431(g)(4)), *"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…"* Some affiliates may not be health

care entities — a hospital may own a childcare center, for example. Including these non-health care entities would exceed the office's statutory authority since entities that do not provide, arrange, or pay for health care would be included. In addition, it is unclear what being "financially responsible" for another entity means. Therefore, paragraph (4) should be deleted, and the regulations should instead say "health care entity and its affiliates that provide, arrange, or pay for, health care services" only where including affiliates is appropriate in context. Otherwise, certain sections of these regulations are unclear or lack justification. What's more, including "affiliates" within the definition of "health care entity" would have the unintended consequence of turning each affiliate into a submitter and unnecessarily inundating the office with notices.

We note that "health care entity" is defined to exclude physician organizations with fewer than 25 physicians unless they qualify as a "high-cost outlier" according to state and federal agency data resources— information unknown to the provider community. We ask the office to clarify whether this threshold refers to owners, employees, or contractors, and whether it refers to full-time equivalent physicians or a headcount. Additionally, we ask the office to clarify how health care entities can access government data and information to identify high-cost outliers.

Right-Size the Definition of a Transaction. Subdivision (q) of Section 97431 defines a "transaction" to include *"agreements involving the provision of health care services… that… entail a change, directly or indirectly, to… operations… involving any health care entity."* Pursuant to this definition, any contract or agreement executed by a health care entity meeting a materiality criterion in Section 97435 (which could be as simple as a $25 million fair market value) would be subject to the notice and review requirement. Under this definition, health care entities would have to file a notice for an enormous array of routine transactions, including, for example:

- A hospital entering into a customary medical office lease with a physician group
- A hospital leasing an office building for its call center, case management, or other personnel to move into
- A health care entity purchasing land to expand a new medical office building or clinic
- A health care entity contracting with a construction company to remodel or retrofit a building
- A radiology group buying equipment for a new imaging center
- A hospital replacing outdated beds, exam tables, and operating room equipment throughout its facilities
- A hospital entering into a union contract
- A hospital updating its electronic medical records system
- A hospital switching food service or durable medical equipment vendors
- A hospital signing a contract with a health plan to be an in-network provider
- A county hospital hiring three new neurosurgeons to establish a neurosurgery residency program
- A hospital contracting with a different anesthesiology or radiology group
- A health system's contract with drug/device manufacturers to purchase prescription and nonprescription products and supplies
- A nonprofit hospital seeking bond financing

The legislative intent was not to have the office review everyday transactions such as those listed above. What's more, without changes to the rule, the office will be overwhelmed with notices — and ordinary operations, investments, and improvements in the California health care industry will grind to a halt, seriously compromising patients' access to care and to newer, higher-quality technology and services.

Accordingly, CHA recommends that ***the regulations exempt ordinary business transactions that do not result in a transfer of material assets or control of a health care entity.*** Both the Federal Trade Commission and the California attorney general have adopted such exemptions.[1] For the same purpose, the Oregon Health Authority regulations include a long list of excluded transactions.

CHA also recommends that the language of Section 97431(q) more closely track the governing statute. Specifically, the phrase "ownership, operations, or governance structure" should be revised to "control, responsibility, or governance," which is the phrase used in Health and Safety Code Section 127507(c)(1) and defined in the draft regulations in Section 97435(e).To address these three related objectives, we recommend the following revisions to Section 97431(q):

> *Transaction" includes mergers, acquisitions, affiliations, or other agreements involving the provision of health care services in California that involve a change of assets (sell, transfer, lease, exchange, option, encumber, convey, or dispose) or entail a ~~change~~, transfer, directly or indirectly, ~~to ownership, operations, or governance structure involving any~~ of control, responsibility, or governance of the health care entity's assets or operations. A "transaction" shall not include a change or transfer in the ordinary course of business or bonds, mortgages, deeds of trust, or other obligations that are not voting securities.*

For clarity, we also recommend the following technical amendment to the beginning of subdivision (c):

> *(c) Circumstances requiring filing. Except as provided in subdivision (f), a ~~A~~ transaction is a material change pursuant to section 127507(c)(1) of the Code if any of the following circumstances exist:...*

Conform to the Materiality Requirements in Statute. Subdivision (c) of Section 97435 lists various circumstances that trigger the filing of a notice. However, many of these circumstances do not comply with the governing statute, Health and Safety Code Section 127507(c)(1). This statute requires notice 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, to comply with the statute, each paragraph of subdivision (c) must:

1. Include a *transfer* of assets or control, and
2. Include a threshold dollar amount of assets and/or threshold measure of control *that is being transferred*.

We believe that paragraphs (c)(2), (c)(6), (c)(7), and (c)(9) of the regulations fail to comply with this statutory authority, as described in more detail below.

Recognize the Office's Lack of Out-of-State Jurisdiction. In addition, each of the paragraphs in subdivision (c) must be revised to clarify that only California-based assets, operations, and revenue should be considered. Otherwise, the proposed regulations may be misinterpreted as requiring California health care entities to submit notices even if a proposed transaction occurs wholly outside of California. Also, any dollar amount included in this section should be pegged to an inflation adjustment or other

[1] See, for example, 15 U.S.C. Section 18a(c) and 16 CFR Section 802.1, which exempt transfers "in the ordinary course of business" and "bonds, mortgages, deed of trust, or other obligations which are not voting securities." See also 11 CCR Section 999.5(a)(4), which exempts an "agreement or transaction... in the usual and regular course of the activities" of the entity.

benchmark to prevent an inadvertent increase over time in the transactions subject to review and ensure that only significant transactions are subject to review.

Clarify Which Party(ies) Must Provide Notice. It should be made clear exactly which entity (or entities) is the submitter. For example, the Federal Trade Commission specifies that the acquiring entity is the submitter. Only in those situations where a transaction will result in the acquired entity (the "target") also acquiring an interest will the target also be required to file a notice. As currently written, the draft regulations appear to require every health care entity and affiliate involved in a transaction to file a notice, which is inefficient for the parties as well as the office.

Establish a Reasonable Asset Transfer Materiality Threshold Pegged to Inflation. The $25 million threshold in Section 97435(c)(1) is much 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 set 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.

In addition, paragraph (c)(1) of Section 97435 includes any transaction valued at $25 million or more that concerns the provision of health care services. Given that a "transaction" can be just an "agreement," does the $25 million relate to the annual value of the agreement or the lifetime value? If the agreement is "evergreen" — that is, it continues until terminated — what time period should be considered to determine the agreement's value? These ambiguities should be clarified so not to foreclose efficiencies and improvements to California health care services. Finally, Section 97435(c)(1) should be limited to transactions affecting only California health care entities.

