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DATE: January 23, 2023

TO: Hearing Attendees and Commenters –
OAR 333-505-0036, "Hospital Requirements during Emergency Impacting Standards of Care"

FROM: Brittany Hall, Hearing Officer and Administrative Rules Coordinator

cc: Dana Selover, MD, MPH; Section Manager
Health Care Regulation and Quality Improvement

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Period

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Hearing Officer Report

Date of Hearing: December 21, 2022, via Microsoft Teams.

Purpose of Hearing: The purpose of this hearing is to receive testimony regarding the Oregon Health Authority (Authority), Public Health Division, Health Care Regulation and Quality Improvement's proposed permanent amendments to OAR 333-505-0036.

As the state continues to experience acute staffing shortages and respond to various emergencies impacting standard of care, the Oregon Health Authority (Authority) is proposing to amend and make permanent the temporary rule requiring hospitals to report information to the Authority and provide information to the public and to patients when implementing crisis standards of care that result in triage decisions being made for patient care. The rule has been amended to make the protections applicable to all emergency situations when crisis standards of care are implemented by a hospital and triage decisions are being made regarding critical care resources. This proposed permanent rule replaces temporary OAR 333-505-0036 effective July 29, 2022 through January 24, 2023 (Temporary Administrative Order PH 166-2022).

Hearing Officer: Brittany Hall

Testimony Received: Two individuals provided oral testimony at the hearing. This testimony is briefly summarized as follows:

Meghan Bours Slotemaker, Executive Vice President and General Counsel, Oregon Association of Hospitals and Health Systems (OAHHS)

Meghan Bours Slotemaker testified that the proposed rule makes significant departures from earlier draft versions of the rule that was shared with the Rule Advisory Committee (RAC) and from prior iterations of the rule. OAHHS is concerned that the RAC did not have an opportunity to consider or provide feedback on key provisions of the proposed rule, and that if the rule is adopted, it would lead to unintended consequences for patients, confusion in our communities, increase healthcare provider burnout and result in added cost to our healthcare system, further jeopardizing access to quality care in Oregon.

Meghan Bours Slotemaker testified that the OAHHS supports the current version of the rule's definition of "triage decisions." Hospitals have invested time and resources to develop procedures to comply with the current rule, and the definition in the current rule (not the proposed rule) appropriately reflects the crucial role that the state has in triage decisions and in developing a tool available to all hospitals to use and for our communities to access and understand. OAHHS is concerned about the use of "potentially life-saving resources" in the new proposed definition because this is a new concept that is undefined, ambiguous and will create confusion for hospitals and in communities. The proposed definition of "triage decisions" also eliminates the link to OHA's Oregon Interim Crisis Care Tool, which has been and is a core component of triage decisions and shouldn't change. Further, the proposed definition of "triage decisions" does not contain the term "crisis standards of care." OAHHS requests that OHA adopt in the final rule the definition of "triage decisions" and "crisis standards of care" that were proposed to the RAC. If OHA declines to revert to those definitions, OAHHS asks that the proposed definitions be revised to more appropriately link triage decisions and crisis standards of care to each other and to clarify the crucial role of the OHA Tool.

Meghan Bours Slotemaker also testified on the posting requirement that has been added to the proposed rule and stated that OAHHS fears that the posting requirement could result in people not seeking care when they need it. OAHHS understands that there's interest in knowing what tool will be used to make triage decisions and that is another reason why the proposed rule should clarify the crucial role of the OHA Tool. Concerns about the posting requirement could be mitigated if the proposed rule appropriately centers on OHA's Tool.

Andi Easton, Vice President of Government Affairs, Oregon Association of Hospitals and Health Systems also submitted written comments. Those comments are attached to this report as Exhibit 1.

Agency response: The Authority thanks Meghan Bours Slotemaker and Andi Easton for their comments on behalf of the Oregon Association of Hospital and Health Systems.

The current temporary rule, OAR 333-505-0036, expires on January 24, 2023. This proposed, permanent rule ensures that the provisions for equity and transparency continue when a hospital has to triage and prioritize patient care in critical care settings during an emergency.

