January 19, 2025

Ms. Lucinda Sallaway
Senior Rules Analyst, Administrative Counsel & Rules
Arizona Department of Health Services
150 N. 18th Ave, Suite 200, Phoenix, AZ 85007

Sent via email: Lucinda.Sallaway@azdhs.gov

Dear Ms. Sallaway:

Thank you for the opportunity to comment on the January 2025 draft of the Arizona Department of Health Services' (ADHS) Health Care Institution (HCI)/Memory Care rules. I write to you on behalf of the Arizona Hospital and Healthcare Association and our more than 80 hospital, healthcare, and affiliated health system members. My comments today focus on Article 1 of the draft rules, specifically R9-10-101, R9-10-102(E), R9-10-106(H), R9-10-106(I), and R9-10-111(B).

R9-10-101 Definitions

The draft rules add a definition for "immediate jeopardy," which is defined as:

"Immediate jeopardy" is a situation in which a patient or resident has suffered or is likely to suffer serious injury, harm, impairment or death as a result of a licensee's noncompliance with one or more health and safety requirements.

This definition aligns with the definition of immediate jeopardy in 42 CFR 489.3, which should provide consistency for providers who must comply with both federal and state law. **However, in order to further ensure this consistency, we ask ADHS to utilize the interpretive guidelines in the State Operations Manual Appendix Q (updated 7/31/19) when applying the state definition.**

R9-10-102(E)

<u>On-site monitoring</u>

Laws 2024, Ch. 100 requires ADHS to establish a "model in rule" for on-site monitoring of HCIs that are found to be not in substantial compliance with licensure requirements. R9-10-102(E) establishes "the model" as follows:

E. The Department may conduct on-site monitoring of health care institutions that are found to not be in substantial compliance with the applicable licensure requirements specified in this Chapter. On-site monitoring may apply to licensed health care institutions that:

1. Have repeated noncompliance with the same or related requirements, or

2. Pose a direct risk to patient or resident health and safety.

To better understand how this "model" will be operationalized, we seek clarification on the following:

1. What constitutes "repeated noncompliance," including in the context of "related requirements"?
2. What constitutes a "direct risk" to patient health and safety?

During the stakeholder meeting, Department staff noted that any agreement for on-site monitoring would be part of the provider agreement. To provide further clarification under the rule, we request that this provision be added to R9-10-102(E) along with a definition of "provider agreement" in R9-10-101.

R9-10-106(H)

<u>On-site Monitoring Fee</u>

Laws 2024, Ch. 100 requires ADHS to establish an on-site monitoring fee. Subsection H of R9-10-106 implements this provision:

H. The Department may charge up to $1,000 per visit for an on-site monitoring fee according to A.R.S. § 36-405(D).

We seek clarification on the following:

1. Is the fee a daily fee? What if the ADHS team is only present for half a day; will the fee be prorated?
2. The rule stipulates "up to $1000." What criteria will be used to determine this cap or another amount? Will there be a fee schedule?
3. What are the qualifications for on-site monitoring personnel?

R9-10-106(I)

<u>In-service Training Fee</u>

Laws 2024, Ch. 100 allows ADHS to provide "in-service training" to HCIs that request training related to regulatory compliance outside of the survey process.

We are still unclear as to what qualifies as "in service-training" compared to general compliance/licensure questions that our members and/or their legal counsel (or even AzHHA staff) ask ADHS personnel. **As such, we request ADHS define "in-service training." Also, will the**

Department develop a fee schedule to delineate what training would constitute a $500/hour versus a lower amount?

R9-10-111(B)

Enforcement Actions; Civil Monetary Penalties (CMP)

Laws 2024, Ch. 100 increased the CMP cap that ADHS can assess from $500/violation to $1000 and clarified that it could be assessed for each patient or resident impacted. The bill also added factors that ADHS should consider when assessing the penalty and specified that ADHS "establish a model in rule" that considers these factors.

As we read R9-10-111(B), ADHS appears to be establishing aggravating factors that would allow them to assess the $1000 cap (paragraph 1) and mitigating factors that would reduce the penalty (paragraph 2). However, it is not clear whether there is a baseline against which these factors will be applied and how the factors will be weighed. Moreover, how do these aggravating/mitigating factors relate to the severity/remedy matrix tiers in table 1.2?

Table 1.2. Severity and Remedy Matrix

Adding the matrix to the rules provides some additional transparency regarding how enforcement is operationalized, which we support. However, we believe there needs to be additional language added to the rules that provides context for how the Department applies the matrix. This would include, for example, definitions of "provider agreement" and "written plan of correction."

Summary

While we understand ADHS' desire to finalize the draft rules by the end of the month to meet the June 30, 2025, deadline for enactment of ARS § 36-405.03, we believe more time is necessary to address the questions and comments we have raised. As such, we recommend proceeding with the sections of the rulemaking that address memory care standards but pulling out the fees and penalties sections and addressing those in a separate HCI Fees rulemaking for which a docket opening was filed on May 6, 2024.

Thank you for the opportunity to comment on the draft rules. Please let me know if you have any questions.

Sincerely,

Debbie Johnston
Senior Advisor