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.*

Ensure Covered Transactions Include Only Those That Transfer a Material Amount of Assets or Control. Paragraph (c)(2) of Section 97435 includes any transaction likely to increase annual revenue by at least $10 million or 20% of annual revenue at normal or stabilized levels of operation. However, the governing statute, Health and Safety Code Section 127507(c)(1), requires notice only when a health care entity (1) *transfers* "a material amount of its assets *to one or more entities*" or (2) *transfers* control of "a material amount of the assets or operations *to one or more entities*." Therefore, paragraph (c)(2) must be amended to state that a *transfer* of assets or *transfer* of control (of assets or operations) is required before notice is triggered — a transfer being *the movement from one party to another* of some existing

assets or control. A materiality threshold for the assets or control *that is moved* must also be added to comply with the statutory authority. Otherwise, this criterion captures many transactions that are simply ordinary business transactions, such as a hospital signing a contract with a managed care company for additional lines of business or opening a crisis stabilization unit.

This criterion has additional problems that must be addressed:

- It requires a great deal of speculation by the parties. We instead recommend that notice requirements be based on objective criteria, not speculation about the future.
- 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. Do we 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, do we use the net increase to determine whether a notice is required?
- Section 97435(d) defines "revenue" to mean the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years. This definition makes no sense in the context of paragraph 97435(c)(2). The definition of revenue in subdivision (d) is backward-looking while the intent of paragraph (c)(2) appears to be forward-looking. The definition of revenue in subdivision (d) refers to annual revenue averaged over a three-year period; it is not clear whether paragraph (c)(2) also refers to annual revenue averaged over a three-year period (at normal or stabilized levels of utilization or operation), or a simple one-year period.

CHA recommends that this criterion be deleted. At the very least, it must be better defined to include a *transfer* of a *material amount* of assets or control in order to comply with the governing statute. We again recommend the adoption of the Federal Trade Commission threshold for assets. We also recommend "control" be defined to mean more than 50% voting authority, as described in more detail on page 11. To the extent any revenue thresholds are maintained within this criterion, we request the office to avoid speculation about possible impacts on revenues and instead utilize the same definition of revenue contained in subdivision (d).

Conform to State 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 20% 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 20% threshold is too low and will capture transactions beyond the intent of the legislation. CHA recommends a threshold of more than 50% of assets, which will capture significant transactions. Finally, CHA recommends that this paragraph be clarified to mean (a) California-based assets and (b) 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-based assets, at fair market value.

Remove Authority to Review Immaterial Transactions Relating to Payer Contract Negotiations and Administration. Paragraph (c)(5) of Section 97435 requires a notice for transactions that "contemplate" an entity negotiating or administering a contract with a payer on behalf of one or more providers. This criterion does not include any materiality threshold. We note again that the governing statute, Health and Safety Code Section 127507(c)(1), requires notice only when a health care entity *transfers "a material amount* of its assets to one or more entities" or *transfers* control of "*a material amount* of the assets or operations to one or more entities." Therefore, paragraph(c)(2) must be amended to comply with the statutory authority. If a large physician organization decides to allow a hospital to negotiate a tiny contract on its behalf, this would not involve transferring "a material amount of the assets or operations" to the hospital.

Indeed, paragraph (c)(5) seems to capture every bundled payment agreement, value-based care model, and clinically integrated network, no matter how small. For example, it seems that the draft regulations require notice to the office by a hospital that enters into a bundled payment arrangement with a payer to provide hip replacements if the hospital needs to contract with a skilled-nursing facility to provide these patients a few days of post-acute care or contract with a medical transportation company to transport them. We do not believe the office's governing statute intended such small, routine, value-based transactions to be subject to notice and review where such arrangements have the exceptional power to meet the goals of the office: reduce the costs of care and increase quality. This will make the use of arrangements intended to promote quality, efficiency, and access more expensive and thereby disincentivize health care entities from using such arrangements. CHA recommends that this paragraph be deleted. Any significant transactions would already be captured by the other paragraphs of subdivision (c). Alternatively, if this paragraph is intended to capture significant transactions that are not defined in the other paragraphs of this subdivision, CHA recommends clarifying this language and/or adding examples while being sure to include a materiality threshold. Finally, the terms "contemplate" and "administer" are vague and subjective and should be deleted.

Conform to Statute by Including Only Transfers of Assets. Paragraph (c)(6) of Section 97435 (regarding formation of a new health care entity) raises the same concerns as discussed in our comments about paragraph (c)(2) — the provision exceeds statutory authority in that it does not specify that a *transfer* of assets or control must occur, and it does not specify a threshold to determine the amount of assets or control that must be *transferred* to be deemed material. Instead, it focuses on a result (resulting revenue or resulting control of assets). In addition, this criterion requires a great deal of speculation by the parties, the time horizon is unclear, and the definition of "revenue" is problematic. Please see our comments related to paragraph (c)(2), above. We ask for this paragraph to be deleted.

Paragraph (c)(7) of Section 97435 (regarding affiliations) again exceeds statutory authority in that it does not specify a threshold amount of assets or control *being transferred*. Instead, it looks only at the amount of revenue the parties have. This does not accord with the enabling statute. In addition, the term "joining" is very unclear. Does this provision mean that notice is required each time an imaging center "joins" a clinic to conduct free mammograms in an underserved community if either the clinic or the imaging center has at least $10 million in annual revenue? Or something else? CHA strongly recommends deleting the word "joining." In addition, an asset/control transfer materiality threshold must be added to comply with the statutory authority for these regulations. We also recommend clarifying that the threshold applies only to California-based assets or control.

Expand Exemptions for Collaborations. We are alarmed by the second sentence of paragraph (c)(7) of Section 97435, which states that for purposes of this "subsection," an "affiliation does not include a collaboration on clinical trials or graduate medical education programs." This language seems to indicate that collaborations on clinical trials or graduate medical education (GME) *are* considered an "affiliation" under other subsections. We recommend that this exception be moved to Section 97431(a) so that it applies to the entire article, not just to paragraph (c)(7). The exception should also be expanded to include other research (in addition to clinical trials), undergraduate medical education programs, and other health care and sciences training programs (such as a hospital collaborating with a California State University campus to train nursing, pharmacist, or physical therapy students). The governing statute did not contemplate entities providing notice before entering into research or training collaborations, and it is simply not possible to complete the CMIR process prior to applying for research grants — and grantors will not fund California research if it is contingent on office approval. Instead, grant money will go to other states. In addition, the information to be submitted to the office as part of the notice does not make sense in the context of research or training.