In an emergency, a hospital experiencing a significant reduction in staff or scarce resources may decide that critical care resources must be prioritized and patient triage decisions made. These decisions may be made using any Authority adopted crisis standards of care and related tools, including the Authority's current Interim Crisis Care Tool, or similar hospital policies or standards based on crisis care principles adopted by the Authority. The rule has never required use of the Authority's crisis standards of care or related tools, nor has the Authority ever indicated it intended to require its standards or tools through this rule.

The changes to rule text from those shared during the Rulemaking Advisory Committee (RAC) do not eliminate the link to the Authority's crisis care tool or a similar tool – it is referred to in the definition of "crisis standard of care". The reference was removed from the definition of "triage decisions" because it made the two definitions, "crisis standards of care" and "triage decisions" circular. To resolve this issue, the reference to the Authority's adopted crisis standards of care was moved from the triage definition to the crisis standards of care definition.

The Authority recognizes that the RAC did not have an opportunity to discuss the term 'potentially lifesaving' and also recognizeS that the term 'critical care resources' is frequently used in the Oregon Interim Crisis Care tool. As such the Authority is amending the definition for 'triage decisions' as follows:

> (e) "Triage decisions" means the decisions necessary to provide equitable prioritization of ~~potentially life-saving~~ critical care resources for patients during an emergency.

Community members expressed during the RAC meeting, the difficulty in finding information about how hospitals were responding during the COVID-19 pandemic. Questions were raised as to why individuals are forced to request information while in the middle of a health crisis. The Authority agrees that posting the crisis standards of care allows for full transparency and the posting requirement will remain unchanged. For convenience, the OHA tool is currently available in multiple languages: https://www.oregon.gov/oha/Pages/Resource-Allocation-Advisory-Committee.aspx. The Authority encourages hospitals and health systems to have a plain language, summarized version of the crisis standards of care for accessibility.

The Authority disagrees that the version of the rules provided to the RAC and posted for public comment were significantly different. The changes reflected in the version posted for public comment were intended to provide clarity in the definitions, since, as

stated above they were circular and therefore redundant. Aside from the use of the phrase “potentially life-saving resources” instead of “critical care resources”, in substance the draft versions were not significantly different. It is not clear what “unintended consequences” the commenters believe would follow from adoption of the current draft.

Jackie Fabrick, Manager of Government Affairs, Providence Health & Services

Jackie Fabrick testified that Providence is concerned that the proposed rules differ significantly from the version that was shared with the Rule Advisory Committee (RAC) on October 24, 2022. The RAC did not review the current iteration of the proposed rule and if this version is adopted, there will be unintended consequences. Providence recommends that regulatory language establish a clear threshold to know when hospitals have reached a level of crisis where critical care resources are being allocated.

Providence supports the definitions of "triage decisions" and "crisis standards of care" as defined in the current rule, not the proposed rule. The definitions in the current rule appropriately reflect the role the state has in triage decisions and developing a tool that our communities can access and understand. Providence has also developed policies, procedures, and training that comply with the current definitions. The timeline to re-develop policies, processes, and workflows to reflect the proposed language would need to be extended by 6 to 12 months.

Providence has three primary concerns specific to the proposed definition of "triage decisions": 1) It introduces "potentially life-saving resources," which is a new term that is ambiguous and can be broadly interpreted; 2) It removes the link to OHA's Oregon Interim Crisis Care Tool, or similar, which has been a core component of previous iterations of the rule; and 3) It removes the term or the reference to "crisis standards of care".

Providence recommends that OHA return to the definitions of "triage decisions" and "crisis standards of care" that were reviewed with the RAC. Those definitions balanced level of crisis with state and patient notification, and documentation requirements.

Scott Marsal, MD, Chief Medical Officer, Providence Portland Medical Center, Providence Health & Services also submitted written comments. Those comments are attached to this report as Exhibit 2.

Agency response: The Authority thanks Jackie Fabrick and Dr. Scott Marsal for their comments on behalf of Providence Health and Services and refers Jackie Fabrick to the information provided in response to Meghan Bours Slotemaker.

