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 1, 2021, implementing House Bill 2362. OAHHS participated in the Rules Advisory Committee (RAC) meetings on October 25 and November 4, 2021. We look forward to participating in the third RAC meeting and urge you to schedule additional RAC meetings in light of the gravity of the work at hand.

We reiterate that HB 2362 and its implementing regulations will have far-reaching impacts across the healthcare delivery system, and it is critical that the new Health Care Market Oversight Program:

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

The latest draft of the rules falls short of these themes. The breadth, expense, burden and lack of clarity in these draft rules presents substantial concerns regarding what health care could look like in Oregon.

We continue to be concerned about the volume and types of transactions subject to review. The new concept of pooling "price negotiation power" is rife with unintended consequences and would deter the collaborative purchasing of goods or services solely for the purpose of getting a lower price and keeping health care costs down. Several examples of this were shared by RAC members during the November 4 meeting, such as hospitals jointly purchasing vaccines or supplies, or joining a group purchasing organization. Even proponents of the legislation stated that this was not their intent. Additionally, the changes to the definition of "control" do not go far enough to reflect the true level of authority needed to control a typical health care entity in Oregon and are not aligned with other legal control definitions.

During the legislative session, HB 2362 and its resulting oversight program were envisioned by proponents to follow the model developed in Massachusetts. The scope of the relevant Massachusetts regulations is far more limited in what is subject to notice and review requirements than what is stated in OHA's draft rules.[1]

The expansion of the definition of "essential services" in the second draft of the rules is also problematic and clearly contrary to the statutory language. Section 1(2) of HB 2362 states, "'Essential services'" means: (a) Services that are funded on the prioritized list described in ORS 414.690; and (b) Services that are essential to achieve health equity." The change in draft OAR 409-070-0005 (14) to the phrase, "**based upon** the prioritized list…" (emphasis added) broadens the definition well beyond the statute and reduces clarity and predictability for entities in evaluating what is subject to review. Exacerbating this lack of clarity are still-missing definitions for what it means for a service to be "essential to achieve health equity" and what it means to "eliminate or significantly reduce" essential services.

One important change that OHA can make to align the rules with the legislation is to state explicitly that, for an affiliation to be covered under Section -0010 (4), it must eliminate or significantly reduce essential services. In making that change, OHA would clarify whether some of the day-to-day "affiliations" are or are not subject to the rules.

RAC members expressed widespread concern about the process for transactions that are exempt from review. OAHHS continues to object to the detailed filing processes set forth for emergency exemptions and exemptions for adoption of Advanced Value-based Payment methodologies. It is unclear whether the rules require filing of a notice and payment of fees for other exempt transactions. Requiring notice and payment of fees for exempt transactions is not contemplated by the statute and runs contrary to the notion that they are, in fact, exempt.[2] Such filings will result in a waste of resources that could be better used to drive health care costs down for consumers and improve their care. No exempt transaction should require a filing or a fee.

The fees proposed by OHA are excessive. They bear no relation to the transactions at issue and will discourage transactions (which some RAC members said was their goal). The Agency's proposed fee schedule is incongruent with the types of transactions subject to review under these rules and threatens to further strain health care resources without any benefit to consumers. Several points to this effect were made by RAC members, including: fees are prohibitively high, especially for smaller entities and smaller transactions; the Agency should provide a written explanation of what costs the fees are necessary to cover, particularly given that the Agency (and DOJ) will charge, in their sole discretion, consulting costs over and above these fees; and fees should be based on the size of the transaction rather than the revenue of the entities involved. It is unreasonable to expect, for example, that a physician group would ever join an IPA if the lowest possible filing fee is $25,000.

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[1] *See* 958 CMR 7.02, defining "Material Change" to include mergers, acquisitions, and other affiliations "that would result in an **increase in annual Net Patient Service Revenue of the Provider or Provider Organization of ten million dollars or more**, or in the Provider or Provider Organization having a **near-majority of market share** in a given service or region" (emphasis added).

[2] Consider, for example, that the Anti-Kickback Statute and Stark laws set forth Safe Harbors that do not require filing.

There was robust discussion in the RAC meeting regarding the 30-day and comprehensive review processes described in the rules. As OAHHS and other RAC members asserted, a lack of response by the Agency within 30 days of notice filing should default to an approval of the transaction without conditions. This process is necessary to maintain accountability and ensure that transactions meeting the criteria for approval are allowed to proceed, to the benefit of consumers, without undue delay. There was also consensus among many RAC members that the criteria for review in -0060 (8) deviate substantially and unacceptably from the criteria set forth in the legislation.

In addition to these major themes, we offer detailed feedback below on the individual sections of the rule discussed in the November 4 meeting.

**1. Form and Contents of Notice (-0045)**

- The form for filing the notice is excessively lengthy and burdensome and reaches beyond the scope of the legislature's intent. As the RAC members suggested, we encourage the Authority to consider adopting a simplified form like the one used in Washington.

