August 31, 2023

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Sent via email: CMIR@hcai.ca.gov

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

Dear Ms. Brubaker:

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

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

We recommend that the office reconsider its current approach of seeking maximal noticing, information submission, and timeline authority at the outset to one that focuses on the key areas of concern. Then, over time and using its streamlined (emergency) rulemaking power, the office may progressively expand the scope of its market oversight functions if, and to the extent that, experience shows this is needed. Below is an Executive Summary of our central concerns and feedback. This is followed by our detailed comments, analysis, and requested revisions.

Executive Summary

CHA has significant concerns with the CMIR regulations as currently drafted. We ask for a large number of meaningful changes to ensure the regulations accord with the office's authorizing statute and prevent avoidable and widespread negative impacts on California's health care providers and their patients.

Focus on the Most Impactful Transactions. As drafted, the regulations establish noticing and materiality requirements that would capture an enormous array of basic market and operations activities that extend far beyond what was intended by the authorizing legislation. We urge the office to substantially narrow the draft regulations to focus its efforts on transactions likely to have significant effects on the health care market, prevent the office from being overwhelmed by notices and information from filing entities, and lighten the burden placed on health care entities—including small and rural entities—seeking business and operational relationships to continue delivering accessible and high-quality care in their communities.

- **Exempt Transactions in the Ordinary Course of Business.** Due to its overly broad definition of a "transaction," the current draft regulations would require 90-day notice for changes in operations above a given dollar threshold. For many providers, this would include routine transactions such as contracting with a health plan to be an in-network provider, updating an electronic medical record system, securing a loan, or leasing new medical office space. Mandating advance notice and subjecting health care entities to a costly and slow review process for the hundreds or thousands of such transactions that they conduct annually is neither what the Legislature intended nor what would be conducive to a functioning health care delivery system. The regulations must be revised to categorically exempt transactions in the ordinary course of business from the definition of a transaction, or enumerate an expansive list of transactions explicitly exempted from office oversight under the CMIR process.
- **Conform to the Materiality Requirements in Statute.** State statute requires notice of a material change only when a health care entity *transfers* "a material amount of its assets to one or more entities" or *transfers* control, responsibility, or governance of "a material amount of the assets or operations *to one or more entities*." In other words, each paragraph of subdivision (c) must:
  (1) Include a *transfer* of assets or control, and
  (2) Include a threshold dollar amount of assets and/or threshold measure of control *that is being transferred*

  As described later, several of the conditions requiring notice of a material change under the regulations fail to comply with this statutory imperative. These include the conditions requiring notice for transactions that raise revenues by $10 million (even for entities making tens of billions of dollars annually), affiliations where an entity has $10 million in annual revenue, and transactions among parties that have previously consummated another transaction.
- **Establish Reasonable Asset Transfer Materiality Thresholds Pegged to Inflation**. The $25 million threshold in Section 97435(c)(1) is much too low, neither recognizing the size of California nor the 30% inflation that has occurred since Massachusetts set the precedent for this threshold. To prevent ever smaller transactions (in real dollar terms) from falling under the review process, CHA recommends that any adopted threshold be updated regularly to account for inflation. To address both these concerns we recommend adopting the Federal Trade Commission benchmark.
- **Conform With Generally Accepted Definition of "Control."** The draft regulations define a change in control as a transaction that transfers more than 10% of the control of a health care entity. This threshold is far too low. A person or corporation with a 10% interest in a health care entity does not, under any scenario, have control over the health care entity. Moreover, the threshold belies substantial legal precedent as to the meaning of "control." Both the California

Corporations Code and the Federal Trade Commission set a 50% threshold for defining control. As a rule of statutory construction, the Legislature is presumed to know existing law when enacting new laws. As such, they undoubtedly knew the definition of "control" and chose to use that term in the governing statute. We recommend the 50% threshold be adopted.