Other Comments: One individual or organization submitted written comments to the Authority within the period allotted for public comment, which closed at 5:00 PM on December 21, 2022. These comments are briefly summarized as follows:

Mark Bonanno, JD, MPH, General Counsel and Vice President of Health Policy, Oregon Medical Association

Mark Bonanno wrote on behalf of the Oregon Medical Association (OMA) that "OMA supports the development of statewide crisis standards under the authority and with the support of OHA that take into account considerations of health equity and are a practical tool for hospitals and clinicians when needed in an emergency setting especially when health care resources are scarce or unavailable and critical decisions must be made immediately to save as many lives as possible."

Mark Bonanno further wrote that the OMA participated on a Rules Advisory Committee (RAC) convened by OHA to review a proposed draft of OAR 333-505-0036 and expressed concern that the draft of the rule text provided to the RAC on October 24, 2022 "departs significantly from the version in the current notice of proposed rulemaking and there is insufficient explanation provided in the rule summary about why such significant amendments were made." They wrote that "because the proposed rule amendments compared to the RAC draft feel arbitrary rather than based upon RAC consensus and recommendations, we respectfully request that OHA reconstitute the RAC to appropriately weigh and make recommendations on the proposed changes." They also noted that "there likely will be significant added cost for stakeholders associated with the departure from earlier versions of the rule and the draft, and the current statement of fiscal and economic impact does not adequately address those added costs."

Mark Bonanno's written comments on behalf of the OMA detail points to demonstrate why a request to reconstitute a RAC is being made. Of particular concern are the changes that were made to the definitions of "crisis standards of care" and "triage decisions" in the version of the proposed text that was filed with the notice of proposed rulemaking that departs from the draft provided to the RAC.

Mark Bonanno's written comments are attached to this report as Exhibit 3.

Agency response: The Authority thanks Mark Bonanno for their comments on behalf of the Oregon Medical Association and refers Mark Bonanno to the information provided in response to Meghan Bours Slotemaker.

EXHIBIT 1

Oregon Association of Hospitals and Health Systems

December 21, 2022

Oregon Health Authority
Public Health Division
Mellony Bernal
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
Delivered electronically to: publichealth.rules@odhsoha.oregon.gov

Dear Mellony Bernal:

The Oregon Association of Hospitals and Health Systems (OAHHS) is a mission-driven, nonprofit association representing Oregon's 62 community hospitals. Together, hospitals are the sixth largest private employer statewide, employing more than 70,000 employees. OAHHS is committed to fostering a stronger, safer Oregon with equitable access to quality health care. We appreciate the opportunity to provide comments on proposed rule OAR 333-505-0036, Hospital Requirements during Emergency Impacting Standards of Care.

The proposed rule makes significant departures from the earlier draft version of the rule that was shared with the Rulemaking Advisory Committee (RAC) and from prior iterations of the rule, including OAR 333-505-0035 and the existing temporary rule, OAR 333-505-0036. We are concerned that the RAC did not have an opportunity to consider or provide feedback on certain key provisions of the proposed rule, and that these changes, if adopted, will lead to unintended consequences for patients, confusion in our communities, increase health care provider burnout, and result in added costs to our health care system, further jeopardizing access to quality care in Oregon.

The State's Role

The State of Oregon has a unique and crucial role in preventing the need for hospitals to make triage decisions. We are committed to continuing to work in partnership with the Governor's Office, OHA, and others to find solutions that decrease the likelihood triage decisions will be made. We thank the State for the support it has provided.

What one person sees as fair and equitable may not be viewed as fair or equitable to another person. That is one reason why the State must make important decisions, informed by community and stakeholder feedback, to develop standards in a triage tool that the State can stand behind. A perfect tool is impossible, and even if a perfect tool were used perfectly to make a triage decision, a patient and their loved one's face loss. Providers will suffer in a different way, exacerbating burnout and their sense of moral injury. This is the context in which we provide comments on this very important rule.

Definitions

Proposed Rule OAR 333-505-0036(2)(a); (2)(e)

Under current rule (but not the proposed rule), "triage decisions" is defined as "the decisions necessary to provide equitable prioritization of critical care resources for patients using Oregon Health Authority's Oregon Interim Crisis Care Tool or similar hospital crisis standards of care." *See* OAR 333-505-0035(2)(e). OAHHS supports the current rule's definition of triage decisions. Hospitals have invested time and resources to develop procedures to comply with this rule. The definition in current rule (but not the proposed rule) appropriately reflects the crucial role that the State has in

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triage decisions and in developing a tool available to all hospitals to use and for our communities to access and understand.

