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 dated November 10, 2021, implementing House Bill 2362.

Oregon has long been a leader in charting the future of health care delivery and reform to best serve patients. Oregon's approach has been thoughtful, leading to greater innovation, lower cost, and better outcomes. Oregonians have benefitted from increased access to care from community-based hospitals, clinics, and other critical providers. Collaboration and change have been key to the maintenance of services and the transformation of services. With these rules, Oregon is on the verge of creating an agency review process that will prioritize the status quo and, as a result, prevent future opportunities to keep improving care delivery, innovation, and access for patients. We do not want to look back in 3, 5, and 10 years and discover that all collaborative health innovation has been halted and that services have been reduced. Given the breadth of OHA's approach, the costs involved in OHA review, and the uncertainties relating to implementation, we believe our concerns for our patients are well-founded.

OAHHS participated in the Rules Advisory Committee (RAC) meetings on October 25, November 4, and November 15, 2021. This letter summarizes the feedback we provided during the RAC meetings regarding the most recent draft of the rules and provides additional detail.

The November 10 draft made several improvements over prior versions. We acknowledge the steps the Agency has taken to better define what types of transactions are subject to review, to make the review process more predictable, and to bring several concepts back within the boundaries of the legislation. We ask the Agency to continue working with RAC members, subject matter experts, and other interested parties to further refine the large universe of transactions the rules may capture, ensuring consistency with the statutory language and legislative intent. We also remain concerned that several aspects of the review process still involve vague, subjective criteria that may be unfairly or inconsistently applied. Vague or subjective criteria increase uncertainty, which will stifle innovation and increase cost. In what follows, we further explain these and other remaining issues and recommendations.

1. Definitions (-0005)

a. The definition of "essential services" has been brought back in line with the statute. However, "services that are essential to achieve health equity" remains undefined and leaves significant uncertainty about what is covered.

b. As we have previously argued, the threshold for what constitutes "control" remains too broad. True control will often not arise until an entity holds at least 51% of decision-making authority and, depending on the organization, even that threshold may be too low. By continuing to sweep minority governance changes and intra-family governance changes into the scope of the rules, OHA is vastly broadening the number of reviews. We submit that such breadth does not further the legislative objective, decreases innovation, and increases cost and administrative burden.

c. We reiterate that the new definition of "administrative services" is helpful but needs additional clarity, particularly around the meaning of "the rendering of health care to patients." A broad interpretation could include, for example, real estate transactions or joint purchases of insurance. It is also unnecessary to exclude the provision of pharmaceuticals from this definition given the existing regulatory structure in this area.

2. Covered Transactions (-0010)

a. Revised section (1)(c)(B) uses the term "corporate affiliation," which remains undefined. This term should be defined consistent with the legislation and our proposed definition of "control."

b. HB 2362, Section 1(10)(c) states that new contracts, new clinical affiliations, and new contracting affiliations are covered only if they eliminate or significantly reduce essential services. Revised section (1)(c)(C) of the draft rule still does not align with this aspect of the legislation. For such a transaction to be covered, it **must** eliminate or significantly reduce essential services **and,** in addition, meet any additional criteria specified by the rules. "Eliminate or significantly reduce essential services" should not be an option on a list. It is a requirement in HB 2362. ***This change is essential to fit the rules within the legislation and it will also serve to reduce unintended consequences.***[1]

c. Revised section (1)(c)(C)(ii), "change control of an entity," should read, "change control of a health care entity" to be consistent with the statute.

[1] Nov 17 Rules Development Update slides (slides available at: https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/For-Legislators-Health-Care-Market-Oversight_HCMO_Program-11.17.21.pdf) reflect this criterion correctly on Slide 3, indicating that "Contracts that significantly reduce or eliminate essential services" are subject to review. However, on slide 8, alternative criteria are listed that could trigger a review, as in the latest draft of the rules. This discrepancy must be remedied by revising the rules to reflect the statutory requirements described above.

d. There is considerable ambiguity in the new "significantly increase market concentration" concept in revised sections (1)(c)(C)(iii) and (iv). We encourage OHA to clarify how "significance" will be measured and how "market" and "concentration" will be defined, as well as how the causal connection—which must exist—to the transaction will be evaluated.

e. We acknowledge the Agency's addition of criteria in revised section (2) to help define the elimination or significant reduction of essential services. However, as discussed in the RAC meeting, the criteria 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.

   Additionally, it remains unclear what level of change in these criteria would be considered "significant." We also continue to recommend that these factors be evaluated using relevant data to estimate the likely practical effect of the transaction, and with attention to the causal connection between the services and the transaction.

f. We reiterate that the criteria for covered transactions must remain consistent with the legislation and should not introduce new concepts.