Establish Clear and Speedy Timelines for CMIR. Under the current draft regulations, the full CMIR process would take a minimum of 250 days — over two months longer than Oregon's comparable deadline. This would add hundreds of thousands of dollars to the cost of transactions and produce a chilling effect on prospective collaborations, regardless of how beneficial the arrangement would be to California patients and communities. To prevent the discouragement of constructive collaborations, prolonged uncertainty surrounding the outcome of a proposed transaction, and inadvertently raising health care costs, we urge the office to expedite and clarify its timelines for the CMIR process. We request several practical changes to deadlines to reduce the timeline to 200 days—comparable to that in other states. We further ask the office to clarify the office's missing deadline for publishing preliminary reviews, establish reasonable protections against overly long and potentially unrestricted tolling against the office's deadlines, simplify the reference date for "closing" a transaction, create an expedited review process for urgent transactions, and adopt additional reasonable rules that hold the office accountable to achieving its deadlines.

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

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

Clearly Formulate Criteria for Determining Whether to Conduct a Full CMIR. While the draft regulations list the factors the office will consider when determining whether to conduct or waive a full CMIR, they provide no clarity about how the office will evaluate those factors. In fact, the draft regulations allow the office to make arbitrary decisions about which transactions will be subject to a CMIR based entirely on lax speculation. As a result, health care entities would have little to no ability to anticipate whether an intended transaction will be delayed by 250 or more days. Moreover, the automatic inclusion of any transaction involving a general acute care or specialty hospital shows a preconceived and undeserved bias by the office against hospitals and hospital transactions. We strongly encourage the office to clarify the criteria via regulation to identify when a CMIR will be required and, in doing so, conform with statute.

Reasonable Information Submission Requirements for Parties to a Transaction. Overly expansive information submission requirements on parties to a transaction place unnecessary burdens on health

care entities, increase compliance costs, and exacerbate the risk that sensitive and confidential information will be released into the public domain. Accordingly, in identifying the information parties to a transaction must submit prior to and during the CMIR process, the office must seek to gather the minimum kinds and amounts of information necessary to fulfill its statutory prerogatives. The information submission requirements — as currently drafted — should be scaled back to balance the office's need for information with the negative impacts that overly onerous reporting requirements would have on health care entities' basic market activities. In addition to several other requested changes, we recommend the office limit the submission requirements accompanying an initial notice of a material change to those of Massachusetts and Oregon, as well as California state agencies, including the Department of Justice. Additional information necessary to inform a full CMIR should be collected only when the office elects to conduct a full review following a waiver decision.

Protect Sensitive Non-Public Information Provided to the Office. Health care entities maintain large amounts of data to fulfill their patients' clinical needs, manage their finances and operations, and compete in the health care marketplace. Protecting the confidentiality of these data is critical. We appreciate that the office has the difficult task of balancing public transparency with the parties' rights to keep sensitive proprietary information confidential. CHA recommends that Hart-Scott-Rodino filings and contact information for individuals other than the designated public contact be deemed confidential. In addition, we request that the office establish a process to inform the submitter if it denies a confidentiality request and provide an opportunity for the submitter to appeal the denial before the office makes the information public.

Focus on the Most Impactful Transactions

The office's authorizing statute establishes a clear intent for the office to *"analyze those transactions likely to have significant effects"* on the health care market (Health & Safety Code Section 127507(a)). To faithfully operationalize this intent and allow the office to devote its limited resources to where it can achieve the greatest impact, it must establish reasonable noticing and materiality thresholds. The current draft regulations do the opposite, and instead, capture a vast array of transactions and operational activities that a health care entity undertakes on a routine basis. Finalizing the rule in its current form risks seriously impeding basic market activities by and among health care entities and would overburden the office with notices for activities outside of the scope of what is intended under state statute.

