Oregon Association of Hospitals and Health Systems

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Directors Allen and Vandehey,

On behalf of Oregon's 62 hospitals and the communities they serve, the Oregon Association of Hospitals and Health Systems (OAHHS) is providing these written comments in response to the Notice of Proposed Rulemaking filed December 21, 2021, regarding "Oregon Health Authority's review of health care entities' proposed material change transactions" – the rules implementing House Bill 2362 (2021).

OAHHS participated actively throughout the Rules Advisory Committee (RAC) process to provide input on the Oregon Health Authority's development of the Health Care Market Oversight (HCMO) Program. We consistently advocated for rules that reflect the statutory language and legislative intent of HB 2362 and that:

- Operate with fair, objective, consistent, and predictable processes;
- Promote efficiency and avoid introducing expenses that ultimately increase the cost of health care; and
- Encourage innovation in care delivery without delay.

After four meetings of the RAC and five iterations of the rules, we still cannot determine what is covered by the law and rules nor determine how OHA will judge whether a transaction is, in its mind, permissible. Basic, fundamental questions remain, and we are concerned that hospitals still do not know:

- Whether they are required to file notice of a proposed material change transaction for any particular transaction;
- What level of review the transaction is likely to undergo;
- How much the review will cost; and
- Whether the transaction is likely to be approved.

The proposed rules incorporate few changes from the draft rules circulated prior to the fourth RAC meeting (revised 12/2/2021). In the appendix to this letter, we list previously requested

technical changes that have not yet been made. In this letter, we focus on a few requests of particular importance.

1. **Address the following concepts through rulemaking, as explicitly directed by HB 2362, and not through "sub-regulatory guidance."**

   - What it means to "eliminate or significantly reduce" essential services (HB 2362, Section 1 (10)(c));
   - Criteria for when to conduct a comprehensive review and appoint a review board (HB 2362, Section 2 (8)(c)); and
   - Criteria for approval or denial of a material change transaction (HB 2362, Section 2(2)).

   We support the development of some sub-regulatory resources, such as a safe harbor list of excluded transactions, example scenarios describing how regulatory definitions or criteria apply, and flow charts to illustrate the filing and review process. However, such guidance is not the appropriate mechanism to define or establish core concepts and criteria for which rulemaking is required by statute. The Authority's current approach denies interested parties the due process of administrative rulemaking, creates an unacceptable risk of arbitrary, inconsistent, and unfair decision making, and ultimately wastes resources.

   Creating more guidance documents does not necessarily create clarity. For example, the analytic framework is astonishing in its breadth and depth – and yet, because it is merely a "menu of potential analyses from which HCMO will choose…" (p. 1), entities still do not know how to prepare for a review. Further, this framework can change at any time with no notice or comment.

   "Eliminate or significantly reduce essential services"

   We again propose that "eliminate or significantly reduce essential services" should mean that access to a service within the service areas of the entities, taken as a whole and among all service providers in the service areas, would be reduced, as a direct result of the material change transaction, by more than 50% and the remaining service providers will not have the capacity to increase service provision sufficient to meet the current need for the essential service within the service areas.

   The first Technical Advisory Group meeting on January 14, 2022 illustrated how sub-regulatory guidance could be used to expand key concepts beyond what was included in the legislation. For example, HB 2362 allows review of new contracts, new clinical affiliations and new contracting affiliations that "***will"*** eliminate or significantly reduce essential services (Section 1 (10)(c), emphasis added). The proposed guidance document issued on January 12, 2022 creates a test wherein a 50% reduction in ***any one service*** in ***any one*** of the listed categories would be considered "significant" and trigger review if that reduction occurs within 12 months of the transaction in question, regardless of whether the reduction in services is the direct result of the transaction and without a holistic look at any offsetting benefits of the transaction or the context of the service

area.[1] The word "will" in HB 2362 indicates a much higher level of foreseeability and causality than the presumptions set forth in the draft guidance. In other words, there must be direct causality. HB 2362 also uses the term "essential ***services***" (Section 1 (10)(c), emphasis added), which is consistent with our proposed holistic look at the service area in question. If the legislature intended for a reduction in any single service to trigger this review process, it would have so stated.

Ultimately, the draft guidance document presented to the TAG creates more questions than it answers and further pushes the HCMO Program outside the boundaries of HB 2362. Under the proposed analysis, day-to-day decisions that any health care organization might make about how best to serve its patients and communities may become subject to a costly and unpredictable government review process when they are made in collaboration with another entity. This will have a chilling effect on innovation and collaboration. This is an illogical and irresponsible use of health care dollars, and we do not believe it reflects the intent of our legislators.

Criteria for when to conduct a comprehensive review and appoint a review board

The rules should make clear when entities should plan for a comprehensive review and when a review board will be appointed. The engagement of review boards should be limited to major transactions with potential for significant adverse impacts on access, equity, and cost to consumers.