3. Examples of Transactions

a. OAHHS appreciates the creation of this list. As several RAC members asked during the meeting, it would be helpful to understand how OHA expects entities to use these examples and whether they are considered "safe harbors" if the list indicates that they do not require review.

b. As stated above, the statute only covers new contracts, clinical affiliations and contractual affiliations that eliminate or significantly reduce essential services. *See* HB 2362, Section 1 (10)(c). As a result, it is incorrect to include any contract, clinical affiliation or contractual affiliation that does not eliminate or significantly reduce essential services. The elimination or significant reduction of essential services is a gating requirement, not a factor in a multi-pronged approach as represented throughout the chart.

c. The following examples continue to raise concern:

   i. ***The sale of 25% of the assets of a medical group*** – this does not create a change of control in the medical group. (1)(b) now says that a covered transaction includes "an acquisition of control of a health care entity, including acquiring all or substantially all of its assets and operations[.]" It does not say that acquisition of a minority of the assets is a change of control. The Agency should be careful not to confuse voting/governance control with a minor sale of assets. Additionally, it is unclear how assets would be measured in such a case.

   ii. ***"An affiliation that will result in a change in governance of a subsidiary" because it leads to a "change in control"*** – the Agency should not include internal reorganizations and governance changes within entities. This was not the intent of the legislation and there is no reason to believe that these transactions would have any effect on the objectives of the legislation.

   iii. ***The inclusion of some new joint ventures and exclusion of others*** – additional clear criteria are needed to navigate the differences between these examples.

   iv. ***A medical group affiliating with an IPA*** – First, this is a "new contract" under the legislation and, as such, it is not a covered transaction unless it eliminates or significantly reduces essential services, which it would not. This is a key point. Second, OHA is providing no factual analysis to determine whether there is an increase in market concentration (which would only become relevant if essential services were eliminated or significantly reduced). Not all IPAs involve collective pricing. OHA appears to be drawing conclusions without verifying assumptions.

4. Excluded Transactions (-0020)

a. We support the elimination of the notice and fee requirements for excluded transactions.

b. Please clarify that a "provider" as used in revised section (2)(a)(B) can be a legal entity or a natural person. This is consistent with the intent to exclude downstream provider contracts as "medical services contracts."

5. Fees

a. We support the reduction in fees for emergency and preliminary reviews; however, there remains substantial uncertainty around when a transaction may move from 30-day to comprehensive review, and the cost increase associated with that is substantial and potentially prohibitive. Parties need to be provided with an estimate of their likely costs as early in the process as possible.

b. As we and several RAC members have communicated previously, the fee amounts should be tied to the size of the transaction to ensure that the fee is not in excess of costs incurred by OHA. The statute says that fees should be "sufficient" to reimburse OHA. *See* HB 2362, Section 4 (1).

c. To further the goal of transparency, we encourage the Agency to communicate the cost structure that underlies the fee amounts.

6. Emergency Transactions (-0022)

a. We appreciate the added flexibility in these procedures in the latest draft of the rules; however, the changes do not go far enough. We continue to recommend a verbal emergency exemption process with a faster turnaround time and an immediate appeal mechanism.

b. As an alternative to public disclosure or comment at the time of the emergency, the Agency could consider releasing an annual report of transactions that have gone through this process.

7. Optional Application for Determination of Covered Transaction Status (-0042)

While this process provides some value to parties planning a transaction, it does not go far enough to ensure clarity and predictability throughout the review process. Ample opportunities for informal consultation and ongoing dialogue with the Agency throughout the planning and review process are essential.

8. Form and Contents of Notice (-0045)

a. We appreciate that statements of revenue and revenue projections are no longer required in all cases to be prepared or presented in accordance with generally accepted accounting practices and by a duly qualified and credentialed accounting expert. As previous RAC member feedback indicated, these requirements are typically not operationally feasible. Therefore, we further encourage the Agency to eliminate section (7), which still permits the Agency to require them at its discretion.

b. It remains unclear how the Analytic Framework discussed in this section will be developed and what opportunities will exist for interested parties to provide input. As with other aspects of the Program, it is essential that such a framework promote a consistent and predictable process rather than introduce another layer

of ambiguity. Other questions raised during the RAC meeting included how often the framework would be updated and how an update would impact any pending reviews at that time.

c. We look forward to the opportunity to comment on the revised forms before they are finalized. Many RAC members, including those whose opinions frequently differ on other aspects of the rules, agreed that the forms are too burdensome and require irrelevant information.