Reasonably Scope Oversight of "Serial Transactions." We believe that paragraph (c)(9) of Section 97435 is intended to capture a series of transactions that, separately, are not considered "material changes," but in aggregate represent a material change. However, due to the broad definition of the word "transaction," this paragraph will capture very small, everyday agreements. In addition, it appears that only one of the parties must be a "health care entity," although the agreement must pertain to the provision of health care services. A small set of examples of the vast number of transactions involving health care entities that would require notice under this paragraph include:

- A payer entering into a second or subsequent single-patient case agreement with a hospital or skilled-nursing facility
- A hospital entering into a call coverage agreement with a physician or physician group with whom it had previously contracted
- A hospital system contracting with a medical transportation company to serve an additional facility or change operational obligations for a prior contract
- A hospital leasing a second office space to a physician
- A hospital leasing office space to a physician with whom it had contracted to provide medical director services for the pediatrics unit
- Any health care provider renewing or expanding a lease for office space
- A change to an electronic medical record contract
- A contract renewal to be in-network with a payer that requires any changes in operations

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 should be more precise, as shown below. 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 that this paragraph be deleted or the following language be substituted for the proposed language:

> *(c)(9) A health care entity that is a party to the transaction has consummated one or more transactions regarding the provision of health care services in California with another health care entity that is a party to the current transaction within three years prior to the expected closing date of the current transaction, where the transactions, if consummated simultaneously, would have constituted a material change transaction as defined in this article.*

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 10% in paragraphs (1) and (3) is far too low and contradicts legal precedent. A person or corporation with a 10% interest in a health care entity does not, under any scenario, have control over the health care entity. The 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.[2] 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 10%), 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 10% 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 10%), 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.

[2] "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.)

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

In addition, the criterion described in paragraph (2) of Section 97435(e) is overly broad and lacks clarity. What is "partial voting control"? An entity either has control or it does not. Anything less than full control is merely potential influence. Does a change of even a single board member represent a transfer of "partial voting control"? If not, what is required by this paragraph? Again, it appears that the office borrowed the language from the California attorney general's regulations (11 CCR Section 999.5(a)(3)(B)) but arbitrarily inserted a 10% threshold, which completely changes the effect of the regulation. In addition, CHA recommends separating paragraph (2) into two distinct paragraphs. The placement of the commas in this paragraph makes it unclear whether the phrase "that would transfer full or partial voting control…" applies to only the first part of the sentence (substitution of members of the governing body) or also to the second part of the sentence ("any arrangement, written or oral…").

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? CHA recommends deleting this paragraph.

Finally, we note that health care entities cannot control their directors. For example, a hospital cannot prevent its directors from resigning or dying. In such cases it would be impossible for a health care entity to provide 90 days' advance notice.

(1) CHA recommends the following language be substituted for the proposed language: *There is a substitution or addition of a new corporate member or members that transfers more than 50% of the voting shares of the health care entity*
(2) *There is a substitution of one or more members of the governing body of a health care entity that transfers more than 50% of the voting control of the members of the governing body of the health care entity; or*
(3) *There is an arrangement, written or oral, that transfers more than 50% of the voting control of the members of the governing body of a health care entity*

Notwithstanding Section 97435(a), if a health care entity 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, the health care entity shall provide notice as soon as reasonably possible. 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. 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

California health care entities have significant experience operating under state oversight when it comes to their transactions, such as seeking attorney general or Department of Managed Health Care approval. Even when relatively small transactions are involved, these state reviews regularly take months if not years to complete, adding hundreds of thousands of dollars in costs to these transactions. This has a chilling effect on prospective arrangements, regardless of how beneficial the arrangement would be to California patients and communities. To prevent the discouragement of constructive arrangements, prolonged uncertainty surrounding the outcome of a proposed transaction, and inadvertently raising health care costs, we urge the office to expedite and clarify its timelines for the CMIR process. This is all the more essential for health care entities seeking a rescuer to avoid bankruptcy and closure, as the extended review period established in the draft regulations could be the difference between providers continuing to serve their communities or having to shut their doors.

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 establish special processes for critical and time-sensitive transactions that are necessary for protecting access to care. While the office may wish to complete reviews faster than its regulatory deadlines, the record for other state agencies in beating their deadlines is nonexistent. Rather, the triggering of extensions is the norm. As such, establishing deadlines to which the office is accountable now is absolutely essential.

Reduce Time Allotted for Cost and Market Impact Review. The draft regulations would 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 recommend 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.

Establish Expedited Review Process for Urgent Transactions. The closure of Madera Community Hospital is an unfortunate reminder of what can happen when a prospective affiliation or arrangement for a hospital in financial distress falls apart. Speed in the execution of transactions is absolutely essential to save a hospital on the brink of closure or a physician organization struggling in a rural or underserved area. We urge the office to use its authority under subparagraph (a)(3)(B) of Health and Safety Code Section 127507.2 to create an expedited process for urgent transactions, including those required to

prevent hospital closures. To effectuate this, we recommend the office create a mechanism for requesting an expedited waiver from the full CMIR process, a set of eligibility criteria for the office to determine which transactions qualify for an expedited waiver, and a deadline of 15 days following the receipt of a notice of material change for the office to grant an expedited waiver or proceed through the standard CMIR process. Such a timeline would be consistent with that of the Federal Trade Commission for transactions involving an organization in bankruptcy proceedings.

Consider Expediting Additional Deadlines. In addition to our various recommendations to reasonably accelerate and clarify the review timelines, we ask the office to consider expediting additional deadlines pursuant to its authority under subparagraph (a)(3)(B) of Health and 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 authority to toll any time period in which it is awaiting the provision of information it deems necessary to complete its review. In effect, this 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 only made more 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 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 are concerned that the involvement of multiple regulatory bodies may 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 is unclear, given how referrals to and from these external entities are intended to occur under statute. For example, 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 request 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 draft regulations 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…*

