



Health Care Market Oversight Program
409-070 Summary of Rules Hearing Input and OHA Responses

November 2022

The Health Care Market Oversight (HCMO) program hosted a Rules Advisory Committee (RAC) meeting on July 25, 2022, to present proposed rules and hear input from RAC members. The HCMO program published all written comments received as well as a summary of the input heard during the RAC meeting. All materials are published on the HCMO website.

A Rules Hearing occurred on October 20, 2022, during which no comments were offered. However, two organizations submitted written input for the rules hearing. These documents are also published on the HCMO website.

This document summarizes input received in connection with the Rules Hearing and responds to each point.

- 1. Input from a coalition of interested parties including Cascade AIDS Project, Basic Rights Oregon, Family Forward Oregon, Oregon Nurses Association, Oregon primary Care Association, OSPIRG, Planned Parenthood Advocates of Oregon, Pro-Choice Oregon, and SEIU Local 49 – submitted October 19, 2022 (https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/Public-Comment-from-EAC-Coalition_Oct-20-2022-SOC-HCMO-Rules-Hearing.pdf)

Table with 2 columns: Comment and OHA's Response. Contains 4 rows of feedback and responses.

- 2. Input from Timothy McCrystal, Ropes and Gray LLP – submitted October 24, 2022 (https://www.oregon.gov/oha/HPA/HP/HCMOPageDocs/Oregon-Health-Authority-Letter-10-24-22_Ropes-Gray.pdf)

Comment	OHA's Response
<p>Regarding Materiality Standards for Out-of-State Transactions (OAR 409-070-0010):</p> <p>Under ORS 415.500((6)(a) and OAR 409-070-0015, a covered transaction involving an out-of-state entity is a “Material Change Transaction” subject to review if it satisfies two prongs: (i) it exceeds relevant revenue thresholds; and (ii) it “may result in increases in the price of health care services or limit access to health care services in this state.” Assessing whether a transaction “may result in increases in the price of health care services or limit access to health care services in this state” requires a highly complex analysis of pricing, demand, and competition. Under the antitrust laws, federal antitrust regulators and courts typically make such predictions only after gathering significant amounts of data and evidence from merging parties and third parties and then using complex econometric methods to make predictions about competitive impacts. The public does not have the ability to demonstrate that such condition is or is not present in a given transaction (and therefore review is not required).</p> <p>To that end, we ask that OHA establish the factors by which it will evaluate a transaction to determine whether it “may result in increases in the price of health care services or limit access to health care services in this state.” In particular, we ask OHA to further clarify how these criteria will be applied in transactions involving out-of-state entities, which may serve an important benefit to the public.</p>	<p>The criteria in the cited statute and regulations are such that if there is a possibility that a transaction involving a health care entity located in this state and an out-of-state entity may result in price increases or limit access (and all other applicable criteria are met), the transaction is subject to review.</p> <p>Entities may avail themselves of an optional application for determination of covered transaction status, as per OAR 409-070-0042.</p> <p>The program previously published the HCMO Analytic Framework, which outlines factors used to evaluate a transaction regarding changes in price and access. This analytic framework applies to transactions involving in-state entities as well as transactions involving out-of-state entities.</p>
<p>Further, OHA should consider adding further clarity regarding the rules and process by which parties to an out-of-state transaction may certify to OHA that their proposed transaction would not have such effects, and can thus determine they are not “Material Change Transactions” subject to review by OHA. The statutory trigger for review includes both elements. Presumably, if parties can demonstrate or certify to not increase prices or limit access, then OHA should consider whether review is needed in these circumstances.</p>	<p>OHA does not require entities to obtain a certification from the Authority as to the inapplicability of a given transaction involving a health care entity located in this state and an out-of-state entity. Transactions classified under OAR 409-070-0015(2) that involve out-of-state entities are not subject to HCMO review if the transaction will not result in any increases in the price of health care services nor any reductions in access to health care services in this state.</p> <p>Entities may avail themselves of an optional application for determination of covered</p>

Comment	OHA's Response
	transaction status, as outlined in OAR 409-070-0042.
<p>Regarding the definition of “Health Care Entity” (OAR 409-070-0005(16): While we appreciate OHA’s efforts in the Proposed Rule to clarify the meaning of “health care entity,” we believe that further clarity is needed with respect to the regulatory definition of this term under OAR 409-070-0005(16)(g). Specifically, we noticed a discrepancy between the rule and the statutory language that raises several questions and issues:</p> <p>i) Proposed Rule Changes: “Health care entity includes . . . [a]ny other person or business entity that is a parent organization of, has control over, is controlled by, or is under common control with, an entity that has [as] a primary function the provision of health care items or services.” OAR 409-070-0005(16)(g).</p> <p>Note: We separately flag that the word “as” appears to be missing prior to “a primary function.”</p> <p>ii) Statute: “Health care entity includes . . . [a]ny other entity that has as a primary function the provision of health care items or services or that is a parent organization of, or is an entity closely related to, an entity that has as a primary function the provision of health care items or services.” ORS 15.500(4)(F).</p>	<p>The word “as” as recommended by the commenter is already present in the proposed rules.</p>
<p>Notwithstanding the Proposed Rule departing substantially from the statutory definition, OHA does not explain why it has elected to make this change. Accordingly, we request that OHA offer additional clarification and explanation with respect to the substitution for the “closely related to” language in the statute with the three specific relationships referenced in the rule and the impact of this substitution in terms of the types of health care-related companies that were meant to be covered by this statute. It would be helpful to confirm that the three specified relationships define the scope of how the agency will construe “closely related to.”</p> <p>i. On its face, the term “closely related to” is ambiguous and can be interpreted broadly to encompass entities with little nexus to the provision of health care services in Oregon—including, in OHA’s own language, entities that are “many levels removed from patient care” and have a “limited footprint. . . in Oregon.”¹ We believe that such a broad interpretation would be outside of the scope of the legislative intent of HB 2362, which demonstrates a clear focus on overseeing health care consolidation in the Oregon marketplace involving health care providers and entities intimately involved in the delivery of health care services such as hospitals, health insurance companies, and provider groups. We presume that the language in the rule was intended to provide clarity and put limits on the statute’s reach.</p> <p>ii. The public will benefit from such a more refined definition with criteria in order to clarify that the statute does not reach non-traditional health care industry participants such as service companies engaged in the health care industry, that do not provide health care items or services—management service organizations, electronic medical record companies, device and equipment suppliers, etc. From our experience with</p>	<p>The proposed rule, OAR 409-070-0005(16)(g) does not depart from the statutory definition.</p> <p>The rule clarifies the statutory language, which states “Health care entity includes...any other entity...that is a parent organization of, or is an entity closely related to, an entity that has as a primary function the provision of health care items or services.” The proposed rule language clarifies that “closely related to” means an entity that has control over, is controlled by, or is under common control with an entity that has as a primary function the provision of health care services.</p> <p>The commenter requests a different kind of clarification: what other types of entities are closely related to an entity that has as a primary function the provision of health care items or services. OHA</p>