Criteria for approval or denial of a material change transaction

The rules should specify how entities must demonstrate that they meet the criteria for approval of a material change transaction. Further, the rules should state that the evaluation of whether a material change transaction meets the criteria for approval must be based on the foreseeable impacts of the transaction, supported by relevant data and

[1] Examples we have provided in previous comment letters (on 11/19/2021 and 12/14/2021) demonstrating the need for a holistic look at the results of a transaction include:

i. A transaction may increase time or distance to access due to a change in location but offer more services, offer better care, and decrease wait times for appointments.

ii. A reduction of providers may not necessarily lead to a significant reduction in services.

iii. Managed care may place restrictions on providers to increase appropriate service utilization, control cost, and decrease waste. It may also place appropriate barriers to care, such as prior authorizations and consults to ensure that care is necessary. Consider, for example, a requirement that physical therapy be pursued before advanced imaging or surgery is offered for back pain. The rule incorrectly assumes that efforts made to decrease cost and improve efficacy are inappropriate activities.

iv. Changes in services may be necessary to address shifting community needs, such as adjusting the availability of pediatric vs. geriatric care, or may help optimize care delivery and access, such as closing a dialysis center because more in-home dialysis services are available.

other evidence, and balanced by consideration of the foreseeable impacts of not completing the transaction.

Instead, the rules as drafted add new criteria not included in the statute and fail to provide the clarity that would enable entities to anticipate whether a proposed transaction would meet the criteria. Clarity is an important component to ensuring a fair process.

2. **Tailor the concept of "control" to focus on the material change transactions with the most significant potential community impact.**

   Proponents of HB 2362 expressed concern about large mergers and acquisitions, and OHA also stated this as its focus early in the RAC process. However, despite having pivoted in a significantly new direction with each iteration of the rules, the Authority has been unsuccessful in narrowing its focus to these most significant transactions. OHA should ensure that its rules do not broaden the scope of the HCMO Program beyond what the statute requires.

   Given that the legislation includes certain "corporate affiliations" in addition to mergers and acquisitions (*see* HB 2362, Section 1 (1) and (10)(d)), one way the Authority could better tailor the rules to the statutory requirements is by adopting, as we have previously proposed, ***a definition of control that turns on the ability of a person to control the decision making of the governing body of an entity***. The current definitions of control in proposed OAR 409-070-0025 set low thresholds that do not speak directly to control over decision making and will encompass far more transactions than the legislature intended. These definitions also refer to concepts that do not apply to many health care entities in Oregon, such as "voting securities."

   Further, because control can look very different depending on the organization, ***any presumption of control should be rebuttable***. Guidance in the form of examples or a running list of the Agency's determinations regarding control would be welcome, but the essential components of the definition itself should be appropriately articulated in the rule.

We continue to sound the alarm that the Health Care Market Oversight Program is not ready for implementation. Instead of incentivizing continued progress toward lower cost, better outcomes, and improved access, the Program threatens to disrupt the delivery of healthcare in a manner that will stagnate improvements and harm those we all seek to help. When the original law was passed, legislators expressed concerns over large-scale mergers and acquisitions with the potential for significant adverse impacts on access, equity, and cost to consumers. However, the resulting review and oversight program reaches well beyond this scope and into the micromanagement of healthcare delivery, seeking to address purported problems that do not exist and mandating excessive fees and process on a healthcare system still reeling from the ongoing impacts of COVID-19. **To move forward with such a program would be irresponsible to Oregonians.**

While we maintain that HB 2362 is far from perfect, OHA has an opportunity to make some improvements to the Program in this final stage of rulemaking to reduce the unintended consequences of HB 2362 on our patients and communities.

OAHHS requests that OHA revise the rules to reflect the recommendations made by hospitals and health systems. We request that the Program be delayed through action by the Governor or the legislature. We also urge OHA, the legislature, and the proponents of HB 2362 to work with us on our legislative proposals to fix inherent flaws in HB 2362 and craft a predictable, focused program worthy of Oregon's ability to be a leader in healthcare transformation and innovation.

Sincerely,

Andi Easton
Vice president of government affairs
Oregon Association of Hospitals and Health Systems

Appendix

The following recommendations were made in our most recent letter, submitted on December 14, 2021, in response to the version of the draft rules dated December 2, 2021. These recommendations have not been addressed in the current proposed rules.

1. **Definitions (-0005)**

    a. The definition of "control" remains unchanged and is still too broad; further, there are situations in which it may conflict with the revisions to (-0025). As stated above, control arises when a person controls the decision making of the governing body of a health care entity. This may take various forms depending on the facts and circumstances of a situation. The rules must be flexible enough to apply to the breadth of real-world transactions while capturing only those transactions that truly change the control of a health care entity, where a change in control is a qualifier for review.