Simplify the Reference Date for the Closing of a Transaction in the Noticing Timeline. The deadline for providing advance notice of a material change pursuant to subdivision (a) of Section 97435 includes ambiguous and conflicting reference dates relating to the closing of a transaction. Specifically, the regulations require notice of a material change at least 90 days prior to *"entering into the agreement or transaction,"* which is defined in subdivision (a) of Section 97435 as referring to *"the date any parties' respective rights vest in a binding agreement or all contingencies to the agreement or transaction are met or waived."* In many agreements, contingencies can be met or waived far in advance of the intended closing

date. Including this phrase could have the effect of requiring notice much earlier than the statutory intent to require 90-days' advance notice of a prospective transaction. Moreover, the parties will often not know in advance the dates on which various contingencies will be met or waived, meaning that this provision could require the parties to file a notice prior to or simultaneously with learning whether consummation of the transaction will actually be pursued. We ask the office to revise this section and instead adopt similar language to that of both the Massachusetts Health Policy Commission and the Oregon Health Authority to define entering into an agreement as being *"the date when the proposed transaction will be consummated or closed."*

Green Light Transactions If Office Does Not Meet Regulatory Deadlines. As previously noted, we have serious concerns regarding the potential for the CMIR process to delay and ultimately derail transactions that are in the public interest. While this likely will occur even when the office meets its process deadlines, it is only more likely in circumstances when the office does not meet its 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, which could result in months- or years-long delays in completing a transaction. 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 consummated 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 the relevant deadline:*
> *(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.

CHA recommends 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. For this reason, 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. Moreover, the enabling statute dictates that the office do so via regulation: paragraph (c)(3) of Health and 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 draft regulations include provisions fulfilling the first and third of these statutory mandates, but neglect to establish appropriate fees that give health care entities reasonable notice of the potential costs of the CMIR process, or assurances that the fees will, in fact, be appropriate. We ask the office to include in revised regulations a provision that would ensure that fees charged are reasonable and in accord with the economical costs of conducting a review. In particular, we ask the office to add a new subdivision (g) in Section 97435 to read 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 fee 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 are 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. These benefits include, but are not limited to:

- Providing a lifeline for financially distressed hospitals or struggling physician groups in rural or underserved areas
- Promoting economies of scale and the associated cost savings for patients
- Opening new opportunities for integrated and coordinated care
- Empowering providers to implement value-based payment programs and assume risk

To this end and to fulfill its statutory mandate, we 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 and 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 250 or more days. Moreover, the draft regulations would allow the office to make seemingly arbitrary decisions about which transactions will be subject to a CMIR.

Health care entities need a certain degree of predictability and certainty in order to function and grow in their capacity to serve their patients. Moreover, for those health care entities experiencing financial distress, timing is critical to understanding what operational alternatives and transactions may be available to maintain health care access in a community. We strongly encourage the office to establish clear and objective criteria via regulation to clarify when a CMIR will be required.

In addition, we take exception to the automatic inclusion of any transaction involving a general acute care or specialty[3] 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.

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:"

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

(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.

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 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

Overly expansive information submission requirements on parties to a transaction place unnecessary burdens on health care entities, raise compliance costs, and exacerbate the risk that sensitive and confidential information will be released into the public domain. Accordingly, in identifying the information parties to a transaction must submit prior to and during the CMIR process, the office must seek to gather the minimum kinds and amounts of information necessary to fulfill its statutory prerogatives. 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.

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 received 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.)

Place Reasonable Limits on Prior Transactions That Must Be Reported. Large health care entities have conducted untold numbers of small and immaterial market transactions within the last decade — including patient transfer agreements with other hospitals, leases of medical office space or specialized equipment, call coverage contracts with physician groups, and letters of agreement with health plans to treat or transfer out-of-network patients. Tracking each of these transactions has not been a requirement of any government agency or an activity undertaken by these entities — and, as such, they have no way of complying with the requirement under paragraph (b)(11) of Section 97439 as written. We strongly urge the office to revise this requirement to do the following:

- Apply the office's "circumstances requiring filing criteria" and materiality thresholds, or, for the latter, a modified version thereof, to this provision — otherwise, a single referral agreement with a single physician would have to be reported
- 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. Paragraph (b)(5) 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 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. Subparagraph (b)(1)(F) of Section 97439 requires a health care entity providing notice of a material change to submit a copy of each California and non-California license it holds. First, this provision seems to require a health care entity to submit non-health care-related licenses it holds, such as business licenses, business tax permits, hazardous waste disposal licenses, resale permits, elevator permits, building permits, childcare licenses, etc. Second, even if this provision is limited to healthcare-related licenses, a single hospital holds scores of these licenses as well. For example, a hospital must have at least one pharmacy license from the California Board of Pharmacy, but in addition, each automated drug delivery system (a pill counting/storage machine) requires a separate license, a centralized hospital packaging pharmacy license may be needed, and a sterile compounding pharmacy license may be needed. Similarly, each mammography machine needs a separate license from the California Department of Public Health, Radiologic Health Branch.

It is not useful for the office to review documentation of each license held by a large health care entity. In addition, it would be incredibly onerous for health care entities to collect and provide this documentation. We recommend the office more clearly specify in the draft regulations which licenses must be submitted. For hospitals, we recommend that the office require the submission of only the hospital license issued by the California Department of Public Health.

Establish a Threshold for Reporting on Services Provided in Other States. Many health care providers provide incidental services to patients beyond their typical operating area, particularly through the growing modality of telehealth. Such incidental services to non-local patients are not relevant to the office's interest in obtaining information on a health care entity's major regions of operations within California. Accordingly, we ask the department to revise paragraphs (b)(2) and (b)(3) of Section 97439 to plainly state that such reporting is limited to counties of operation within California, consistent with the requirement under subparagraph (b)(5)(E) of the same section.

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 fulfill their patients' clinical needs, manage their finances and operations, 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. 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 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 a process to inform the submitter if the office denies a confidentiality request and provide an opportunity for the submitter to appeal the denial, before the office makes the information public.

Conclusion

CHA has significant concerns with the CMIR regulations as currently drafted. Accordingly, we are asking for meaningful 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

August 31, 2023

Megan Brubaker
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Re: 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 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.

As noted above, our comments include the following recommendations:

1. Sutter recommends that the emergency regulations create an expedited process as allowed pursuant to California Health & Safety Code Section 127507.2 to account for the urgency of certain transactions. OHCA has 60 days to determine if it will perform a Cost & Market Impact Review; 90 days to conduct the review (with an ability to automatically extend for 45 days); and transactions cannot move forward for 60 days until after the final report is issued. If all timelines are fully utilized, this means a transaction could be suspended for 255 days without adding additional time for OHCA tolling its process while waiting for responses, including waiting for responses from third parties pursuant to OHCA's subpoena power.