We were surprised to see the definition of "triage decisions" in this proposed rule. The definition in the proposed rule is: "'Triage decisions' means the decisions necessary to provide equitable prioritization of potentially life-saving resources for patients during an emergency."

This proposed definition introduces "potentially life-saving resources", a new, undefined concept that is ambiguous and will create confusion for hospitals and our community members about when the requirements in section (3) of the proposed rule would apply. OHA provided no rationale for this change in its Notice of Proposed Rulemaking, nor was it presented to or discussed with the RAC. The implications of it have not been explored, and we view it as fraught with issues. Both patients and hospitals need clarity, not further ambiguity.

The proposed definition of "triage decisions" also eliminates the link to OHA's Oregon Interim Crisis Care Tool. OHA's Oregon Interim Crisis Care Tool has been and is a core component of triage decisions. That should not change. Yet, in this proposed rule, OHA's Tool is not at the core—it has been downgraded to an example that is found in the definition of "crisis standards of care." This does not provide sufficient clarity to hospitals or our communities.

Further, in this proposed rule, the definition of "triage decisions" does not contain the term, "crisis standards of care." In contrast, under current rule, the definition of "triage decisions" contains the term "crisis standards of care." This is a critical missing link in the proposed rule, as the two definitions work together. As drafted, "triage decisions" are the basis of the section (3) requirements yet there is no link to "crisis standards of care." That is illogical. It is also a significant departure from the current rule.

The draft definition of "triage decisions" presented to the RAC was generally consistent with the language in the prior iterations of the rule. The definition was established following several rounds of review and comment. Hospitals have shaped policies and procedures accordingly, and we have significant concerns with the proposed rule's abrupt and significant departure from OHA's current and former standards.

We request that OHA adopt in the final rule the definitions of "triage decisions" and "crisis standards of care" that were proposed to the RAC:

- **"Triage decisions" means the decisions necessary to provide equitable prioritization of critical care resources for patients using Oregon Health Authority's adopted crisis standards of care and related tools or similar hospital protocols or standards that ensure equitable care decisions.**
- **"Crisis standards of care" means policies or standards adopted by a hospital to be implemented during an emergency for objective prioritization of care, prioritization of patients, and limitations on services because of the emergency.**

If OHA declines to revert to these definitions, we ask that the proposed definitions be revised to more appropriately link to each other and to clarify the crucial role of OHA's Tool. Example revisions could be:

- "Triage decisions" means the decisions necessary to provide equitable prioritization of [*potentially life-saving*] **critical care** resources for patients during an emergency **using crisis standards of care**.

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- "Crisis standards of care" means **the Oregon Health Authority's adopted crisis standards of care and related tools or similar** policies or standards adopted by a hospital to be implemented during an emergency to make triage decisions [*, such as but not limited to Oregon Health Authority adopted crisis standards of care and related tools*].

We acknowledge that OHA's work through the Resource Allocation Advisory Committee (ORAAC) is ongoing and, at this time, what OHA has provided to hospitals and the public is an Interim Crisis Care Tool. The current definition of "triage decisions" in rule refers to that Interim Tool, rather than "the Oregon Health Authority's adopted crisis standards of care and related tools." We request the proposed rule (before being finalized) make clear that OHA's "adopted crisis standards of care and related tools" means, at this time, OHA's Interim Crisis Care Tool.

Hospital Posting Requirement

Proposed Rule OAR 333-505-0036(3)(c)

We are supportive of the portion of the rule that requires the hospital to communicate the outcome of the triage decision to the patient, their support person, or the individual legally authorized to act on behalf of the patient, and (among other things) immediately provide a copy of the crisis standard of care used to make the triage decision. *See* Proposed Rule OAR 333-505-0036 (3)(d).

The proposed rule adds a requirement to "Post the crisis standard of care the hospital is using to make triage decisions on its website in the five most common spoken languages in the county where the hospital is located." *See* Proposed Rule OAR 333-505-0036(3)(c).

