The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW,
Room 445-G
Washington, D.C. 20201

RE: CMS-3419-P; Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates.

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to provide input on the Conditions of Participation for Rural Emergency Hospitals. This new program should increase access to evidence-based treatment for patients with an opioid use disorder (OUD) in rural areas. However, given the ongoing scope of the opioid overdose epidemic, CMS should take additional actions. We recommend that CMS increase access to evidence-based treatment by clarifying in the Conditions of Participation that emergency departments operated by Rural Emergency Hospitals must meet the existing standard of care when treating patients with an opioid use disorder. Doing this will help people access needed treatment and save additional lives. Thank you for your consideration of these comments.

Background

The Consolidated Appropriations Act of 2021, which established the Rural Emergency Hospital provider type, emphasizes the value of emergency services in rural communities; among other provisions it requires that Rural Emergency Hospitals provide "*emergency department services*" that are staffed 24 hours a day, 7 days a week. To implement this, the proposed Conditions of Participation regulations from CMS state that Rural Emergency Departments must "*provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice*." (§ 485.516)

In the proposed payment rules for Rural Emergency Hospitals laid out in the Outpatient Prospective Payment System for Calendar Year 2023, CMS suggests that Medicare pay Rural Emergency Hospitals 5% above typical Medicare rates for outpatient services as outlined by CMS. Substance use disorder treatment is specifically cited as an example of the type of treatment that would receive this higher rate.

Need for additional substance use treatment options in rural areas

People living in rural communities have high rates of substance use disorders and drug overdoses. Additionally, people in rural areas with an opioid use disorder have particular

difficulty[1] accessing gold standards of treatment, including methadone and buprenorphine. (One recent meta-analysis found that treatment with methadone or buprenorphine reduced mortality[2] by 50%.) More than half of all rural counties do not have any provider who can prescribe buprenorphine for an opioid use disorder, and 30% of residents of rural areas live in counties without any buprenorphine prescriber. The average drive time[3] in rural areas to the nearest opioid treatment program (OTP) is nearly 50 minutes each way; many people using methadone must show up at the opioid treatment program daily. Accordingly, expanding locations to start treatment in rural areas is needed to get more people with opioid use disorder into care and save lives.

The 5% increase in payment rates for outpatient services may encourage Rural Emergency Hospitals to provide needed outpatient substance use disorder treatment, including offering buprenorphine and methadone, as medically appropriate. CMS states that, *"given the data provided related to substance use in rural communities, we would expect that some [Rural Emergency Hospitals] may be interested in being opioid treatment providers." (p. 40360)*

Emergency department standard of care for patients with an opioid use disorder

The standard of practice in the emergency department for treatment of someone with an opioid use disorder has been laid out in recent consensus recommendations[4] issued by the American College of Emergency Physicians and endorsed by other organizations. These recommendations include:

1. *Identifying patients with opioid use disorder and assessing the degree of withdrawal;*
2. *Initiating evidence-based care, including the use of pharmaceutical interventions; and*
3. *Providing a direct, specific referral to a provider that can continue the care, including buprenorphine or other opioid agonist medication.*

Being able to start patients with an opioid use disorder on treatment in the emergency department is particularly important as people may be more receptive to initiating treatment in the aftermath of their overdose. Recognizing the valuable role of emergency departments in

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[1] Rao T, Latimore A, Ortega Hinojosa A, Kestner L, Patel P (2021). Exploring Urban-Rural Disparities in Accessing Treatment for Opioid Use Disorder. American Institutes for Research. https://www.air.org/resource/equity-focus/exploring-urban-rural-disparities-accessing-treatment-opioid-use-disorder

[2] Santo T Jr, Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis [published correction appears in JAMA Psychiatry. 2021 Sep 1;78(9):1044] [published correction appears in JAMA Psychiatry. 2022 May 1;79(5):516]. *JAMA Psychiatry*. 2021;78(9):979-993. doi:10.1001/jamapsychiatry.2021.0976

[3] Joudrey PJ, Edelman EJ, Wang EA. Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States. *JAMA.* 2019;322(13):1310–1312. doi:10.1001/jama.2019.12562