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

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

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

Clarify Who Counts as a Health Care Entity and an Affiliate. The office's governing statutory authority already defines "health care entity" in Health & Safety Code Section 127500.2(k): A "health care entity" is a "payer, provider, or a fully integrated delivery system." The regulations exceed their statutory authority in Section 97431(g) by adding to this definition (in Section 97431(g)(4)), *"affiliates, subsidiaries, or other entities that control, govern, or are financially responsible for the health care entity or that are subject to the control, governance, or financial control of the health care entity…"* Some affiliates may not be health

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

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

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

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

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

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

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

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

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

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

Conform to the Materiality Requirements in Statute. Subdivision (c) of Section 97435 lists various circumstances that trigger the filing of a notice. However, many of these circumstances do not comply with the governing statute, Health and Safety Code Section 127507(c)(1). This statute requires notice only when a health care entity *transfers* "*a material amount of its assets* to one or more entities" or *transfers* control, responsibility, or governance of "*a material amount of the assets or operations* to one or more entities." In other words, to comply with the statute, each paragraph of subdivision (c) must:

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

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

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

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

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

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

Establish a Reasonable Asset Transfer Materiality Threshold Pegged to Inflation. The $25 million threshold in Section 97435(c)(1) is much too low. It fails to recognize the size of California as well as the significant inflation that has occurred since the out-of-state agencies the office is modeled after set their respective thresholds. The $25 million threshold appears to be based on the one adopted by Massachusetts in 2015. Since that year, the U.S. has experienced 30% cumulative inflation for all goods and services. As a result, Massachusetts has experienced more and more transactions falling under its threshold that were not intended to be subject to review. In addition, the Massachusetts health care marketplace is much smaller than California's — Massachusetts serves only 7 million people, compared with California's nearly 40 million people. While $25 million may have been material in Massachusetts eight years ago, it is not an appropriate threshold today in California. In fact, such a threshold would capture transactions that account for five thousandths of one percent of total California health expenditures. Moreover, to prevent ever smaller transactions, in real dollar terms, from falling under the review process, CHA also recommends that any threshold that is adopted be pegged to an inflation index or other benchmark. To address both these concerns we recommend adopting the Federal Trade Commission benchmark.

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

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

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

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

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

This criterion has additional problems that must be addressed:

- It requires a great deal of speculation by the parties. We instead recommend that notice requirements be based on objective criteria, not speculation about the future.
- How far in the future must/can the parties look to determine "normal" or "stabilized" level of operations? For health care facilities that serve a growing community, this could be eight to ten years in the future. Do we use year 1 dollars or year 10 dollars? (inflation adjustment)
- If a transaction is expected to increase revenue at one facility, but decrease revenue at another facility, do we use the net increase to determine whether a notice is required?
- Section 97435(d) defines "revenue" to mean the total average annual California-derived revenue received for all health care services by all affiliates over the three most recent fiscal years. This definition makes no sense in the context of paragraph 97435(c)(2). The definition of revenue in subdivision (d) is backward-looking while the intent of paragraph (c)(2) appears to be forward-looking. The definition of revenue in subdivision (d) refers to annual revenue averaged over a three-year period; it is not clear whether paragraph (c)(2) also refers to annual revenue averaged over a three-year period (at normal or stabilized levels of utilization or operation), or a simple one-year period.

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

Conform to State Statute and Clarify Noticing Requirements Related to Asset Sales. Paragraph (c)(3) of Section 97435 requires an entity to provide notice of a transaction involving 20% or more of the assets of "any" health care entity in the transaction. However, the authorizing statute (Health & Safety Code Section 127507(c)(1)(a)) allows only "its" assets to be considered — meaning the submitter's assets — not other entities' assets. Paragraph (c)(3) must be revised to comply with the statutory authority. In addition, the 20% threshold is too low and will capture transactions beyond the intent of the legislation. CHA recommends a threshold of more than 50% of assets, which will capture significant transactions. Finally, CHA recommends that this paragraph be clarified to mean (a) California-based assets and (b) the fair market value of assets (rather than acquisition cost, book value, or replacement cost of assets). Most significant transactions will be subject to a fair market value analysis or fairness opinion, and using fair market value also aligns with the fair market value requirement in laws that apply to health care entities (such as Stark and the anti-kickback statute and their CA equivalents). The Federal Trade Commission also uses fair market value for Hart-Scott-Rodino filings.

