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 regarding the draft rules and accompanying materials dated December 2, 2021, implementing House Bill 2362.

Program Implementation Should Be Delayed Because Key Issues Have Not Been Addressed or Resolved

Throughout the Rules Advisory Committee (RAC) process to date, OAHHS has consistently advocated for rules that reflect the statutory language and legislative intent 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.

We acknowledge that the Agency has been receptive to feedback from interested parties and has made some corrections and clarifications to the rules through this iterative process; however, we are concerned that the Agency responded to several requests to bring the rules within the bounds of the legislation by simply reiterating statutory language and deferring several key concepts to a Technical Advisory Group (TAG) and sub-regulatory guidance. This approach introduces another layer of ambiguity and uncertainty by delaying the development of critical standards until the implementation date or beyond and by holding health care entities to an evolving and changing Agency interpretation ("we don't know what we don't know") without the due process of administrative rulemaking, even when rulemaking was explicitly directed by the Legislature. ***Ultimately, this approach continues to disincentivize collaboration and innovation in our health system while driving up costs, all to the detriment of patients and consumers.***

We support the development of some sub-regulatory resources, such as a safe harbor list of excluded transactions and flow charts to illustrate the filing and review process. However,

guidance is not the appropriate mechanism to address core concepts for which rulemaking is required by statute, including:

- 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)).

This proposed approach creates an unacceptable risk of arbitrary, inconsistent, and unfair decision making and wastes resources. The discussion at the December 7 RAC meeting also reflected differences of opinion in how a TAG should be formulated, which adds to our concern about this tactic. Ironically, RAC members who profess to represent consumers and community members stated that they wish to limit TAG membership to a small group of select people. That approach is particularly problematic.

Instead of pushing tough issues to a different process with few procedural guardrails, we implore the Agency to take the requisite time to address them through rulemaking. Again, we ask that the rollout of the new Program be delayed to allow the robust discussion on these topics to continue. At the very least, we encourage the Agency to conduct a phased rollout, beginning only with mergers and acquisitions.

Which Transactions Are Covered Remains Unknown

One of the greatest challenges in developing these rules has been, and remains, identifying the types of transactions subject to review. With each revision, the Agency has pivoted in a significantly new direction. While some necessary course corrections have been made, there is still a need for considerable delineation and definition of these concepts, including what constitutes control, or a change in control, of a health care entity. OHA's latest approach sets forth presumptions based on voting control of certain percentages of voting securities (*see* draft OAR 409-070-0025) and OHA plans to publish guidance and clarifying examples to refine the concept of control through sub-regulatory guidance. This approach is too rigid and lacks an understanding of governance, especially in the context of nonprofit entities where there are no securities. To echo comments of several RAC members throughout the four meetings, an irrebuttable presumption of control based on 51% of voting control does not reflect the complex reality of the governance dynamics of a given health care entity. Control may take various forms depending on the facts and circumstances of a particular situation.

Rather than drawing rigid boundaries that may not accommodate real-world transactions, ***the Agency should develop a definition of control that turns on the ability of a person to control the decision making of the governing body of an entity***. Further, 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.

Identifying which transactions are subject to review also turns on what it means to "eliminate or significantly reduce" essential services. We oppose the expansion of this concept to encompass transactions beyond those for which the statutory language explicitly requires review, and we again emphasize that this concept should be defined through rulemaking rather than sub-regulatory guidance.

These issues and others are discussed further below in our detailed comments on each section of the revised draft rules.

Detailed Comments

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.

    b. The new definition of "corporate affiliation" introduces the term "corporate system," which is undefined.

    c. For clarity, we recommend that the definition of "provider" state, "…administer **or provide** medical or mental health services."

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)(d) 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)(d)(i) and appropriately narrow the scope. In other words, (i) and either (ii) or (iii) 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.

e. We reiterate that the considerations set forth in Section (2) to help define the elimination or significant reduction of essential services are difficult to apply and further elevate the concerns previously raised about discouraging beneficial collaboration across the health system. For instance:

   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.

As discussed above, we have serious concerns about deferring these critical questions to guidance formulated outside the regulatory process. Further, it is likely that the Agency will pull in new concepts and move those forward in "guidance." That approach denies stakeholders and the public the protections of rulemaking to which they are entitled.

3. Emergency Transactions (-0022)

a. We appreciate that the confidentiality of emergency transactions will be maintained and that parties will have an opportunity to appeal a denial of an emergency exemption, and we support the addition of public health emergencies as a type of emergency situation covered under these rules.

b. 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 (3), 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. As stated previously, it is essential that the Analytic Framework promote a consistent and predictable process rather than introduce another layer of ambiguity. Developing it through a sub-regulatory process is not appropriate given that approval of transactions will be subject to the standards in the Analytic Framework.

c. 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.

d. 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. Thank you for adding conflict of interest and confidentiality certification requirements as well as notice to the parties prior to engaging outside advisors.

b. 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, and the use of privileged information is not contemplated in the statute.

c. We maintain that the Agency should set forth criteria to indicate when outside experts will be needed so parties to a transaction can plan accordingly. There should also 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. We appreciate that OHA incorporated prior feedback to correct and clarify the language in Section (2). In the latest draft, there is a typo at -0055 (5). It should say "notwithstanding sections **(2)-(4)**…" instead of "(2) and (3)."

b. 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. The rules still lack criteria for when a review board will be appointed. The rules should set forth clear, objective criteria for appointment of a review board and should limit the engagement of review boards to major transactions that affect many Oregonians. The legislation (HB 2362 Section 2 (8)(c)) requires the Agency to address this through rulemaking, and sub-regulatory guidance is insufficient.

c. 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.

d. The criteria in Section (9) now largely mirror the statutory language, with the exception of three new criteria at (9)(a)(B)-(D). The new criteria should be removed because they are not included in the statute. While mirroring the statutory language is an improvement over prior iterations of the rules, it fails to provide clarity and predictability for entities attempting to anticipate the standards to which they will be held. The legislation directed the Agency to formulate review criteria through rulemaking. Rather than building and expanding on the statutory criteria, as OHA attempted to do in previous drafts and again here, the rules should specify how entities must demonstrate that they meet the criteria. Sub-regulatory guidance is insufficient for defining these standards.

e. We reiterate that review decisions need to be based on the foreseeable impacts of the transaction, supported by relevant data and other evidence, and balanced by consideration of the foreseeable impacts of not completing the transaction.

f. 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.

g. 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. Continuing Jurisdiction (-0080)

We acknowledge the Authority's clarifications to this section. We ask that the Agency further clarify that any additional orders, whether related or unrelated to original orders, can only be issued after a notice and an opportunity for a hearing. We believe that is the Agency intent, but ask for that to be stated more clearly.

12. Fee Schedule (Table 1)

We appreciate the Authority's explanation of some of its projected costs and note that considerable uncertainty remains about the volume of reviews. Given that uncertainty, we question how the Authority was able to determine that administration of the Program will require four FTEs and how the Authority plans to adapt its strategy if the volume of reviews is lower than anticipated.

The Authority must not stop short of its statutory directive to address difficult issues. Relying on a sub-regulatory process to move forward is not consistent with the Authority's own stated goal to achieve "a process that is transparent, robust and informed by the public, including the local

community, through meaningful engagement" (Draft OAR 409-070-0000 (3)(c)), nor is it what the legislature intended. We remain prepared and eager to engage in further conversations on outstanding regulatory issues.

Sincerely,

Andi Easton
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Oregon Association of Hospitals and Health Systems