   We are concerned that these lengthy timelines do not consider when health care entities are financially distressed and seeking a partnership or other type of transaction to avoid filing for bankruptcy and ceasing service to patients, including the most vulnerable populations in government health programs. One merely needs to read the headlines for the month of August to see Babylon Health, with a significant presence in California through its subsidiaries, filing for Chapter 7 protection, or the state loans awarded to seventeen (17) distressed hospitals, including three (3) hospitals which had already filed for bankruptcy protection, to see that many providers of necessary health care are struggling significantly and do not have 7-8 months to wait for OHCA's review.

There needs to be a process to expedite both the 60-day decision timeframe and the Cost & Market Impact Review timeline to avoid health care providers going out of business during the review process and patients being left without access to medically necessary services.

2. Sutter believes the proposed regulations exceed the authority OHCA was granted by the Legislature by pulling in transactions under OHCA review which are outside the scope of the filings required under the California Health Care Quality and Affordability Act.

   California Health & Safety Code Section 12507(c)(1) is clear as to which agreements and transactions are subject to filing, stating:

   > *(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.*

   With this language the Legislature required that the transaction be one which is material ***to one or more of the entities to the transaction***. Thus, Materiality must be reviewed in the context of the assets or operations of the actual health care entities within the transaction and not based on an arbitrary dollar amount as proposed in Section 97435 (c)(1)-(2), of $25 million and $10 million. A flat dollar threshold may be high and significant to certain health care entities but could be a very low dollar threshold in relation to the assets or operations of the entities to the transaction.

   The Legislature required that materiality be determined by looking at the assets & operations ***of the entities to the transaction***. We believe this can only be achieved by setting materiality based on a significant percentage of assets or operations of the entities involved in the transaction. Therefore, we request Section 97435(c)(1)-(2) and any flat-dollar threshold be removed as criteria for determining materiality.

   However, if OHCA needs to set a floor to limit the number of filings reviewed by OHCA, this can still be achieved while still meeting the directive that only those transactions which involve a material amount of the actual assets and operations of the entities to the transactions be filed. We suggest the following threshold:

   > *The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of more than 50% of the submitter's total California-based assets, at book value, or $25 million in assets, whichever is greater.*

3. Section 97435(c)(5) of the proposed regulations also goes beyond the authority of the statutes and scope of California Health & Safety Code Section 12507(c)(1). As stated above, Section 12507(c)(1) requires that a material amount of the assets or material amount of the operations

of an entity to the transaction be involved for the filing requirement to be triggered. There is no authority under the California Health Care Quality and Affordability Act for OHCA to determine a transaction is material and must be filed because it "contemplates," or even if actually involves, "negotiating and administering contracts with payers on behalf of one or more providers," as stated in Section 97435(c)(5) of the proposed regulation.

The California Health Care Quality and Affordability Act is also clear what entities to which it applies. Section 97435(c)(5) goes beyond that scope and attempts to give OHCA authority over other types of entities, such as "management service organizations, or other organization."

While the California Health Care Quality and Affordability Act covers Third Party Administrators (an entity which must obtain a license in California) under the definition of Payor, the Act never mentions MSOs or contemplates a wide reach to transactions with any random "other organization."

For these reasons, we recommend Section 97435(c)(5) be removed.

4. Sutter respectfully requests that the regulations define "encumber" and "lease" so as to avoid potentially pulling in traditional bond financing, real estate lease transactions, and other transactions which are unrelated to consolidation, market power, venture capital activity, profit margins, and other market failures on competition, prices, access, quality, and equity as was the stated focus by the Legislature as stated in Section 127507(a).

5. Sutter recommends 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. Similar to DMHC Knox-Keene licensing practices where KKA Applications are not public unless and until the application is approved, Sutter recommends that filings with OHCA which do not result in a CMIR be deemed confidential unless and until the transaction closes. In the case of filings resulting in a CMIR, Sutter believes OHCA should follow Cal. Health & Safety Code Section 127507.2(c)(1) and not disclose the filed records 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 considering any privacy, trade secret, or anticompetitive considerations.

6. We believe the sentence structure in 97435(e)(2) could be read to include a mere substitution of one or more governing body members regardless of impact to voting control. We also believe it is missing a threshold for "partial" voting control. We recommend rephrasing it and adding the same % threshold as will be set in (e)(1) and (e)(3), as follows:

> 2) There is a substitution of one or more members of the governing body of a health care entity that would transfer more than X% voting control of the members of the governing body of a health care entity, or any other arrangement, written or oral, that would transfer more than X% voting control of the members of the governing body of a health care entity; or

We also agree with the California Hospital Association that the current threshold of 10% in Section 97435(e)(1)-(3) is too low and should align with California Corporations Code Section 160(b) which 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 business entity." (See also California Corporations Code Section 5045.)

7. Sutter believes that Section 97435(c)(9) of the proposed regulations exceeds the authority of OHCA as set forth in California Health & Safety Code Section 12507(c)(1). Section 97435(c)(9) provides that one of the circumstances requiring filing is that:

> *A health care entity that is a party to the transaction has consummated any transaction regarding provision of health care services in California with any other party to the transaction within ten years prior to the current transaction.*

This criterion fails to include ***any*** materiality level even though California Health and Safety Code Section 12507(c)(1) states that notices of agreement only need to be filed if the transaction does 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.***
>
> [Bold italicized emphasis added.]

Section 97435(c)(9) of the proposed regulations allows for the mere presence of a prior health care services transaction amongst a health care entity and any other party to the transaction to pull the current transaction into a required review disregarding the limited authority provided in California Health & Safety Code Section 12507(c)(1) and regardless of whether a material amount of the assets or operations of an entity is involved.

Each of the prior transactions could be immaterial and combined not reach the materiality thresholds set in the regulation. Each of the prior transactions could involve nominal funds which combined do not reach the materiality thresholds set in the regulation. Yet, just because there was ANY prior transaction within ten (10) years between two of the health care entities, OHCA proposes that a second transaction should trigger a filing.

This exceeds the scope of the filing standard set in Section 12507(c)(1) and appears to be an attempt by OHCA to review transactions, even immaterial transactions, which occurred prior to April 1, 2024, which the Legislature did not give OHCA authority to review. Additionally, it makes all the information of historic transactions, which were not material and not subject to be filed with OHCA subject to reporting and a matter of public record unless confidentiality is conferred upon those documents.

If OHCA is concerned that a single transaction will be broken into several smaller transactions to avoid a filing requirement, a different safeguard can be written into the regulation such as, stating that any related transaction with a party within the past year will be considered a single transaction when determining whether a material amount of assets or operations of any entity is involved. However, the transactions need to be demonstrably related and within a close

enough period for OHCA to argue they should have been filed together, with the burden of proof on OHCA. Any transaction whatsoever in a ten (10) year period is far too broad to demonstrate circumvention of statutory requirements.