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

(c)(3) The transaction involves the sale, transfer, lease, exchange, option, encumbrance, or other disposition of more than 50% of the submitter's total California-based assets, at fair market value.

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

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

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

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

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

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

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

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

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

CHA recommends that this paragraph be deleted or the following language be substituted for the proposed language:

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

Conform With Generally Accepted Definition of Control. Subdivision (e) of Section 97435 defines the circumstances in which a transaction is deemed to transfer or change control, responsibility, or governance of a health care entity for purposes of submitting a notice. CHA believes that the threshold of 10% in paragraphs (1) and (3) is far too low and contradicts legal precedent. A person or corporation with a 10% interest in a health care entity does not, under any scenario, have control over the health care entity. The generally accepted definition of "control" refers to having a *majority* interest in a company or on a board thereby being able to make all corporate decisions. California Corporations Code Section 160(b) defines "control" to mean "the ownership directly or indirectly of shares or equity securities possessing more than 50 percent of the voting power of a domestic corporation, a foreign corporation, or an other [sic] business entity." See also California Corporations Code Section 5045, defining "control" as "the power to direct … the management and policies of a corporation.) As a rule of statutory construction, the Legislature is presumed to know existing law when enacting new laws.[2] As such, it undoubtedly knew the definition of "control" and purposely chose to use that term in the governing statute. If it meant for notices to be submitted to the office for merely a change in minority interest (especially as low as 10%), it would have used different language.

We note that the California attorney general's regulations implementing almost identical statutory language ("an agreement or transaction will 'transfer control, responsibility, or governance' if…") uses the term "control" to mean a majority interest. It appears that the office borrowed the language from the California attorney general's regulations (11 CCR Section 999.5(a)(3)(A)) but arbitrarily reduced it to a 10% threshold, which undermines the statutory intent to capture only material changes of control. Again, if the California Legislature wanted to require notices to be submitted to the office for a change of a minority interest (especially as low as 10%), it would not have copied the attorney general's governing statute without change.

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

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

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

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

The term "administrative or operational control or governance" in Section 97435(e)(3) lacks clarity. Health care entities hire a chief executive officer (CEO) to exercise administrative and operational control. Does this paragraph mean that the office must be noticed when a new CEO is hired? When a new chairman of the board is appointed? CHA recommends deleting this paragraph.

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

(1) CHA recommends the following language be substituted for the proposed language: *There is a substitution or addition of a new corporate member or members that transfers more than 50% of the voting shares of the health care entity*

(2) There is a substitution of one or more members of the governing body of a health care entity that transfers more than 50% of the voting control of the members of the governing body of the health care entity; or

(3) There is an arrangement, written or oral, that transfers more than 50% of the voting control of the members of the governing body of a health care entity

Notwithstanding Section 97435(a), if a health care entity experiences a transfer or change in control, responsibility, or governance as described above but cannot provide 90 days' advance notice due to factors beyond its control, the health care entity shall provide notice as soon as reasonably possible. Any updates or appointments related to the composition of governing bodies or boards, such as the conclusion of the term of a board member or members pursuant to applicable corporate bylaws, or the appointment of a new president or chief executive officer or any other health care entity executive by the governing body shall not be considered a transfer or change in control, responsibility, or governance.

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

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

Clear and Speedy Timelines for CMIRs

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

As drafted, finalizing a transaction under the full CMIR process would take a minimum of **250 days** — assuming no delays — which equates to more than eight months after an initial notice of a material change has been filed. This is over a month longer than the Massachusetts Health Policy Commission's comparable deadline, and over two months (nearly 40%) longer than that of the Oregon Health Authority. Below, we offer recommendations on how to expedite the timelines for completing reviews, clarify ambiguous deadlines, and establish special processes for critical and time-sensitive transactions that are necessary for protecting access to care. While the office may wish to complete reviews faster than its regulatory deadlines, the record for other state agencies in beating their deadlines is nonexistent. Rather, the triggering of extensions is the norm. As such, establishing deadlines to which the office is accountable now is absolutely essential.

