December 18, 2017

Colby Bower
Assistant Director
Arizona Department of Health Services
150 North 18th Avenue, Suite 200, Phoenix, AZ 85007

Dear Mr. Bower,

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) Notice of Proposed Rulemaking related to opioid prescribing and treatment. 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 throughout the draft rulemaking process. The October and November drafts reflect this hard work. We are grateful for 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. This gives much needed clarity to HCIs. We also support many of the other revisions that ADHS has incorporated into the proposed rule, including several of the definitional changes; new exemptions in Subsection G; and flexibility in the timeline for conducting the substance use risk assessment and physical exam.

Having said this, we have two remaining concerns that have not been addressed in the proposed rule. Our recommendations regarding these issues reflect the input of nearly 200 individuals who participated on multiple calls regarding the draft rules. This includes many Chief Medical Officers, Chief Nursing Officers, Directors of Quality, Emergency Department Directors, Pharmacy Directors and front-line staff. We strongly believe these recommendations will ensure that the health and safety of patients will be advanced while minimizing the administrative burden of the rule on the healthcare delivery system.

Informed Consent

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 proposed rule would add to this list the prescription, ordering and administration of opioids.

We agree with the Department that opioids, like other controlled substances, can pose very real dangers to patients. But these risks vary based 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” (emphasis 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 proposed rule, which governs situations in which opioids are prescribed by a medical practitioner at a healthcare institution.

However, we oppose the inclusion of an informed consent requirement for situations in which opioids are ordered for administration to a patient within the facility (Subsection D of the proposed rule). The risk of addiction associated with opioid treatment in an inpatient setting is not well-documented. Patients are very closely monitored in these settings. Unlike a community setting, they do not have the opportunity to “self-medicate.” The higher risk in an inpatient setting is the occurrence of an opioid-related adverse drug event (ADE), which is already addressed under R9-10-120(B)(2)(a) of the proposed rule. HCIs have been partnering with quality improvement organizations and other stakeholders to implement mitigation strategies to address potential opioid-related ADEs, and the requirement under R9-10-120(B)(2) will focus even more attention on this issue. For this reason, we support its inclusion in the rule.

However, we do not believe the inclusion of an informed consent requirement is warranted for every patient. Instead, the decision to obtain informed consent in this setting should be guided by the clinical findings of the physical examination, prescription drug monitoring program review, and substance use risk assessment, required under R9-10-120(D)(1)(a)(b) and (c). If the findings indicate the patient is at substantial risk for addiction or an ADE, then the medical practitioner should obtain informed consent pursuant to the HCI policies and procedures. With this in mind, we urge the Department to eliminate the requirement for informed consent under R9-10-120(D)(1)(d) and (f). Rather, R9-10-120(B)(1)(c)(v), which requires the administrator of a HCI to establish policies and procedures that include how, when and by whom informed consent is obtained, should govern settings in which an opioid is ordered for in-house administration by HCI staff (Subsection D of the proposed rule).
Discharges to a Post-Acute Inpatient Setting

In an effort to not disrupt continuity of care for patients who are transitioning from an inpatient stay at a short-term acute care hospital to a post-acute care inpatient setting (such as a long-term acute care hospital or inpatient rehabilitation facility), we strongly recommend that the definition of “episode of care” under R9-10-120(A) or the requirements of R9-10-120(D) be revised. Many times patients are transferred to a post-acute care setting while sedated or at night, and often to a separately licensed facility on the same campus as the short-term acute care hospital. Requiring a post-acute care facility to comply with all the requirements of R9-10-120(D) as currently drafted before ordering an opioid in these situations could be upsetting and even detrimental to the patient’s recovery.

For this reason, we recommend one of two alternatives. The first option is to redefine “episode of care” to include transitions of care from a short-term acute care hospital to a post-acute care setting. Such a definition could read:

“Episode of care” means medical services, nursing services, or health-related services provided by one or more healthcare institutions to treat a patient’s clinical condition or procedure for a specific time, ending in discharge or the completion of the patient’s treatment, whichever is later.

Alternatively, R9-10-120(D)(1)(a) could be amended to specifically allow a receiving HCI to meet the risk assessment and physical examination requirements by having a medical practitioner review documentation from the transferring hospital before ordering opioids. Under the current language, a medical practitioner at the post-acute care facility could review documentation of a physical exam from a medical practitioner who referred the patient to the HCI/post-acute care facility. However, in transitions of care, the referring practitioner may not be the practitioner who conducted the physical exam at the sending facility. As such, we recommend that a new subparagraph iii be added to R9-10-120(D)(1)(a) to read:

“By a medical practitioner at a health care institution that transferred the patient for admission to the healthcare institution.”

R9-10-120(D)(1)(c) should also be amended to specifically allow a receiving HCI to meet the substance use risk assessment requirements by reviewing documentation from an assessment conducted by a medical practitioner at a health care institution that transferred the patient for admission to the healthcare institution.

These changes would allow a receiving HCI to be in initial compliance with the physical examination and substance use risk assessment requirements of R9-10-120(D)(1), if a medical practitioner at the facility reviewed documentation from an exam and assessment that occurred at the transferring HCI. Coupled with these changes, we recommend an additional requirement for receiving facilities. If the Department makes the above changes, R9-10-120(D) should be amended by adding a new paragraph 3 that requires within 48 hours of admission a medical practitioner at the receiving facility to conduct a separate physical examination and risk
assessment, if the HCI initially relied on documentation of these from the transferring facility. (This 48 hour time period conforms to Centers for Medicare & Medicaid Services and Joint Commission medication reconciliation requirements for inpatient rehabilitation facilities.)

These changes would shield the patient from unnecessary disruptions during sensitive transitions of care, while protecting the health and safety of those patients and easing the administrative burden on providers.

Clarifications

In addition to the above recommendations, we seek to clarify 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 is intended to 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 confusion for some of our members.

Once again, we appreciate all the work that ADHS staff has put into this rulemaking and the Department’s receptivity to previous stakeholder comments. Thank you for the opportunity to comment on notice of proposed rulemaking. Please do not hesitate to contact me if you have any questions.

Sincerely,

Debbie Johnston