Crisis standards of care are complex documents intended to be used by professionals. Sharing the crisis standard of care in the context of a conversation with a provider or other knowledgeable individual about a specific triage decision makes sense, but in the absence of an opportunity to ask questions, we are concerned simply posting it could raise more questions than it answers. We fear that the posting requirement could result in people not seeking care when they need it.

We understand, however, that there is an interest in knowing what tool will be used to make triage decisions. That is yet another reason why this proposed rule should clarify the crucial role of OHA's Tool. Our concerns with the posting requirement could be mitigated if the proposed rule appropriately centered on OHA's Tool, as we proposed above. For example, if the rule was appropriately centered on OHA's Tool, OHA would have a better opportunity to facilitate understanding.

Triage tools are fraught with ethical and other issues. We should expect that the public will not all agree that the triage tool the State creates will be fair and equitable. That is why the State must be ready to stand behind it and explain it.

Conclusion

Thank you for the opportunity to engage in this important rulemaking.

Respectfully,

Andi Easton

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December 20, 2022

OHA, Public Health Division
Brittany Hall, Administrative Rules Coordinator
800 NE Oregon Street, Suite 930
Portland, Oregon 97232

Via email: publichealth.rules@odhsoha.oregon.gov

RE: OAR 333-505-0036 Hospital Requirements During Emergency Impacting Standard of Care

Dear Ms. Hall:

Throughout the course of the COVID-19 pandemic, Providence and our health system partners statewide have been committed to doing everything in our power to manage capacity and resource constraints. Over the past month, a surge of pediatric RSV, flu and COVID patients has significantly constrained hospital capacity and spotlighted issues we can address through the current rule making process. We appreciate the opportunity to provide feedback and the Oregon Health Authority's continued partnership.

The health care system has faced immense challenges over the last three years, but with state support, Oregon hospitals have avoided a situation that requires us to implement crisis standards that would dictate allocation of critical care resources. Through various iterations of temporary rules, there has been consistency in the understanding that crisis standards of care, specific to resource allocation, should be reserved for a very specific scenario – when critical care decisions are being made using a tool to determine how clinical resources will be allocated. This is an important distinction, because this situation is clearly different than triage decisions made based on the discretion and expertise of a clinical care team.

Outlined below are Providence's recommendations for regulatory language that establish a clear threshold to know when hospitals have reached a level of crisis where critical care resources are being allocated. Based on our learnings from the past couple weeks, we'd also like to articulate why this clarity is important. First, we need to be prudent about how "crisis" is characterized. Our communities are desensitized to health care crisis after three years, we need to reserve the use of the term "crisis standards of care" for the most critical situations when patients and families should expect the standard of care has shifted significantly. Second, we need a threshold that has a clear compliance pathway. Oregon has two different definitions of "crisis standards of care" so even if we are adjusting staffing plans, there is confusion about if resource allocation is occurring. As proposed, the rules would exacerbate this problem rather than creating the clarity we need. When it is not clear what constitutes a crisis, or when everything is labeled a "crisis," it is challenging to appropriately escalate a true crisis.

Definitions: Proposed Rule OAR 333-505-0036(2)(a); (2)(e)

Providence is concerned that the proposed rule differs significantly from the version shared with the Rule Making Advisory Committee (RAC) on Oct. 24, 2022. The RAC did not review this iteration of the rule and, if adopted, will have unintended consequences.

Providence supports the definition of “triage decisions” and “crisis standards of care” as defined in the current rule (not the proposed rule). The definitions in the current rule appropriately reflect the role the State has in triage decisions and developing a tool that our communities can access and understand. Additionally, we have developed policies, procedures, and training that comply with the current definitions – the timeline to re-develop our policies, processes and workflows to reflect proposed language would need to be extended by six to 12 months.

Specific to the definition of “triage decisions” we have three primary concerns. First, it introduces “potentially life-saving resources,” a new term that is ambiguous and can be broadly interpreted as a vaccine or preventative services could be seen as “potentially life-saving.” Second, it removes the link to OHA’s Oregon Interim Crisis Care Tool, or similar, which has been a core component of previous iterations of the rule. Finally, it removes reference to “crisis standards of care.”

