California Hospital Association

September 12, 2023

Mark Ghaly, MD
Chair, Health Care Affordability Board
1215 O St.
Sacramento, CA 95814

SUBJECT: Comments on the August 2023 Health Care Affordability Board Meeting

Dear Dr. Ghaly:

California's hospitals share the Office of Health Care Affordability's (office) commitment to making sure patients receive high-quality, timely, equitable, and affordable health care. On behalf of its more than 400 hospital and health system members, the California Hospital Association (CHA) appreciates the opportunity to comment on the August 2023 proceedings of the Health Care Affordability Board.

Draft Cost and Market Impact 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 July 27, 2023 version of the draft regulations. Our concerns echo those raised by board members at the August Health Care Affordability Board meeting, who expressed worries about the office seeking to collect too much information, from too many entities, about too broad a set of transactions. A particular concern we heard from board members related to the impact that these draft regulations would have on rural health care providers who are struggling to keep their doors open and have the least capacity to comply with a new and burdensome set of regulatory requirements.

The recent closure of Madera Community Hospital shows what can happen when state regulatory processes come into conflict with the needed speedy resolution of a collaboration 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 overly broad 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 and clear statutory prerogatives. Then, over time and using its streamlined (emergency) rulemaking power, the office may progressively expand the scope of its market oversight functions to the extent that experience shows this is needed. Below is a summary of our central concerns and feedback.

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. Consistent with concerns raised by board members, 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. Doing so would accord with the intent of statute and ultimately prevent the office from being overwhelmed by notices and information from filing entities, while also lightening the burden placed on health care entities — including small and rural health providers — that seek 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 the relevant section of the draft regulations (subdivision (c), specifically) must include both of the following:
    - A *transfer* of assets or control
    - A threshold dollar amount of assets and/or 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. 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. CHA recommends that these conditions be deleted or, at the very least, be better defined to include a *transfer* of a *material amount* of assets or control in order to comply with the governing statute.
- **Establish Reasonable Asset Transfer Materiality Thresholds Pegged to Inflation**. The $25 million threshold for providing notice of a material change 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 the 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, it 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. 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. Unfortunately, we do not believe the deadlines established in the draft regulation would represent maximum timelines applicable to only the most complex transactions. Rather, based on our extensive experience under similar review processes from another state agency, the deadlines would represent the norm. Such drawn-out timelines 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.

As one board member described at the August meeting, a delay can kill a transaction. 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
- 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 the 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 would 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 would consider when determining whether to conduct or waive a full CMIR, they provide no clarity about how the office would 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 the 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.

Total Health Care Expenditures

Patient Attribution Challenges Raise Concerns. We appreciate the ongoing public discussions over the office's approach to patient attribution under the spending target program. Given that the credibility of the spending target program rests on the accuracy of the patient-attribution process, it is essential to get the rules right at the outset. Such rules must aim to significantly limit false positives in the form of misattributing a patient to a provider in situations where the provider has no real influence or control over the medical spending and utilization of the patient. In addition to engaging *payers* early in the development of related policies and procedures, we request early and ongoing engagement with *providers*. Ultimately, we hope to see the office set clear and consistent standards for patient attribution across payers and allow providers to validate the patient attribution data submitted by payers.

Spending Targets Must Balance Multiple Objectives and Account for Various Factors. We understand that in September the board will begin focused discussions on spending target methodologies ahead of

adopting the first non-enforceable spending target in June 2024. To prepare for these discussions, we highlight the following key requirement in the statute, which says that spending targets must:

> "Promote the goal of improved affordability for consumers and purchasers of health care, while maintaining quality and equitable care, including consideration of the impact on persons with disabilities and chronic illness."

Over the next several board meetings, we ask for careful discussion and consideration of each of the above elements laid out in law. In doing so before actually setting the state's spending target and associated methodologies, the office and board can ensure they are fulfilling each of the multiple objectives established in state law. Below, we offer several considerations related to statutory requirements applicable to the state's future spending targets.