We recommend that Section 97435(c)(9) of the proposed regulations be removed.

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

OHCA Draft CMIR Regulations – CAHP & ACLHIC Comments			
Section	**Page #**	**Regulation Text**	**Comment**
22 CCR § 97431. Definitions.	1	**§ 97431(a) and (g): Definition of "Affiliate," Definition of "Health Care Entity"** (a) "Affiliation" or "affiliate" refers to 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. (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; (4) Include 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; and (5) 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 a transaction with a physician organization of less than 25 physicians remains subject to the notice filing requirements of section 97435.	**§ 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."
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	**§ 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

		are not limited to, claims processing, utilization management, billing and collections, customer service, provider rate negotiation, network development, and other services and support.	"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.
22 CCR § 97431. Definitions.	2	**§ 97431(q): Definition of "Transaction"** (q) "Transaction" includes mergers, acquisitions, affiliations, or other agreements involving the provision of health care services in California that involve a change 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.	**§ 97431(q): 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: o 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. o The dollar amount thresholds are low, especially given that healthcare services, in general, are expensive. o 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	3	**§ 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	3-4	**§ 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. (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 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. (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	**§ 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 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. • 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. • (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. As such, filing should be required only where a party is acquiring more than 50% of the voting securities or

		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 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.	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. • For (c)(5), this section is not necessary per the above recommendation to key off of the FTC thresholds. • 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. • 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. • 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	4-5	**§ 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. (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	**§ 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?

		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	5	**§ 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	5	**§ 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.	7-10	**§ 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 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, include 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 in the last year, quantity/type of services provided annually). (ii) For health care service plans, health insurers, and risk-bearing organizations,	**§ 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: • 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

		include number of enrollees per patient zip code in the last year. (E) Federal Tax ID # and tax status as for-profit or non-profit (F) California licenses held by the submitter, if any, and identification of any other states where health care-related licenses are held, license type, and numbers. (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) Primary languages used by submitter and all other health care entities in the transaction when providing services to the public and the threshold languages used when providing services to Medi-Cal beneficiaries, as determined by the Department of Health Care Services (5) Description of all other entities involved in transaction. For each entity, describe: (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;	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 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.

		(C) Governance and operational structure (including ownership of or by a health care entity); (D) Annual revenues; (E) Current geographic areas (including zip code and county) of operation; (F) If a health care provider is involved in the transaction, include each provider type, 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), and number of patient visits by county and zip code in the year preceding the transaction; (G) If a payer, describe 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) For all health care entities, the business addresses of any new entity(ies) that will be formed as a result of the transaction. (6) Proposed or anticipated date of transaction closure (7) Description of transaction, which shall include the following: (A) The goals of the transaction;	• 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 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.

		(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) 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) 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) A description of current services provided and expected post-transaction impacts on health care services, which shall include, if applicable: (A) Physical addresses where services are performed; (B) Levels and type of health care services offered, including reproductive health care services, labor and delivery services, pediatric	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.

		services, behavioral health services, cardiac services, and emergency services; (C) 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; (E) Charity care; (F) Community benefit programs; and (G) Medi-Cal and Medicare. (11) Description of any other prior transactions that: (A) Affected or involved the provision of health care services; (B) Involved any of the health care entities in the proposed transaction; and (C) Occurred in the last ten years. (12) 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. Submitters shall upload the following documents in machine-readable portable document format (.pdf), with sections bookmarked, as applicable: (1) 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); (2) Contact information for any individuals signing or responsible for the transaction or side or related agreements; (3) If applicable, any pro forma post-transaction balance sheet for any surviving or successor entity; (4) 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; (5) 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; (6) 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) Any documentation related to the mitigation of any potential adverse impacts of the transaction on the public; and (9) 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.	11	**§ 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 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	**§ 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

		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 agreements, financial documents, compensation documents, contract rates, and unredacted résumés are deemed confidential by the Office. 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 that provides a reasonably detailed statement of the grounds on which confidentiality is claimed and a statement of the specific time for which confidential treatment of the information is necessary. Bases for confidentiality shall include: (1) the information is proprietary or of a confidential business nature, including trade secrets, and has been confidentially maintained by the entity and the release of which would be damaging or prejudicial to the business concern; (2) the information is such that the public interest is served in withholding the information; or (3) the information is confidential based on statute or other law. (3) If a request for confidential treatment is granted, the submitter will be notified in writing, the information will be marked "Confidential'' and kept separate from the public file. The Office and the Department shall keep confidential all nonpublic information and documents designated as confidential pursuant to this section.	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 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. • 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.
22 CCR § 97439. Filing of Notices of Material Change Transactions.	11	**§ 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.	11	**§ 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.	12, 14	**§ 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 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 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 directly affects a general acute care or specialty hospital.	**§ 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 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.

		(E) If the transaction may negatively impact the quality of care. (F) If the transaction between a health care entity located in this state and an out-of-state entity may increase the price of health care services or limit access to health care services in California. (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 the community 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) 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) 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) Any other factors the Office determines to be in the public interest	
22 CCR § 97441. Cost and Market Impact Reviews.	12-15	**§ 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. 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.	**§ 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

		(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. (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 may request review of the Office's determination. The request shall: (A) Be in writing; (B) Be signed by the submitter; (C)Be sent to the Director with a copy to the Office; (D)Be provided to all other submitters involved in the transaction; (E) Set forth specifically and in full detail the grounds upon which submitter considers the determination to be in error; and (F) State the reason(s) why the submitter 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	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 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,

		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. (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	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). • 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.

		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.	

From: Anete Millers
To: OHCA CMIR
Cc: Steffanie Watkins (swatkins@aclhic.com)
Subject: OHCA CMIR Regulations - Comment Submission by CAHP and ACLHIC
Date: Thursday, August 31, 2023 4:57:59 PM
Attachments: OHCA Draft CMIR Regulations (CAHP & ACLHIC Comments).pdf

Dear Ms. Brubaker,

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 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. Attached are the collective comments from our member health plans/insurers, and below are some introductory comments:

Generally, our members' concerns revolve around the following items:

- **The breadth of the language/definitions**. For example, the definitions of "transaction" and "health care entity" are incredibly broad and exceed the language and intent of statute. "Transaction" would include any agreement that impacts operations, and also implies that major technology investments, such as claims/clinical data sharing/etc. could be subject to review. Similarly, OHCA is defining Management Service Organizations (MSOs) as a payer, even though many MSOs are admin services only. CAHP and ACLHIC agree with other stakeholder organizations that have expressed concerns about the breadth of these definitions.

