October 23, 2017

Ruthann M. Smejkal, Ph.D.
Senior Rules Analyst
Arizona Department of Health Services
150 North 18th Avenue, Suite 200, Phoenix, AZ 85007

Dear Ms. Smejkal,

On behalf of the Arizona Hospital and Healthcare Association (AzHHA) and our more than 80 hospital, healthcare and affiliated health system members, thank you for the opportunity to comment on the Arizona Department of Health Services (ADHS) draft opioid prescribing and treatment rule. It is without question that Arizona, like much of the country, is experiencing an unprecedented epidemic with respect to opioid addiction and overdose. We are very supportive of rulemaking's goal to address this crisis.

We furthermore appreciate the effort that ADHS staff has taken to listen to and respond to stakeholder comments on the draft rule. The October draft reflects this hard work, and we support many of the revisions that ADHS has incorporated into the document. Specifically, we support the definitional changes in Subsection A, and the reworked exemptions in Subsection G. We also support the approach the Department has taken in developing separate subsections for healthcare institutions (HCIs) that variably prescribe opioids, order them for in-house administration, or administer (or help with the self-administration) of them. Having said this, we have a number of outstanding concerns, recommendations, and requests for clarification, which are outlined below. We offer these recommendations in an effort to ensure that the health and safety of our patients are not compromised while minimizing the administrative burden of the rule on the healthcare delivery system.

<u>Informed Consent</u>

The important principles underlying voluntary consent cannot be overemphasized for healthcare facilities and practitioners. By signing a standard hospital Conditions of Admission form, a patient provides general consent to an anticipated course of treatment and nursing care during the hospitalization. Under current law, any invasive procedure, including surgery, invasive diagnostic procedure, anesthesia, or any other

procedure that poses substantial risk to the patient, requires specific patient consent before the procedure. The draft rule would add to this list the prescription, ordering and administration of opioids.

We agree with the Department that opioids, like other controlled substances, pose very real dangers to patients. But these risks differ depending on a number of factors, including whether or not the administration of the opioid is closely monitored by and under the supervision of a team of qualified medical professionals. Patients with an opioid prescription who are discharged to the community from a healthcare facility will not be closely monitored, and are at much higher risk of developing an addiction. A number of organizations, including ADHS, have developed prescribing guidelines for this reason.

The Department's 2018 draft Opioid Prescribing Guidelines state that the guidelines are intended "to apply to hospitals, outpatient surgical centers, behavioral health inpatient facilities and nursing care institutions *only in the management of pain upon discharge" (e*mphasis added). We agree that practitioners and healthcare institutions must do more to ensure safer discharges for patients who leave the facility with an opioid prescription. And obtaining informed consent is an important component of this stewardship. **For this reason, we support the informed consent requirement included in Subsection C of the draft rule, which governs situations in which opioids are prescribed by a medical practitioner at a healthcare institution.**

However, we do not recommend that informed consent be a required component for situations in which opioids are ordered for administration to the patient within the facility (Subsection D). The risk of addiction associated with opioid treatment in this setting is less clear. Patients are closely monitored in these settings, and the newly proposed quality management requirements under Subsection B.2 of the draft rule will focus even more attention on potential opioid-related adverse drug events (ADEs).[1]

Instead, we believe the decision to obtain informed consent in this setting should be guided by the substance use risk assessment, required under Subsection D.1.c. If a patient's assessment indicates he or she is at substantial risk for addiction or an ADE, then the HCI should obtain informed consent pursuant to its policies and procedures. Moreover, both the risk assessment and informed consent, if applicable, should be able to occur within a reasonable time frame before a patient's admission to the HCI. This would align with the physical examination requirements under D.1.a.ii and with many existing informed consent practices for elective surgeries.

[1] In addition, HCIs have been partnering with quality improvement organizations and other stakeholders to implement mitigation strategies to address potential opioid-related ADEs.

In order to streamline the informed consent process for surgical or other patients for whom informed consent is already required, we further recommend that an HCI be permitted to include opioid treatment informed consent with the procedure-related consent, if opioid treatment is affiliated with the procedure (e.g., used to treat perioperative pain). We also seek to clarify that informed consent would only be required once during a patient's episode of care, if it is indicated by the risk assessment.

Discharges to Post-Acute Settings

In an effort to protect and not disrupt continuity of care, we strongly recommend that Subsection D be amended to establish different requirements for patients who are discharged from one acute care setting to another. These patients are still undergoing a single episode of care, albeit at different facilities, and as such the definition for "episode of care" does not apply.

For patients who are discharged to an inpatient setting with discharge instructions to continue opioid administration, the medical practitioner at the receiving facility should not be subject to D.1.a and c as drafted. Instead, we recommend including an alternative process, such that:

- Prior to ordering opioids, a medical practitioner at the receiving facility is required to review documentation from the physical examination and the risk assessment that occurred at the discharging HCI.
- Within 48 hours of admission a medical practitioner at the receiving facility should then conduct a separate physical examination and risk assessment, which other practitioners at the facility could refer to, if they subsequently order opioids. (This 48 hour time period conforms to CMS and Joint Commission medication reconciliation requirements for inpatient rehabilitation facilities.)

Proposed Discharge Plan Requirements

Subsection C, paragraph 3 would require a medical practitioner that is authorized by policies and procedures to prescribe opioids to include in the patient's discharge plan, if applicable, how medically indicated pain control will occur after discharge to meet the patient's need. **With respect to hospitals, we believe this draft provision is unnecessary and redundant as the requirement is addressed under R9-10-209, which governs discharge planning.** R9-10-209 requires a hospital administrator to ensure that the discharge plan "identifies the specific needs of the patient after discharge." This would include how medically indicated pain is to be controlled. If patients are currently being discharged from hospitals without adequate discharge instructions for how to control medically indicated pain—which we understand is the

rationale for this provision, then the facility would be in potential violation of R9-10-209. A second, redundant rule is unnecessary.

Moreover, the proposed provision could incent patients suffering from addiction to pressure medical practitioners to write opioid prescriptions, which would only exacerbate their addiction. This would in essence perpetuate the very cycle the rulemaking is trying to break. **For this reason, we are strongly opposed to Subsection B, paragraph f and Subsection C, paragraph 3.**

Clarifications

In addition to the above recommendations, we seek clarification on two issues. First, we seek clarification that HCIs (such as hospitals and outpatient surgical centers) in which medical practitioners order opioids for in-house administration, and which would be subject to Subsection D of the draft rule, would not also be subject to Subsection E, even though they also have personnel who administer the opioids. It is our understanding that Subsection E would generally apply to residential facilities where a patient is prescribed an opioid by a medical practitioner not on the HCI's staff, but the HCI's personnel administers the opioid. However, the text of Subsection E is not clear in this regard, and it has created some confusion for our members.

Second, under D.1.c, we would like to clarify how the Department intends to interpret the term 'immediately." We urge ADHS to permit HCIs flexibility in defining the term within their policies and procedures.

Once again, thank you for the opportunity to comment on the Department's draft rule. Please do not hesitate to contact me if you have any questions.

Sincerely,

Debbie Johnston