August 18, 2017

Dr. Cara Christ
Director
Arizona Department of Health Services
150 N. 18th Avenue
Phoenix, AZ85007

Re: Emergency Rules

Dear Dr. Christ:

Thank you for meeting with me this week to address the Arizona Hospital and Healthcare Association's (AzHHA) and our members' concerns over the expanded opioid testing requirements. We appreciate your commitment to working closely with hospitals to craft effective measures for meeting the directives set forth in the Governor's Enhanced Surveillance Advisory (Advisory) and Declaration of Emergency (Declaration). We are very grateful that you and your staff took the time to listen to and respond to our members' concerns regarding the challenges of collecting and transferring specimens to the State Lab for testing when this testing is unrelated to individual patient treatment. We want to continue to work with your staff on crafting policies that will effectuate the goals of the Advisory and Declaration.

As we discussed at our meeting, one directive of the Declaration was emergency rulemaking for opioid prescribing and treatment within health care institutions. AzHHA commends the Arizona Department of Health Services (ADHS) for its expeditious and thoughtful response to the Governor's direction in promulgating the emergency opioid rule. *See* A.A.C. § R9-10-120. However, as you know the emergency rules did not have the benefit of public comment and revision prior to certification. The purpose of this letter is to formally present concerns that I raised in our August 14 meeting. **We believe the rule as adopted creates an inadvertent danger to public health, safety and welfare, and we are urging ADHS to issue a new emergency rule that either amends, or repeals and replaces, the current rule consistent with the Declaration.**

The Declaration directed ADHS to develop rules for opioid prescribing and treatment within health care institutions. The focus of the Declaration is on <u>prescribing</u> opioids as part of the patient's treatment. This aligns with our discussion August 14—where you stated the goal of the rule was to "capture" patients who leave a facility with opioids or an opioid prescription. Prescribing generally means to issue a signed, written order to a

pharmacist—*e.g.*, to write a prescription. *See, e.g.*, R4-17-101(13) (defining prescribe); *see also* A.R.S. § 32-1901(79) (definition of "prescription"). This makes sense given the data shows that more than two-thirds of suspected opioid overdoses had an opioid prescription two months prior to the overdose.[1]

However, as we discussed, the current rule applies to all health care institutions where opioids are "prescribed, ordered, or administered" as part of treatment. A.A.C. § R9-10-120 (emphasis added). This means that the rule extends to opioid treatment in acute care, emergent, and surgical settings. Given our conversation, AzHHA does not believe that ADHS nor the Declaration intended for the emergency rule to apply to acute care or surgical settings—where implementation could unsafely delay care or more significantly violate medical standards of care.

Enforcing the emergency rule in emergency care settings creates unintended consequences that will impede care and harm patients by slowing pain relief for patient in dire circumstances. "Ordering" and "administering" opioid medications is different from "prescribing" medications. Prescribing is more narrowly defined than "ordering" or "administering" a medication. "Ordering" broadly means any written or verbal order from a practitioner to administer a medication. A.R.S. § 32-1901(53). Administering means the direct application of the medication to the patient. *Id.* § 32-1901(1).

Here is an example to illustrate the difference between "prescribing" and "ordering" or "administering" an opiate in a hospital setting. An unconscious patient with multiple bone fractures caused by a car accident presents in a hospital's Emergency Department (ED). The ED doctor orders morphine to relieve the patient's acute pain. A nurse then administers the morphine to the patient. This is ordering and administering an opioid for treatment in an acute care setting. The patient later undergoes surgery and is given other opioid medications intravenously pursuant to the surgeon's order. This is also ordering and administering an opioid for treatment purposes. Upon discharge the patient is given a seven-day prescription of hydrocodone to treat pain. This is an example of prescribing an opiate as part of treatment. It is the latter circumstance, we believe, that the Declaration is intended to reach.

It is not surprising that a participant in one of the recent ADHS webinars commented: "[i]t is insane" to require a hospital in an acute care or surgical setting to comply with the emergency rule. This is because the rule contains no exception for emergencies. Instead, the rule has detailed requirements that must be satisfied before prescribing, ordering or administering an opioid, including performing a substance abuse assessment of the patient, checking the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database, obtaining specific informed consent and other time-consuming requirements. § R9-10-120. The only exception to

[1] See ADHS, Opioid Report (June 15-August 10, 2017), http://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/opioid-report.pdf (last visited Aug. 16, 2017).

the requirements is for patients with a "terminal condition." *Id.* § R9-10-120(E). A "terminal condition" is narrowly defined as the "final stage of an incurable or irreversible aliment, caused by injury, disease, or illness and from which, to a reasonable degree of medical certainty, there is no recovery." *Id.* § R9-10-120(A)(5).