- We acknowledge the addition of (8) as an Analytic Framework and support the principles stated therein; however, it is unclear how the Agency will develop this framework to meet these principles and if interested parties will be able to weigh in on the framework. 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.

**2. Retention of Outside Advisors (-0050)**

- Per HB 2362, Sect. 2 (14), please add to (1) that the experts hired must be "professionals" and "qualified and have expertise in the transaction."

- Costs passed to parties should be itemized, for outside professionals only (not internal resources), and be limited to the specific transaction.

**3. Preliminary 30-day Review Process (-0055)**

- The filers should have the right to have an informal consultation with OHA either prior or just after the notice filing. While we acknowledge that OHA added provisions for technical assistance (what form to use, as an example) and declaratory rulings, these do not meet the need to have a discussion with those in a position to exercise judgment.

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

- 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.

- In (3), add that OHA must issue a written decision to approve, approve with conditions, or require comprehensive review. If no decision is issued within 30 days, the transaction is approved.

## 4. Comprehensive Review (-0060)

- In (3), add that review board members must file conflict of interest statements (HB 2362, Sect 2 (11)(b)).

- There are no criteria in the rules for when to appoint a review board. 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.

- In (8), the criteria for review are very broad and go beyond the legislation and the legislative intent. Examples of extraordinary breadth include: (8)(a), (c), (d)(A), (d)(C).

- Section (8) should contain a criterion to consider the effect of no transaction. Anticipated negative effects of a transaction or lack thereof must be foreseeable and supported by relevant data and other evidence, not based on conjecture.

## 5. Suspension of a Transaction (-0065)

It is 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.

## 6. Confidentiality (-0070)

Section (3) enables the Agency to force disclosure of confidential information to a review board in contravention of the legislation. Confidential materials cannot be disclosed to the review board.

## 7. Contested Case Hearings (-0075)

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

- In general, the Agency must ensure that these provisions comply fully with the Administrative Procedure Act. This includes the right of a party in a contested case hearing to raise issues or provide evidence outside of what is reflected in the final order, contrary to what is currently stated in section (5). Section -0075 (1) of the draft rules states that a person is entitled to a hearing if "aggrieved by any act, threatened act or failure of the Authority to act under section 2 of the 2021 Act or OAR 409-070-0000 to OAR 409-070-0085." Such a grievance could occur at any of several decision points throughout the review process that may not be reflected in the final order.

## 8. Continuing Jurisdiction (-0080)

OHA's jurisdiction must be limited in time, in accordance with the statute (see HB 2362 Section 2 (19), providing for 1-, 2-, and 5-year reports), and specific to the conditions of approval it has imposed.

## 9. Scope and Purpose (-0000)

We fully support the stated goals in the revised draft rules to "promote alignment among entities to improve efficiency and increase value in Oregon's health care system." However, per our earlier comments, there remains a disconnect between what the rules purport to accomplish and what their effect will be as written.

## 10. Definitions (-0005)

- With respect to our earlier comments on the definition of "eliminate or significantly reduce essential services," we recommend the following: "eliminate or significantly reduce essential services" means 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 definition of "control" (-0005(7)) remains too broad, even with the presumption removed. As several RAC members reiterated, 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.

- The definition of "control affiliate" (-0005(8)) should be removed. This concept is beyond the scope of the legislation and legislative intent, which is limited to "health care entity."

- The definition of "significant portion" (-0005(20)) should be removed, as should its use in -0010(2)(h), because it is beyond the scope of the legislation and was deliberately excluded from the bill during the legislative session.[3]

- 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.

- The new definition of "price negotiation power" is vague and unworkable. It does not define "pool" or "economic power" and does not describe how these concepts would be measured or otherwise evaluated. As we have argued previously, a broad interpretation of this concept leads to serious adverse impacts on our health system by discouraging collaboration and innovation.

While OHA has continued to indicate that it intends to focus its review on large transactions that risk exacerbating health inequities, increase costs to consumers, or threaten access to essential

[3] The definition of "material change transaction" in HB 2362 as introduced included a list of items "occurring during a single transaction or in a series of related transactions within a consecutive 12-month period." This qualifier was removed in later versions of the legislation.

services, the revised draft rules still fail to define these transactions accurately and unambiguously. As such, the rules continue to have the unintended consequence of driving health care entities away from the collaborative innovation that is essential to achieving Oregon's goals around access, quality, equity, and cost.

We appreciate that the Agency has scheduled an additional RAC meeting and plans to share another draft of the rules prior to that discussion. We encourage OHA to take the time necessary to gather thorough feedback on these rules and engage in collaborative problem solving to make them consistent with the legislature's intent. There is still much work to be done before the Program will be ready to launch. Instead of a full rollout in March 2022, we recommend implementing the Program solely for mergers and acquisitions at that time and delaying review of other contracts and affiliations until an adequate rulemaking process can be completed to ensure that the scope of the rules accurately reflects the legislation and that the Program is clear, objective, efficient and feasible, avoiding unintended adverse consequences for patients or consumers.

Sincerely,

Andi Easton
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Oregon Association of Hospitals and Health Systems