- **The dollar thresholds are too low.** Based on realistic and ongoing market conditions, both locally and nationally, the thresholds in the current draft of this rulemaking do not seem to account for inflation and other market changes. We strongly recommend that OHCA revise the regulations to mirror the 2023 FTC thresholds.

- **The proposed metrics for evaluating cost and market impacts omit any consideration of the positive impacts the transaction may have**.

- **OHCA's determinations about market impact will, in many cases, be speculative in nature and therefore highly subjective**.

- **The timelines are unnecessarily long and could negatively impact future transactions**. When accompanied by the "tolling" language, the timelines as written could deter transactions, have the countereffect of limiting competition, and could impact day-to-day operational contracts for health care stakeholders resulting in massively increased costs for

their core business.

- **The confidentiality language is not sufficient**. As currently written, the confidentiality language in the proposed rule would not protect sensitive and proprietary business documents. In determining what is confidential, OHCA should consider how information could be used by competitors in order to understand the public harm/benefit in rejecting a request for confidential treatment.

- **Requesting clarification regarding the referral process from DMHC/CDI/AG to OHCA**. Health plan transactions are only subject to review if they are referred for review per the statute, which should be expressed clearly in the rulemaking.

CAHP and ACLHIC thank you for your consideration of our feedback. We are committed to working with HCAI and OHCA to draft regulations that are consistent with the Legislature's intent and which best serve the needs of California's consumers. Please contact me if you have any questions or require additional information.

Best regards,

Anete Millers
Director of Regulatory Affairs
California Association of Health Plans
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Advocating for California's health plans since 1984

Purchaser Business Group on Health

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August 31, 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: Proposed 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. The HCAI and OHCA staff did an excellent job in developing the proposed CMIR regulations, and we want to recognize that work. **We support the core elements of the proposed 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.

Evidence of Benefits
The legislation requires OHCA to assess the likely benefits as well as the negative effects of proposed transactions. To ensure that this is done rigorously, *the regulations should require the entities to produce evidence, e.g., academic research or post-merger analyses of other transactions.* Furthermore, the expected benefits should be quantified wherever possible, e.g., expected lower costs and prices, improvement in specific quality measures, etc. In addition, the regulations should establish a process to collect information for up to five years post-transaction to determine whether the expected benefits actually occurred.

Confidentiality
The regulations should be clarified by stating that information is confidential only if it has been confidentially maintained or is not otherwise publicly available. Confidentiality should not be applied to items that must be made transparent per federal and state rules, e.g., negotiated rates and hospital pricing. We appreciated the verbal statement to this effect from OHCA staff during the August 22 meeting of the Health Care Affordability Board, but it needs to be explicit in the regulations.

Market Failure and Market Power
The regulations should *clarify that the CMIR process includes reviews for market failure or market power* and is not limited to transactions.

Thresholds for Inclusion and Criteria for Assessment
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. In conducting the assessment of proposed transactions, however, it is very important to look closely at those in underserved areas to ensure that problem of access to critical services is maintained. In the review process, OHCA should also ensure that the CMIR program is not setting up barriers to the expanded use of value-based payment models.

Thank you for the opportunity to offer comments on the proposed CMIR regulations, and please contact us if you have any questions or need additional information.

Sincerely,

William E. Kramer
Senior Advisor for Health Policy

CALIFORNIA MEDICAL ASSOCIATION

August 31, 2023

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

Sent via email: *CMIR@hcai.ca.gov*

Re: "Promotion of Competitive Health Care Markets" draft regulations

Dear Ms. Brubaker:

On behalf of the California Medical Association (CMA) and our nearly 50,000 physician and medical student members, CMA would like to thank the Office of Health Care Affordability (OHCA) for the opportunity to comment on these draft regulations and requests that substantial changes be made before sharing your next draft. It is helpful that the statute provides for your draft regulations to go before the Health Care Affordability Board, as that provided an additional opportunity to hear from stakeholders, including CMA, in addition to the feedback you received from Board members about necessary changes to the draft.

CMA broadly outlined our concerns at OHCA's August 15, 2023 Public Workshop about the proposed emergency regulations. This letter addresses those broad concerns. CMA will follow up with specific amendments and more detailed comments, as warranted, in subsequent public comment periods, and after discussing these issues with OHCA staff and gaining a better understanding of the expectations for next steps given the significant concerns that have been raised about the first draft.

The statute calls on OHCA to review transactions likely to significantly impact market competition, the state's ability to meet cost targets, or affordability for consumers and purchasers. As we read the "Promotion of Competitive Health Care Markets" draft regulations, we are paying particular attention to any of the provisions that fail to meet the standards for rulemaking such as clarity, consistency, and authority. We are also focused on areas in which the draft regulations may deviate from the intent of the statute, increase administrative burden, increase costs, or have a negative impact on the health care delivery system and patient access to care.

One concern shared by many parties is the length of time the proposed Notice of Material Change and Cost and Market Impact Review (CMIR) process would take under these draft regulations. This would be a costly and time-consuming process for the parties, and for OHCA. It is not in the best interest of health care consumers for health care entities to be required to compile the substantial information required in the notice of material change for every small, commonplace, routine transaction that is unlikely to significantly impact

competition or affordability. The current draft includes commonplace transactions that don't involve the transfer of "a material amount of the assets" of a party, which is the triggering threshold in the statute.

For those transactions that do warrant a CMIR, we would urge you to streamline the process, so that reviews don't take ten months or longer. A lengthy process will discourage many small transactions that might improve patient access to care from occurring and will likely prevent other small transactions from coming to completion once a notice of material change is submitted to OHCA. Even for larger transactions, the review process should not take more than a few months. OHCA's role is to identify transactions that are "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" and then refer such a proposed transaction to another state entity with the authority to take action. (Health & Safety Code § 127507.2(a)(1).) The Office's purpose is not to create a situation in which those unlikely to ever meet that threshold collapse during the lengthy review process or a small or distressed entity is forced to close.

Many of the triggers in draft § 97435(c) and the corresponding provisions in (e) have such low thresholds that the Office would likely receive thousands of unnecessary filings each year and have to review and sort through them before it could focus on those the statute intends for OHCA to examine. For example, if a health care entity intends to have "a substitution of one or more members of the governing body", that would trigger the requirement to submit a notice of material change. The substitution of one member should not trigger such a filing and the associated requirement to wait at least 60 days to hear back from OHCA.