Delaying pain relief to obtain informed consent from an unconscious patient's health care decision maker falls below the standard of care. The CMS EMTALA regulations recognize this in making pain an emergency medical condition. *See* 42 C.F.R. § 489.24 (EMTALA defines "emergency medical condition" to include "severe pain"). So too is delaying treatment for patients in emergent circumstances to conduct a substance abuse risk assessment or to access and review the controlled substance database. We appreciate ADHS's public and other informal statements that hospitals should not comply with the rule if it would violate the standard of care. However, ADHS has also stated that it expects hospitals to draft policies and procedures that satisfy the rule's requirements. This places hospitals in an impossible position.

We believe that the better solution is for ADHS to issue a new emergency rule that either amends, or repeals and replaces, the current rule consistent with the Declaration. The Declaration expressly authorizes ADHS to engage in such rulemaking, and Arizona law permits ADHS to amend or repeal a rule if necessary to "protect the public health, safety or welfare" or to "[a]void serious prejudice to the public interest or the interest of the parties concerned." A.R.S. § 41-1026(A). The current rule inadvertently threatens public health and welfare by delaying necessary care for patients in acute care settings. It also seriously prejudices the interests of hospitals by placing hospitals in the untenable position of drafting compliant policies and procedures that violate the standard of care.

This immediate issue could be addressed by limiting application of the rule to opioid prescriptions. For example, the requirements of R9-10-120(B) could be limited to a "licensee of a health care institution where opioids are prescribed~~, ordered, or administered~~ as part of treatment." Subsection (C) could be similarly limited by striking the following language: "an administrator shall ensure that before prescribing an opioid ~~or ordering the administration of any opioid~~ as part of the treatment for a patient, an individual authorized by policies and procedures to prescribe ~~or order~~ an opioid in treating a patient. . . ." The only necessary change to Subsection (D) would be replacing the term "administer" with "prescribe." We further suggest amending Subsection (E) to state: "The requirements in subsection (B), (C), and (D) do not apply to a health care institution's (1) ~~prescription,~~ ordering~~,~~ or administering of opioids as part of treatment for a patient, or (2) prescription of opioids as part of treatment for a patient with a terminal condition." Collectively these changes will narrow the rule's application in the hospital setting to when a patient leaves with a opioid prescription.

Amending the rule as proposed above would have the twin benefits of removing the unintended threat to public health and welfare created by the current rule, and bringing it in line with the Declaration's direction to promulgate an emergency rule for "opioid

prescribing." This action would also address our members' most immediate concerns with the emergency rule.

We understand that ADHS also intends to submit the emergency rule to the normal rulemaking process in accordance with A.R.S. §§ 41-1026(D)(4) and 41-1022. We respectfully request that ADHS issue an "alternative proposed rule" that incorporates the above requested changes and addresses other issues identified by our members. AzHHA held a member meeting on August 16 regarding the emergency rule and requested that members provide us with their compliance concerns. AzHHA intends to supplement this letter with further proposed revisions based on member feedback. We urge ADHS to consider these revisions as it moves through the normal rulemaking process.

Irrespective of how ADHS moves forward in the rulemaking process, AzHHA requests that ADHS promptly issue a substantive policy statement regarding enforcement of, and compliance with, the current emergency rule. ADHS has stated in public webinars and informal meetings that it will not commence enforcement actions and does not expect hospitals to comply with the rule if it violates standard of care practices. But not all affected health care institutions and public officials with enforcement authority have participated in these webinars and meetings. A substantive policy statement on enforcement and compliance expectations will ensure that the rule is consistently applied and understood by all interested parties.

Thank you for considering our input and requests concerning this important regulatory measure. AzHHA and our members are strongly committed to addressing the opioid epidemic. We hope to work closely with ADHS to craft a rule that balances commonsense measures to reduce opioid abuse while protecting healthcare providers' ability to treatment patients in accordance with established standards of care.

Most sincerely,

Debbie Johnston

Debbie Johnston
Senior Vice president, Policy Development