- **Affordability.** California's hospitals share the office's goal of promoting affordable care, recognizing the concerns of Californians related to health care cost growth and the burden that cost sharing has on workers and patients. Furthermore, we recognize the inefficiencies in the U.S. health care sector, which are clearly summarized in a 2019 JAMA article.[1] Such inefficiencies are due to several factors, including:
    - Huge administrative challenges imposed on providers due to a lack of standardization in payer policies — the largest single factor identified in the JAMA study.
    - High costs for pharmaceuticals and certain other services – with pharmaceutical pricing failures being overwhelmingly implicated in the JAMA study.
    - Failures to provide appropriate preventive care and therefore providing more treatment than is necessary in acute care settings — the third-largest factor identified in the JAMA study.
    - Enormous complexity within our systems of care without adequate resources dedicated to helping coordinate care — a factor implicated in the overreliance on acute care.

  We believe that the office's prerogative must be to address affordability challenges that are due to inefficiencies such as those described above. Success cannot mean lowering costs at the expense of equitable access to high-quality care. Therefore, in setting, monitoring, and enforcing the state's spending targets and related policies, the office and board must remain steadfastly focused on the objectives of improving the value proposition and cost-effectiveness of care — rather than myopically cutting costs. Moreover, the office and board must recognize that achieving practice transformation to improve the value of care will take time, which must be accounted for in how the state's spending targets are initially implemented.
- **Quality.** State statute contains a potential contradiction: it has the state's spending targets taking effect beginning in 2025 while requiring that they be established in a manner that maintains quality. And yet, the statute does not require the office to set and measure quality standards until midway through 2026. This puts the cart before the horse by asking the office and board to say how much the state should spend on health care before deciding on what we want our health care system to achieve. We therefore ask the office to accelerate its consideration of how quality — and value more broadly — is to be maintained and improved within the context of

[1] Shrank, William H., et al. "Waste in the US Health Care System." *JAMA*, vol. 322, no. 15, 7 Oct. 2019.

the state's spending targets. While standard measures such as well-child visits and control of diabetes should be part of these discussions, we urge the office to look at additional measures of the overall health care system's performance. Are wait times for primary care and specialty visits increasing or decreasing? Are travel times to emergency care going up or down?[2] Are new medical technologies diffusing and becoming available as quickly as possible? Are new and effective care modalities such as Hospital at Home and telehealth being adopted? Patients want these improvements and innovations — they don't want the same access to the same treatments and care that have historically been available. Accordingly, monitoring macro trends such as those listed above is an important role for the office to play to prevent unintended consequences from its regulatory activities.

- **Equity.** Unequal access to health care and health resources is a major driver of health disparities. This is why investments are needed to eliminate disparities in access to not only traditional health care services but also social supports and care management services. The office's spending targets and related policies must recognize the need for and impacts of these new investments. If spending targets are set, monitored, and enforced without such recognition, they will serve to discourage the investments and punish those health care entities that nevertheless make them, undermining a critical pillar of the office's work. For example, the managed care organization tax agreement recently enacted will support increased payments to providers to address structural inequities in access to care for Medi-Cal beneficiaries. This will raise providers' revenues, increasing the risk that they run afoul of the state's spending target and are subject to the lengthy and costly enforcement process. Above and beyond public policy changes, hospitals regularly make investments and undertake other initiatives to address health inequities in their communities. As the office and board shift to thinking about establishing spending targets, we recommend that the question of how to incorporate equity into the spending target program remain at the forefront of policymakers' minds.

Thank you for the opportunity to comment on the August board meeting.

Sincerely,

Ben Johnson
Vice President, Policy

cc: Elizabeth Landsberg, Director, Department of Health Care Access and Information
Vishaal Pegany, Deputy Director, Office of Health Care Affordability
Members of the Health Care Affordability Board

[2] See the following study for the impact of higher emergency transport time on mortality rates from cardiac arrest: Jena, Anupam B., et al. "Delays in Emergency Care and Mortality during Major U.S. Marathons." *New England Journal of Medicine*, vol. 376, no. 15, 13 Apr. 2017, pp. 1441–1450, https://doi.org/10.1056/nejmsa1614073.