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

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

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

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

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

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

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

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

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

Additionally, paragraph (d)(2) of Section 97441 gives the office the authority to toll any time period in which it is awaiting the provision of information it deems necessary to complete its review. In effect, this gives the office the power to delay a transaction for an unlimited period of time if, in its sole discretion, it determines a notice or any supplemental information provided is incomplete. This is only made more problematic given the expansive, subjective, and speculative nature of the information required in the notices and the authority of the office to request more information, again at its sole discretion. To address these shortcomings in the regulation, we recommend the office place the following conditions on tolling while awaiting more information:

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

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

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

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

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

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

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

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

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

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

Green Light Transactions If Office Does Not Meet Regulatory Deadlines. As previously noted, we have serious concerns regarding the potential for the CMIR process to delay and ultimately derail transactions that are in the public interest. While this likely will occur even when the office meets its process deadlines, it is only more likely in circumstances when the office does not meet its deadlines. Under the current draft regulations, health care entities have little to no recourse in the event the office fails to meet a regulatory deadline, which could result in months- or years-long delays in completing a transaction. To prevent such delays and give assurance that the process will not be unduly prolonged, we urge the office to plainly state that transactions may be consummated without risk of further review if the office fails to meet its regulatory deadlines.

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

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

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

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

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

Establish Reasonable Fees for CMIR Activities

Existing governmental reviews of collaborations among health care entities regularly entail hundreds of thousands of dollars in costs to reimburse government agencies for their use of outside consultants and experts. Because government agencies simply pass along these costs to regulated entities, the fees consultants charge to government agencies often greatly exceed the amounts these same consultants

charge directly to health care entities for similar work. For this reason, it is critical for the office to put in place reasonable protections regarding the fees that will be charged to health care entities under the CMIR process. Moreover, the enabling statute dictates that the office do so via regulation: paragraph (c)(3) of Health and Safety Code Section 127507 requires the office to *"adopt regulations for proposed material changes that warrant notification, establish appropriate fees, and consider appropriate thresholds, including, but not limited to, annual gross and net revenues and market share in a given service or region."* The draft regulations include provisions fulfilling the first and third of these statutory mandates, but neglect to establish appropriate fees that give health care entities reasonable notice of the potential costs of the CMIR process, or assurances that the fees will, in fact, be appropriate. We ask the office to include in revised regulations a provision that would ensure that fees charged are reasonable and in accord with the economical costs of conducting a review. In particular, we ask the office to add a new subdivision (g) in Section 97435 to read as follows:

(g) Fees.

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

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

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

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

Ensure Benefits of Proposed Transactions Are Given Appropriate Consideration

The office's authorizing statute requires that the benefits of proposed transactions be considered in the CMIR process. The draft regulations are silent on whether and how the office will consider these benefits. The regulations must be revised to affirm and enumerate the office's responsibilities to give the benefits of proposed transactions their proper consideration. These benefits include, but are not limited to:

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

To this end and to fulfill its statutory mandate, we ask the office to revise the beginning of subdivision (e) of Section 97441 of the draft regulations to state:

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

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

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

Clearly Formulate Criteria for Determining Whether to Conduct a Full CMIR

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

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

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

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

In addition, we take exception to the automatic inclusion of any transaction involving a general acute care or specialty[3] hospital in the list of factors for deciding whether to conduct a full review (in Section 97441(a)(2)). This shows a preconceived bias by the office against hospitals and hospital transactions, which is undeserved. The California marketplace has more than 400 hospitals — and more than half are losing money on operations. In contrast, five health plans control 70% of the California market and have more than $225 billion in annual revenues.

