American Hospital Association

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May 31, 2016

Kana Enomoto, M.A.
Acting Administrator
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
ATTN: CDR Jinhee Lee, Pharm.D.
5600 Fishers Lane, Room 13E21C
Rockville, Maryland 20857

RE: Medication-assisted Treatment for Opioid Use Disorders (RIN 0930-AA22)

Dear Ms. Enomoto:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed rule to increase access to medication-assisted treatment (MAT) for opioid use disorder.

The AHA supports SAMHSA's proposal to increase the number of patients a physician may treat with buprenorphine for opioid use disorder. Under current rules, qualified practitioners may initially request a waiver under the Controlled Substances Act to treat a maximum of 30 patients at a time. After one year, the practitioner may request to treat up to 100 patients at a time. The proposed rule would allow eligible practitioners to ultimately treat up to 200 patients with buprenorphine. In addition, SAMHSA proposes that eligible practitioners with a current waiver to prescribe for up to 100 patients could request a temporary increase to treat up to 200 patients in emergency situations.

Every day hospitals see the devastation caused by the opioid epidemic, and they appreciate the many steps the administration is taking to support providers and first responders as they work to save lives. Increasing the patient treatment limits for MAT is aligned with other important federal government actions, such as the allocation of additional federal funding for MAT, as well as Naloxone, and the development of opioid prescribing guidelines for chronic pain by the Centers for Disease Control and Prevention (CDC). SAMHSA's proposed rule expands access to MAT and incorporates an integrated, holistic approach that includes both medication and behavioral health and supportive services. We believe that is the correct approach and urge SAMHSA to

quickly approve an increase in the patient limits. In addition, we offer comments on specific proposals below.

Emergency Situations. The AHA supports SAMHSA's proposal to allow practitioners with a current waiver to treat up to 100 patients to request a temporary increase to treat up to 200 patients in order to address emergency situations. We ask SAMHSA to also explore the feasibility of structuring emergency waivers for physicians approved to treat 30 patients under certain circumstances so they could treat more patients if needed. For example, if a practice includes one physician who can treat 100 patients and a second physician who can treat 30, could the second physician treat additional patients if the first physician is placed on medical leave unexpectedly? If not, the second physician may be able to provide some cross-coverage but would hit his or her patient limit quickly. We recognize and appreciate the basis for the current incremental framework, designed to allow physicians to gain experience in offering buprenorphine treatment before accepting a larger volume of patients. At the same time, we ask SAMHSA to consider whether there may be physicians currently limited to 30 patients who have more than a year of experience who could treat additional patients, for example. Additionally, we inquire as to whether there may be extra safeguards or parameters that could be put in place for physicians with less experience, so that they could treat additional patients on a temporary basis, where there is a demonstrated need, in an emergency.

Cross-coverage Situations. We note that the paperwork required to count patients could be confusing with regard to cross-coverage situations. In the proposed rule, SAMHSA defines "patient" as "any individual who receives MAT from a practitioner or program subject to this part." Cross-coverage arrangements may be impacted under this definition. For example, SAMHSA states that "if a practitioner provides cross-coverage for another practitioner, and in the course of that coverage the covering practitioner provides a prescription for buprenorphine, the patient counts towards the cross-covering practitioner's patient limit until the prescription has expired." If the proposed definition of "patient" is approved, we ask SAMHSA to clarify in the final rule whether it already has or could provide record-keeping tools and resources to assist physicians in these cross-coverage arrangements.

Reporting Requirements. The AHA urges SAMHSA to keep the reporting requirements manageable. In the proposed rule, practitioners who are approved for the increased patient limit would need to submit annual reports to SAMHSA, along with documentation and data, as requested by SAMHSA. We understand the need for documentation and reporting and also recognize the potential for administrative requirements to deter physicians from offering treatment due to time and resource constraints. We expect that SAMHSA will provide clearer information about the requirements in the final rule. SAMHSA also should consider providing tools, resources and/or best practices for how to: (1) efficiently meet the reporting requirements, especially for those without electronic health records; and (2) demonstrate compliance with eligibility and attestation requirements, such as adherence to diversion control plans and the use of patient data to improve outcomes.

Thank you again for your leadership in proposing these changes to expand access to MAT. Ultimately, ending the epidemic will require the collaboration and commitment of a wide cross-

section of community stakeholders working together with support from state and federal leaders. In the meantime, hospitals and health systems are employing numerous strategies to fight this multifaceted and serious public health problem, such as implementing standard protocols for prescribing opioids in the emergency department; assisting patients with substance-use disorder by offering treatment or referrals and engaging peer counselors to encourage patients to seek treatment; reviewing alternative ways to address pain management; and collaborating with other community organizations to develop a coordinated response. We welcome additional opportunities to partner with SAMHSA to support hospitals as they work in their communities to reduce opioid addiction, overdose and death.

If you have any questions about our comments, feel free to contact me or Evelyn Knolle, senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development