2. **Covered Transactions (-0010)**

    a. Section (1)(a) includes a "consolidation" of a health care entity with another entity. HB 2362, Section 1 (10), refers only to a "merger." Consolidation is not in the statute, and it is unnecessary to include.

    b. The definition of an "acquisition" should not include the provision of comprehensive management services ((2)(d)). Several RAC members pointed out that these are not acquisitions or exercises of control. It appears that OHA may be including this provision to target a very narrow situation where a change of control has occurred, and if so, that should be clearly and specifically defined.

    c. Section (2)(e) should be eliminated. It describes a merger rather than an acquisition and is already covered under (1)(a).

    d. The criteria for inclusion of new partnerships, joint ventures, accountable care organizations, parent organizations, or management services organizations between or among health care entities in Section (1)(e) are very broad and could capture essentially every new joint venture and accountable care organization if they act as an entity that contracts with payers. A better approach is to add "and" at the end of (1)(e)(A) and appropriately narrow the scope. In other words, (A) and either (B) or (C) would be required to pull a new partnership, joint venture, accountable care organization, parent, or management services organization into the scope of a covered transaction.

3. **Emergency Transactions (-0022)**

    a. We note that Section (1) was changed to require that "…the transaction is urgently needed to protect the interest of consumers **and** to preserve the solvency

of an entity other than a domestic health insurer." We request that the Agency change this back to "or." The statute does not require that the transaction involve a lack of solvency (*see* HB 2362, Section 2 (8)(a)), and a public health emergency transaction, for instance, may not involve solvency.

4. Disclaimers of Control (-0025)

a. As discussed above, what constitutes control of a health care entity is a complex, situation-dependent determination. We acknowledge the Agency's attempt to assign quantifiable and objective standards based on RAC members' feedback. Given the complexity of this issue, however, we recommend that all presumptions of control be rebuttable. We also recommend revising the reference to voting securities to better accommodate differences in governance across organizations.

b. Notice of OHA's findings, as contemplated in Section (2), should not be given to parties outside the transaction. These are confidential, legal decisions and the public is not in an appropriate position to comment on what the law considers to be "control" with respect to a particular entity.

5. Form and Contents of Notice (-0045 and Forms)

a. We appreciate that the form for Notice of Material Change Transaction has been shortened and simplified. However, given that OHA plans to develop sub-regulatory guidance that will affect the review criteria, it is difficult to assess whether the substantive content of the notice is appropriate.

b. The Emergency Exemption form includes some items that do not align with the criteria for exemption. For instance, how a transaction will change support staff or whether the entities have engaged with and received input from consumers are not likely to impact whether the transaction meets the criteria.

c. RAC members expressed concerns at the December 7 meeting about aggregating NPI numbers given the risk of fraud.

6. Retention of Outside Advisors (-0050)

a. We request removal of the reference to privileged information in Section (1). Privileged information should not be requested by or disclosed to OHA or outside advisors during the review.

b. There should be a mechanism for parties to halt the review process if expenses escalate to the point that the transaction is no longer feasible.

7. Preliminary Review (-0055)

a. Regarding the default to comprehensive review still articulated in Section (3), if OHA does not issue a decision within the 30-day preliminary review period, we question what value this default process brings to the transaction or to the

community. It is not clear why OHA would not be able to take some action within 30 days.

8. Comprehensive Review (-0060)

a. We appreciate that review board members will be required to file conflict of interest statements as required by HB 2362, Section 2 (11)(b). We recommend, however, that this take place before members are appointed to the review board in case exclusion due to an actual conflict is necessary.

b. We request that Section (7) be modified to allow the parties to the transaction to review and comment on the proposed findings of fact and conclusions of law, along with the Authority's proposed order, before it is released for public review. This will prevent confusion should the findings or order require any corrections or clarification to findings of fact.

c. The comprehensive review process should not exceed 180 days. If the Agency fails to issue a decision within that time, the transaction should be deemed approved without conditions.

d. The rules should describe the circumstances under which a tribal consultation will be conducted.

9. Suspension of a Transaction (-0065)

It remains unclear why the Agency should have the ability to suspend transactions (per Section (2)) to complete an analysis of whether conditions have been satisfied when the Agency already has the authority to impose penalties for noncompliance.

10. Confidentiality (-0070)

a. We encourage OHA to publish a summary, created by the filing party, of the information in the Notice of Material Change Transaction form rather than publicly posting the form itself. Given the likelihood that the notice will be heavily redacted due to the inclusion of confidential information, a summary will better serve the public.

b. Similarly, we disagree with the suggestion from some of the RAC members that term sheets be disclosed to the public. Again, these are likely to be heavily redacted due to the inclusion of confidential information and are unlikely to further the goal of transparency in any meaningful way.

11. Compliance with Conditions; Information Requests (-0080)

Any additional orders, whether related or unrelated to original orders, should only be issued after a notice and an opportunity for a hearing. We believe that is the Agency intent and ask for that to be stated more clearly.