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<p>the HCMO Program, we understand that OHA has previously taken the position that management service organizations (including dental support organizations) are “health care entities” for review purposes, but there is nothing in the statute nor in the Proposed Rule that provides this authority. The basis for that interpretation remains unclear and should be clarified in the Proposed Rule if OHA will continue to take this position.</p>	<p>published a guidance document titled Entities Subject to Review, which answers this question.</p>
<p>Regarding Comprehensive Review Fee Criteria (OAR 407-070-0030(3)): We understand that, as directed by statute, the Proposed Rule establishes program fees to start on January 1, 2023. Given that the Proposed Rule imposes fees of up to \$100,000, it is critical for OHA to establish precise and fair rules that give entities adequate notice and opportunity to plan for such costs as part of the transaction. To avoid future confusion, we ask that OHA clarify the meaning of certain terms in OAR 409-070-0030(3) with respect to determination of fee amounts for comprehensive reviews.</p> <p>b. Specifically, the Proposed Rule states that the fee amount for a comprehensive review “shall be based on the average annual revenue or projected revenue, as applicable, in accordance with OAR 409-070-0015(1), of the following entity (the “smaller entity”); (i) [f]or transactions between two entities, the entity with smaller revenue; or (ii) [f]or transactions involving more than two entities, the entity with the second largest annual revenue.” OAR 409-070-0030(3). We query which entities should be taken into account for the purpose of calculating fee amounts.</p> <p>i. What does it mean for a transaction to “involve” more than two entities?</p> <p>ii. Are the relevant entities involved in the transaction here the Oregon entities? The parties directly entering into the transaction? Or all entities indirectly owned or affiliated with the parties to the transaction?</p>	<p>For the purposes of calculating the fee and in accordance with ORS 415.512, the relevant entities involved in the transaction are the parties to the transaction. The relevant entities involved in the transaction may include out-of-state entities.</p>
<p>As demonstrated in the transaction notices and reviews to date under the HCMO Program, transactions can be complex, and may indirectly involve dozens of entities. Consider whether the Proposed Rule should address such complexities in detail or be revised to focus on the entities involved in the transaction that generate health care service revenue from Oregon residents. For example, the Notice of Material Change Transaction for Falcon Hospice states that the transaction is occurring between out-of-state entities ten levels above the Oregon hospice locations; and the Notice of Material Change Transaction for Advantage Dental states that the transaction is occurring between out-of-state entities four entity levels above the applicant. We note that if OHA were to decide that the fee amounts under OAR 409-070-0030(3) are based on the revenue of the “parties to the transaction” (in line with the proposed rules changes’ definition of “revenue”), the fees for these two transactions (and any other transactions occurring between out-of-state entities) would be based solely on the revenue of out-of-state entities, which would raise questions whether the regulation has an impermissible extra-territorial reach.</p>	<p>As per ORS 415.512, the size of the fee shall be “proportionate to the size of the parties to the transaction.”</p> <p>ORS 415.500(6), correlates “revenue” with a party to the transaction. The proposed rule change for “revenue” under OAR 409-070-0005(26) seeks to clarify and align such term with the statutory requirements for a material change transaction.</p> <p>Only transactions involving an entity that directly or indirectly operates in Oregon are subject to HCMO review. If a transaction involves an</p>

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	Oregon entity and an out-of-state entity, the fee is calculated using both entities' three-year average annual revenue. The smaller of the two revenues determines the size of the fee for comprehensive review.
<p>Given HB 2362's aim to support statewide goals related to the provision of health care in Oregon, consider whether any fees tied to OHA's reviews should similarly have a nexus to the state and be based on revenue of entities in the state. OHA's prior review reports support such interpretation. In the 30-day review summary report for Falcon Hospice, despite the indirect involvement of numerous entities in the organizational structure (including hospice agencies all over the country), OHA focuses the majority of its review on the impact of the transaction on the two Oregon agencies involved in the transaction. To align the fee determination with the legislative focus on health care in Oregon, consider clarifying that the term "entity" under OAR 409-070-0030(3) only encompasses Oregon entities involved in the transaction.</p>	<p>In accordance with ORS 415.512, the program fees will be "proportionate to the size of the parties to the transaction."</p>