9. Retention of Outside Advisors (-0050)

a. Outside advisors should be required to undergo a check for conflicts of interest.

b. We acknowledge the addition of the cost summary; however, there is still considerable uncertainty and no apparent limit with respect to these costs. Several RAC members supported the inclusion of the statute's "reasonable and actual cost" qualifier on expenses charged to the parties for outside experts. *See* HB 2362, Section 2 (14). Further, to avoid sticker shock, an estimate of consulting fees should be provided early in the process so that a party can weigh whether to pursue the transaction or seek a refund of filing fees.

c. We also acknowledge the Agency's clarification during the RAC meeting that it does not anticipate outside experts will be retained in each case. Given that, it would be helpful for the Agency to set forth some criteria around 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.

10. Preliminary Review (-0055)

a. We maintain that the filers should have the right to have an informal consultation with appropriate decision-makers at OHA either prior or just after the notice filing.

b. We support the temporary provision through 2022 allowing approval of a transaction for which a decision is not issued within 30 days. We request that the Agency extend that date through 2023 and complete an interim report and reconvene interested parties in the fall of 2023 to evaluate the transactions reviewed so far and consider whether this provision should be extended perpetually.

c. The criteria in (2) should additionally state that improving health outcomes is a criterion for approval. HB 2362, Section 2 (9)(a)(B).[2]

[2] This criterion was correctly included in the Nov 17 Rules Development Update (*see* Footnote 1) at slide 7. The rules need to reflect this as well.

d. Please clarify the wording in (2) to reflect the apparent intent that if **at least one** of the criteria in (2) is met, then no further review is needed.

11. Comprehensive Review (-0060)

a. In (3), please add that review board members must file conflict of interest statements as required by HB 2362, Section 2 (11)(b).

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.

c. While we acknowledge that the revisions in draft section (8)(e) align with the legislation, the meaning of "substantial likelihood that the transaction would result in material anticompetitive effects…" remains undefined. Again, the parties need clarity and predictability regarding the standards to which they will be held.

d. As many RAC members expressed, the other criteria in (8) remain vague and ill-defined and do not reflect the statutory language, the legislative intent, or the framework adopted by the Oregon Health Policy Board.[3] Examples of extraordinary breadth include:

   i. (8)(a) – it is unclear how the decision makers would know whether a transaction is "likely to reduce an organization's demonstrated commitment…" or "make it more difficult to achieve health equity in the state."

   ii. (8)(c) – it is unclear what would make a transaction "inequitable or unfair to the public at large…" or how product and geographic markets would be defined.

   iii. (8)(d)(A) – it is unclear how a transaction might "substantially reduce the security of and service to be rendered to consumers…" or "otherwise prejudice the interests of such consumers or other people in this state."

   iv. (8)(d)(C) – it is unclear how the decision makers would evaluate the ability of the parties to "be strongly connected to" the communities they serve, to "support social determinants of health…," or to "satisfy the policy priorities of the Oregon Health Policy Board…"

   The examples listed here, among others in this section, are largely hypothetical considerations and nearly impossible to quantify or evaluate objectively. We have repeatedly argued that review decisions need to be based on the foreseeable impacts of the transaction, supported by relevant data and other evidence, and

[3] Approved on October 5, 2021 and available here: https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/Final_OHPB_Framework_for_HCMO_10.7.21.pdf.

balanced by consideration of the foreseeable impacts of not completing the transaction.

e. 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.

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

12. 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.

13. Contested Case Hearings (-0075)

Again, the parties should be able to appeal exemption denials and a denial of 30-day approval (and requirement for comprehensive review).

14. Continuing Jurisdiction (-0080)

The Agency's jurisdiction must be limited in time and specific to any conditions imposed during the review. As RAC members suggested, the statute provides for follow-up reports at one, two, and five years after the transaction. *See* HB 2362, Section 2 (19). The rules should not extend Agency jurisdiction beyond that.

We applaud the Agency for facilitating the robust engagement of interested parties in this rulemaking effort, and we encourage the Agency to continue integrating feedback and iterating on these important draft rules. While significant progress has been made, much work remains. We again suggest that a phased rollout, focusing first on mergers and acquisitions, may be the best way to ensure the new Health Care Market Oversight Program operates effectively and without unintended adverse consequences for patients and consumers.

We look forward to reviewing the updated filing forms and the next revision of the draft rules.

Sincerely,

Andi Easton
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Oregon Association of Hospitals and Health Systems