California Hospital Association

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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 Revised Draft "Material Change Transactions and Pre-Transaction Review" Regulations

Dear Ms. Brubaker:

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

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

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

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

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

Executive Summary

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

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

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

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

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

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

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

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

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

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

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

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

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

Detailed Comments

Focus on the Most Impactful Transactions

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

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

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

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

(ii) *are subject to the control, governance, or financial control of the health care entity, such as an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks;"*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) (1) A health care entity shall provide the office with written notice of agreements or transactions that will occur on or after April 1, 2024, that do either of the following:
(A) Sell, transfer, lease, exchange, option, encumber, convey, or otherwise dispose of a ***material amount of its assets*** *to one or more entities.*

(B) Transfer control, responsibility, or governance of ***a material amount of the assets or operations*** *of the health care entity to one or more entities.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Clear and Speedy Timelines for CMIRs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Establish Reasonable Fees for CMIR Activities

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

It remains critical that the office charged with promoting health care affordability put in place reasonable protections regarding the fees that will be charged to health care entities under the CMIR process. Moreover, the enabling statute dictates that the office do so via regulation: paragraph (c)(3) of Health & Safety Code Section 127507 requires the office to *"adopt regulations for proposed material changes that warrant notification, establish appropriate fees, and consider appropriate thresholds, including, but not*

limited to, annual gross and net revenues and market share in a given service or region." The revised draft regulations include provisions fulfilling the first and third of these statutory mandates, but neglect to establish appropriate fees that allow health care entities to reasonably anticipate the potential costs of the CMIR process, or assurances that the fees will, in fact, be appropriate. We ask the office to include in the next revision of the regulations a provision that would ensure that fees charged are reasonable and accord with the economical costs of conducting a review. Specifically, we ask the office to add a new subdivision (g) in Section 97435 that reads as follows:

(g) Fees.
(1) The office shall not assess a fee on health care entities for the submission of a notice of material change or to reimburse the office for state employee labor costs or other internal expenses for conducting a cost and market impact review.
(2) The office may assess a fee on a health care entity that has filed a notice of material change that does not receive a waiver from a cost and market impact review. The fee shall not exceed the reasonable, direct, and actual costs of conducting that entity's cost and market impact review charged by external consultants and advisors to the office.
(A) To determine reasonable costs on a total and hourly basis for conducting a cost and market impact review, the office shall conduct and publish on its website a survey of the usual costs of conducting similar reviews by other California state agencies and out-of-state agencies that implement a similar cost and market impact review process. The survey shall also assess costs charged by consultants directly to health care entities for analyses similar to or supportive of cost and market impact reviews. The survey shall stratify costs by the size or complexity of the market transaction under review.
(B) Following the completion of the survey pursuant to subparagraph (g)(2)(A), the office shall establish a maximum schedule for fees charged to health care entities for the completion of a cost and market impact review. The maximum fees shall be stratified to account for the differences in costs associated with transactions of different sizes or complexity.

Ensure Benefits of Proposed Transactions Are Given Appropriate Consideration

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

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

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

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

Clearly Formulate Criteria for Determining Whether to Conduct a Full CMIR

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

> *The office finds that a material change noticed pursuant to Section 127507* ***is likely to have a risk of a significant impact*** *on market competitions, the state's ability to meet cost targets, or costs for purchasers and consumers…* (Health & Safety Code Section 127507.2(a); emphasis added)

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

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

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

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

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

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

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

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

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

Reasonable Information Submission Requirements for Parties to a Transaction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Protect Sensitive Non-Public Information Provided to the Office

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

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

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

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

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

Conclusion

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

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

Sincerely,

Ben Johnson

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

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

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

Article 1. Material Change Transactions and Pre-Transaction Review

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

§ 97431. Definitions.

As used in this Article, the following definitions apply:

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

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

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

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

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

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

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

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

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

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

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

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

Commented [LR2]: Revised to be grammatically correct.