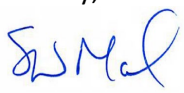
Recommendation:

Providence recommends that OHA return to the definitions that were reviewed with the RAC, those definitions balanced level of crisis with state and patient notification, and documentation requirements:

- "Triage decisions" means the decisions necessary to provide equitable prioritization of critical care resources for patients using Oregon Health Authority’s adopted crisis standards of care and related tools or similar hospital protocols or standards that ensure equitable care decisions.
- "Crisis standards of care" means policies or standards adopted by a hospital to be implemented during an emergency for objective prioritization of care, prioritization of patients, and limitations on services because of the emergency.

Thank you for the opportunity to provide feedback. We look forward to continuing to partner to ensure that quality healthcare is available to all in Oregon.

Sincerely,



Scott Marsal, MD
Chief Medical Officer Providence Portland Medical Center
Providence Health & Services

December 19, 2022

Via Email publichealth.rules@odhsoha.oregon.gov
Mellony Bernal, Rules Coordinator
Public Health Division
Oregon Health Authority
800 NE Oregon Street, Suite 465
Portland, OR 97232

Re: Proposed Rule 333-505-0036

Dear Ms. Bernal,

The Oregon Medical Association (OMA) is a nonprofit organization that represents over 7,700 physicians and physician assistants in the State of Oregon. We value the opportunity to comment on proposed administrative rules of the Oregon Health Authority (OHA). We are providing written public comment on proposed rule OAR 333-505-0036 filed with the Secretary of State on November 10, 2022.

The OMA supports the development of statewide crisis care standards under the authority and with the support of OHA that take into account considerations of health equity and are a practical tool for hospitals and clinicians when needed in an emergency setting especially when health care resources are scarce or unavailable and critical decisions must be made immediately to save as many lives as possible.

OMA participated on a Rules Advisory Committee (RAC) convened by OHA to review a proposed draft of 333-505-0036. The draft provided to the RAC on October 24, 2022 departs significantly from the version in the current notice of proposed rulemaking and there is insufficient explanation provided in the rule summary about why such significant amendments were made. Because the proposed rule amendments compared to the RAC draft feel arbitrary rather than based upon RAC consensus and recommendations, we respectfully request that OHA reconstitute the RAC to appropriately weigh and make recommendations on the proposed changes. There likely will be significant added cost for stakeholders associated with the departure from earlier versions of the rule and the draft, and the current statement of fiscal and economic impact does not adequately address those added costs.

So OHA understands our concerns, the following points are offered to demonstrate why a request to reconstitute a RAC is being made:

- The definition of “crisis standards of care” was changed to refer to triage decisions as well as make it sound like the OHA standards it adopted were optional. This potentially is a radical departure from the direction we believed OHA was taking and is a departure from what other states have done to redevelop and redeploy their crisis standards of care. Some states also received technical assistance from the Department of Health and Human Services Office for Civil Rights when revising standards during the COVID-19 pandemic to address non-discrimination in crisis standard of care plans and practices.
- The definition of “triage decisions” was completely changed to remove any reference to the OHA adopted crisis standards of care and insert a new and vague phrase “potentially life-saving resources.” Again, the lack of a reference to the OHA adopted standards is a radical departure from the direction stakeholders acted on in reliance and is not consistent with other state approaches to crisis standards of care. Further, introducing a vague phrase into the proposed rule only serves to make the rule less clear for hospitals, clinicians and patients.

We feel like the proposed rule is a step backward for the state's public health and equity missions and will be a disservice to both clinicians and patients when both are involuntarily forced into a crisis care setting. Like other states that have taken steps to ensure their state-supported crisis care standards were redeveloped and redeployed to reenforce the critical concept of non-discriminatory health equity, OHA should be doing the same and bringing certainty and clarity to this process.

Respectfully, and urgently, we believe OHA should reconstitute a RAC and bring its public health stakeholders together to review and make recommendations on the proposed rule that appears to have significantly and arbitrarily departed from the draft provided to the RAC.

Thank you for your consideration of our comments. We would be glad to discuss our comments with OHA at any time.

Sincerely,

Mark A. Bonanno, JD MPH
General Counsel and Vice President of Health Policy
Oregon Medical Association