Specifically, CHA recommends amending Section 97441(a)(2) as follows, with the purpose of ensuring that the waiver criteria conform to the statute's overarching intent for the office to analyze transactions "likely to have significant effects:"

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

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

Convey Rationale for Determination to Conduct a Full Review. We appreciate the office's inclusion of a process for health care entities to contest the office's determination that a full CMIR is required, as described in subdivision (c) of Section 97441. However, while the draft regulations require the office to inform the parties of its determination, they do not require the office to provide specific information about the basis for the office's determination. As a result, health care entities wishing to utilize the contestation process would not have sufficient information about the specific findings they should contest to support a reconsideration of the office's decision. We request the office revise subdivision (b) of this section as follows:

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

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

Reasonable Information Submission Requirements for Parties to a Transaction

Overly expansive information submission requirements on parties to a transaction place unnecessary burdens on health care entities, raise compliance costs, and exacerbate the risk that sensitive and confidential information will be released into the public domain. Accordingly, in identifying the information parties to a transaction must submit prior to and during the CMIR process, the office must seek to gather the minimum kinds and amounts of information necessary to fulfill its statutory prerogatives. The information submission requirements — as currently drafted — would impose enormous burdens on health care entities seeking to collaborate and should be scaled back to balance the

office's need for information with the negative impacts that overly onerous reporting requirements would have on health care entities' basic market activities.

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

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

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

- Apply the office's "circumstances requiring filing criteria" and materiality thresholds, or, for the latter, a modified version thereof, to this provision — otherwise, a single referral agreement with a single physician would have to be reported
- Limit the lookback period to three years — a sufficient period through which to gain insight into potential serial transactions
- Make the requirement prospective for material transactions occurring on or after Jan. 1, 2024, so that health care entities can be prepared to comply

Require Information Submission About Parties to the Transaction Only. Paragraph (b)(5) of Section 97439 requires the submitter to provide voluminous information about "all other entities involved in the transaction." This phrase is overly expansive, potentially requiring information to be submitted about an unlimited range of third parties—whether completely independent from the parties or affiliated with them. These entities could include, for example, real estate agents, escrow companies, law firms, appraisers, lenders, and others. Even limiting this phrase to all other "health care" entities "involved in" the transaction would be overly broad, particularly since the term "involved in" is so vague. For a hospital, this could include dozens of entities. We recommend the office limit the information submission requirements to information about the *parties* to the transaction. The office has the ability to request additional information if needed later.

Narrow the Scope of the Reporting of Licensure. Subparagraph (b)(1)(F) of Section 97439 requires a health care entity providing notice of a material change to submit a copy of each California and non-California license it holds. First, this provision seems to require a health care entity to submit non-health care-related licenses it holds, such as business licenses, business tax permits, hazardous waste disposal licenses, resale permits, elevator permits, building permits, childcare licenses, etc. Second, even if this provision is limited to healthcare-related licenses, a single hospital holds scores of these licenses as well. For example, a hospital must have at least one pharmacy license from the California Board of Pharmacy, but in addition, each automated drug delivery system (a pill counting/storage machine) requires a separate license, a centralized hospital packaging pharmacy license may be needed, and a sterile compounding pharmacy license may be needed. Similarly, each mammography machine needs a separate license from the California Department of Public Health, Radiologic Health Branch.

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

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

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

Protect Sensitive Non-Public Information Provided to the Office

Health care entities maintain large amounts of data to fulfill their patients' clinical needs, manage their finances and operations, and compete in the health care marketplace. Protecting the confidentiality of these data is critical. Most entities subject to this review process are private health care entities; requiring them to disclose sensitive information without the guarantee of confidentiality would be

unreasonably burdensome and inconsistent with federal law. We appreciate that the office has the difficult task of balancing public transparency with the parties' rights to keep sensitive proprietary information confidential.

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

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

Conclusion

CHA has significant concerns with the CMIR regulations as currently drafted. Accordingly, we are asking for meaningful changes to properly scope the regulations and ensure they accord with the office's authorizing statute. Otherwise, these regulations will result in avoidable and widespread negative impacts on California's health care providers and their patients.

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

Sincerely,

Ben Johnson

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