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

(ii) are subject to the control, governance, or financial control of the health care entity, such as an organization that acts as an agent of a provider(s) in contracting with payers, negotiating for rates, or developing networks; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 97433. Scope.

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

§ 97435. Material Change Transactions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) The transaction involves the acquisition of a health care entity by another entity and the acquiring entity has consummated a similar transaction(s), in the last ~~ten~~three years, with a health care entity that provides the same or related health care services, and the transaction is more likely than not to increase annual California-derived revenue of any health care entity that is a party to the transaction by 20% or more of annual California-derived revenue at normal or stabilized levels of utilization . The ~~proposed~~ transaction and ~~its~~ such prior related transactions will constitute a single transaction for purposes of determining the ~~revenue thresholds in subsection (b)~~ and asset and control circumstances in subsection (c). However, notice is not required if the 20% of annual revenue is less than $25 million.

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

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

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

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

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

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

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

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

(A) Prior year third-party settlements;

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

(C)Fee for service revenue; or

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

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

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

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

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

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

§ 97437. Pre-Filing Questions.

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

§ 97439. Filing of Notices of Material Change Transactions.

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

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

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

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

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

(A) Business Name

(B) Business Website

(C)Business Mailing Address

(D)Description of organization, including, but not limited to, business lines or segments, ownership type (corporation, partnership, limited liability corporation, etc.), governance and operational structure (including ownership of or by a health care entity).

(i) For health care providers or fully integrated delivery systems, include a summary of provider type (hospital, physician group, etc.), facilities owned or operated, service lines, number of staff, geographic service area(s), and capacity or patients served in California (e.g., number of licensed beds, number of patients per county in the last year).

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

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

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

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

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

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

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

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

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

(B) Ownership type (corporation, partnership, limited liability corporation, etc.), including any affiliates~~, subsidiaries, or other entities that control, govern, or are financially responsible for the health care entity or that are subject to the control, governance, or financial control of the health care entity~~;

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

(D)Annual revenues for prior three years;

(E) Current county or counties of operation;

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

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

(H)If a payer is a party to the transaction, include a description of the county(ies) where coverage is sold, counties in which they are licensed to operate by the Department of Managed Health Care and/or the Department of Insurance, and the number of enrollees residing in the California county in the year preceding the transaction; and

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

(4) Proposed or anticipated date of transaction closure;

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

(A) The goals of the transaction;

(B) A summary of terms of the transaction;

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

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

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

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

(6) The submission date and nature of any applications, forms, notices, or other materials submitted or required regarding the proposed transaction to any other state or federal agency,

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

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

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

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

(i) Name of the court;

(ii) Case number; and

(iii) Names of the parties

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

(A) Counties where services are performed;

(B) Levels and type of health care services offered, such as the full range of reproductive health care and sexual health care services, specialized services for LGBTQ+ populations, labor and delivery services, pediatric services, behavioral health services, cardiac services, and emergency services;

(C)Summary of the number and type of patients served, including but not limited to, age, gender, race, ethnicity, preferred language spoken, disability status, and payer category;

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

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

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

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

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

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

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

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

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

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

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

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

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

(D)Seismic compliance with the Alfred E. Alquist Hospital Facilities Seismic Safety Act of 1983, as amended by the California Hospital Facilities Seismic Safety Act (Health & Saf. Code, §§ 129675- 130070).

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

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

(c) Documents to Be Submitted with Notice.