OHCA was granted emergency rulemaking authority until January 1, 2027. For this and many other reasons, CMA urges OHCA to focus your early attentions on transactions larger than the thresholds proposed in draft § 97435(c). Once the Office has had a year or two of experience, it can use its emergency rulemaking authority to expand the volume of transactions that necessitate a notice of material change or a CMIR if you learn that an initial focused set of regulations is not bringing to OHCA all the transactions that warrant your review. Inundating the Office with thousands of notices that must be reviewed and responded to will delay review of the more significant transactions. Additionally, you will gain knowledge from your first year of experience with the review process (including ways to streamline it), and you will be able to increase staffing to handle a higher volume of submissions over time.

If OHCA keeps any of the triggers in draft § 97435(c), it would be helpful to clarify that the triggers in (c) are only relevant when an entity in (b) is involved in one of these transactions. We appreciate the OHCA staff's comments at the Health Care Affordability Board meeting that that (c) is not intended to apply unless at least one of the parties meets the definition of health care entity, but the triggers in (c) are such low thresholds that many have read (c) to pull in transactions involving two parties that are both exempt under the statute by virtue of having fewer than twenty-five physicians in each entity.

Some of the definitions in the draft regulations are inconsistent with the definitions in statute. The definition of health care entity in the draft regulations should not be broader than in Health and Safety Code § 127500.2, so, as an example, management services

organizations (MSO) which were excluded from the statute should not be included in the regulations, nor should affiliates, subsidiaries or other entities related to health care entities unless they, too, satisfy the definition.

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.

The description in draft § 97441 of how OHCA would determine whether to conduct a CMIR goes beyond the statutory authority in terms of what would trigger a CMIR.

At the same time, some of the provisions in the draft regulations lack clarity. These in part include:

- Draft § 97435(e)(3): It is unclear what constitutes "administrative or operational control or governance" and how one would quantify the administrative/operational control or governance that would be transferred to ascertain whether a contemplated transaction triggers the 10% transfer threshold requiring a material change notice. Additionally, the 10% threshold is quite low and would likely result in unnecessary filings for transactions the statute does not intend to include in this process.

- Draft § 97441(a): Rather than to make the statutory mandate of § 127507.2(a)(1) more specific, this subdivision provides 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. 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.

- Draft § 97441(b): It is unclear when a notice would be considered "complete" and when the 60-day review timeline would be expected to conclude. This is in part due to the broad and extensive list of information required in draft § 97439, some of which consists of vague or open-ended narrative components; and in part due to the office's ability to toll the deadline indefinitely with requests for additional information, including those not required as part of the MCN filing as described in draft § 97439.

We know OHCA does not in any way intend 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, so we request that you delete paragraph (b)(3) of draft § 97435.

CMA is also concerned that 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.

The statute indicates that OHCA will set fees through regulations, and those fees should be included in these regulations. Parties should have an estimate of what level of fees they will pay if they file with OHCA so they can make appropriate business decisions. During the Health Care Affordability Board's August 22, 2023 meeting, it sounded like the intent is to contract out the CMIR work, rather than hiring staff with subject matter expertise and developing that expertise in-house. Relying on contractors gives OHCA leadership less ability to monitor the work, may result in health care consultants having confidential information that could later harm the parties that filed the information, increases the likelihood of conflicts of interest and is likely to be significantly more costly for the health care entities that must file.

In summary, we ask that OHCA's regulations be consistent with the intent of the statute to focus on the transactions likely to significantly impact competition, the state's ability to meet cost targets or affordability for consumers and purchasers. We further urge OHCA to reduce the volume of information that must be submitted as part of the notice of material change, shorten the timeline for the CMIRs and set reasonable fees for the CMIR process. We appreciate your willingness to discuss these issues further.

Sincerely,

Janice M. Rocco

Janice Rocco
Chief of Staff
California Medical Association

cc: Members of the Health Care Affordability Board

CFT A Union of Educators & Classified Professionals

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September 1, 2023

Health and Human Services Secretary Mark Ghaly, M.D.
Director Elizabeth Landsberg, Health Care Access and Information Department
Deputy Director Vishaal Pegany, Office of Health Care Affordability, HCAI
Megan Brubaker, CMIR, Office of Health Care Affordability
2020 W. El Camino, Ste. 1200
Sacramento, CA

Re: Proposed Cost and Market Impact Review Regulations

Dear Dr. Ghaly, Ms. Landsberg, Mr. Pegany, and Ms. Brubaker,

On behalf of CFT, a union of educators & classified professionals, AFT, AFL-CIO, I am writing in support strong oversight of the health care market, including oversight of market failures and market power as well as proposed transactions. We offer the following comments to strengthen the proposed emergency regulations on cost and market impact reviews and to close gaps in those regulations.

1. Lower thresholds for transactions aligned with the OHCA Act and Attorney General review:
   a. A threshold of $6 million in assets or revenue for the acquiring entity and $3 million in assets or revenue for the entity being acquired
   b. Clarity that revenue applies to total revenue from all sources, not net patient revenue.
2. Clarity that market reviews include reviews for market failure or market power as demonstrated by the repeated testimony from Monterey County and are not limited to transactions.
3. Clarity that information is not eligible to be designated confidential unless it is confidentially maintained or not otherwise publicly available.
4. Inclusion of the full range of health care services:
   a. Addition of behavioral health services in health care services
   b. The full range of reproductive health services, including all forms of contraception and abortion in affected services
   c. The full range of LGBTQ services, including gender-affirming care, which was omitted in the current draft.
5. Inclusion of IPAs and Management Service Organizations as health care entities.
6. Expected labor market impacts, including direct health care labor market impacts and indirect impacts on wages and benefit costs for all consumers
7. Requirement that any statements about the potential benefits of a transaction include evidence, if any, such as peer-reviewed studies of similar transactions or post-merger impacts as well as measurable impacts post-transaction for future monitoring.
8. Fees on the health care entity or entities subject to review equal to “all actual, reasonable, and direct costs”, consistent with the Act.
9. Public notice, public comment, public meetings
   a. Public notice of a determination not to conduct a transaction review
   b. Clarity that public comment will be accepted during the period after a transaction is noticed and prior to the preliminary report
   c. Addition of public meetings for significant transactions or upon request of stakeholders

These changes would further strengthen and provide clarity to the proposed regulations as well as being consistent with the OHCA Act and other state law

Sincerely,

Tiffany Mok
Legislative Representative
TM: ac-opeiu#29 afl-cio