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

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

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

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

(3) Documentation related to valuation of the transaction;

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

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

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

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

(8) Certified financial statements for the prior three years and any documentation related to the liabilities, debts, assets, balance sheets, statements of income and expenses, any accompanying footnotes, and revenue of all entities that are parties to the transaction. Certified financial statements mean audited financial reports, or if a health care entity does not routinely prepare audited financial reports, a comprehensive financial statement. The comprehensive financial statement shall include details regarding annual costs, annual receipt, realized capital gains and

losses, and accumulated surplus and accumulated reserves using the standard accounting method routinely used by the health care entity and must be supported by sworn written declarations by the chief financial officer, chief executive officer or other officer who has financial management and oversight responsibility, certifying the comprehensive financial statement is complete, true, and correct in all material matters to the best of their knowledge, and that the health care entity does not routinely prepare audited financial reports, or the most recent audited financial report is not available. For California-derived revenue requirements (as used in this Article), the certification under this paragraph requires that revenue be calculated as it was generated or occurred in California rather than when revenue is booked, accrued, or taxed;

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

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

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

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

(d) Confidentiality of Documents Submitted with Notice.

All of the information provided to the Office by the submitter shall be treated as a public record unless the submitter designates documents or information as confidential when submitting through the Office portal system or thereafter submitted and the Office accepts the designation in accordance with paragraphs (1) through (3) below or unless deemed confidential pursuant to paragraph (2) below.

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

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

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

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

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

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

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

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

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

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

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

§ 97440. Request for Expedited Review.

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

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

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

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

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

(1) Severe financial distress of one or more of the parties to the transaction; or

(2) Any significant reduction in the provision of critical health care services within a geographic region or regions.

(3) As used in subsection (b)(1), "severe financial distress" shall be shown by a grave risk of immediate business failure and the demonstration of a substantial likelihood any party to the transaction (or an entity affected by the transaction) will have to file for bankruptcy under Chapter 11 of the Bankruptcy Act (11 U.S.C. Sec. 1101 et seq.) absent the waiver and the transaction is necessary to ensure continued health care access in the relevant markets.

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

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

(e) The Office shall use best efforts to grant or deny the request by the date indicated by the submitter pursuant to paragraph (a)(3). The Office shall keep the submitter informed as to the likelihood of meeting this time frame and any alternative time frame.

(f) The Office shall notify the submitter in writing of its decision to grant or deny the request. If the request is granted, the transaction may close immediately.

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

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

(1) In determining whether to conduct a cost and market impact review based on the Office's finding a noticed material change is likely to have a risk of a significant impact on market competitions, the state's ability to meet cost targets, or costs for purchasers and consumers, the Office ~~will~~shall consider the factors set forth in subsection (a)(2).

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

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

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

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

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

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

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

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

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

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

(b) Timing of Review of Notice.

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

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

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

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

Commented [LR16]: Health and Safety Code Section 1250(f) is a "special" hospital, not a "specialty" hospital. California law doesn't recognize any such thing as a "specialty" hospital.

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

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

The Office shall notify the submitter in writing of its determination to conduct, or not to conduct, a cost and market impact review. If the Office determines a cost and market impact review is not required, the transaction may close immediately.

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

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

(A) Be in writing;

(B) Be signed by all requesting submitters;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The effect of lessening competition or tending to create a monopoly which could result in raising prices, reducing quality or equity, restricting access, or innovating less.

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

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

(6) Whether the transaction may foreclose competitors of any party to the transaction from a segment of the market or otherwise increase barriers to entry in any health care market.

(7) Whether the parties to the transaction have been parties to any other transactions in the past ~~ten~~three years that have been below the thresholds set forth in section 97435(b).

(8) Consumer concerns including, but not limited to, complaints or other allegations against any health care entity that is a party to the transaction related to access, care, quality, equity, affordability, or coverage.

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

(f) Preliminary Report of Findings.

(1) Upon completion of a cost and market impact review, the Office shall make factual findings and issue a preliminary report of its findings pursuant to subdivision (a)(5) of section 127507.2 of the Code. The Office shall provide a copy of any report prepared by an outside contractor and the preliminary report to the submitter at least 10 business days prior to issuing them publicly. The

submitter. The submitter must inform the Office of any inaccuracies in these reports within 5 business days of receipt. The Office shall correct any inaccuracies prior to making the documents public.

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

(g) Final Report of Findings.

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

§ 97442. Market Power or Market Failure Determinations.

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