[4] Hawk K, Hoppe J, Ketcham E, et al. Consensus Recommendations on the Treatment of Opioid Use Disorder in the Emergency Department. *Ann Emerg Med*. 2021;78(3):434-442. doi:10.1016/j.annemergmed.2021.04.023

starting treatment, recently-passed legislation[5] now requires the Drug Enforcement Administration (DEA) to revise federal rules "*so that practitioners . . . are allowed to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both).*" Earlier this year, the Drug Enforcement Administration announced[6] that, while it works to update federal rules in accordance with the aforementioned legislation, it would allow for requested exceptions to the current rule's requirement – that no more than one day's medication may be administered at one time – so that emergency department practitioners can dispense up to three days of buprenorphine or methadone to patients with acute withdrawal while arranging for the patient's referral for treatment.

Unfortunately, many emergency departments are currently not providing this care. Data[7] from 2019-2021 show that just 8.5% of 150,000 patients presenting to an emergency department for an opioid overdose received a prescription for buprenorphine within the 30 days after their visit. And a recent survey[8] of 100 high-performing hospitals found that only half of them were prepared to start patients on buprenorphine in the emergency department.

Opportunity for CMS to save lives

Rather than merely encouraging emergency departments to start people with an opioid use disorder on live-saving treatment, CMS should clearly state that starting treatment in the emergency department and referring patients to community-based care is the standard of care and must be provided by emergency departments.

CMS has an opportunity to do this by adding in the text accompanying § 485.514 (Condition of participation: Provision of services) that Rural Emergency Hospitals must have evidence-based policies and procedures for the emergency care of patients with an opioid use disorder. CMS should also state this elsewhere – such in the guidance provided to state auditors – that this standard applies to all emergency departments, not just Rural Emergency Hospitals.

To comply with this evidence-based standard, emergency departments could adopt the three-step process identified above: screen patients, offer to start evidence-based care, and refer to the appropriate level of care. As the standard for evidence-based care changes over time, emergency departments could adjust their policies and procedures.

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[5] H.R.8900 - Further Continuing Appropriations Act, 2021, and Other Extensions Act, https://www.congress.gov/bill/116th-congress/house-bill/8900/text

[6] https://www.deadiversion.usdoj.gov/drugreg/Instructions-to-request-exception-to-21CFR1306.07(b)-3-day-rule-(EO-DEA248)-Clean.pdf

[7] Chua KP, Dahlem CHY, Nguyen TD, et al. Naloxone and Buprenorphine Prescribing Following US Emergency Department Visits for Suspected Opioid Overdose: August 2019 to April 2021. *Ann Emerg Med*. 2022;79(3):225-236. doi:10.1016/j.annemergmed.2021.10.005

[8] Plott CF, Thornton RLJ, Punwani E, et al. The development and implementation of a new hospital performance measure to assess hospital contributions to community health and equity [published online ahead of print, 2022 Jul 7]. *Health Serv Res*. 2022;10.1111/1475-6773.14018. doi:10.1111/1475-6773.14018

In addition to requiring that hospitals provide evidence-based care to people with substance use disorders as a Condition of Participation in Medicare and Medicaid, CMS can also warn facilities about other potential violations of federal law that can occur by failing to provide appropriate care to people with substance use disorders. The Legal Action Center has documented areas in which facilities may not be in compliance in their recent report, *EMERGENCY: Hospitals Can Violate Federal Law by Denying Necessary Care for Substance Use Disorders in Emergency Departments.*[9] This could also be communicated by updating the State Operations Manual[10] for the Emergency Medical Treatment & Labor Act (EMTALA).

Improved access to community-based treatment providers facilitates emergency department initiation

Previously, finding a community-based provider to continue treatment with buprenorphine or methadone started in an emergency department could be difficult, which could make it challenging for emergency departments to comply with the standard of care. However, several recent and pending developments make continuing care started in the emergency department easier than in the past:

- During the COVID-19 public health emergency, the Drug Enforcement Administration implemented temporary regulations to permit buprenorphine to be prescribed via telemedicine – even for the first visit. Among other benefits, this permits emergency departments to refer patients to telemedicine providers to continue care. DEA has announced[11] that it is working to make those regulations permanent. Being able to refer patients to telemedicine providers will greatly increase the outpatient treatment options available to emergency departments;
- SAMHSA has eliminated the need for eligible buprenorphine prescribers to take additional training if they are treating no more than thirty patients at one time with buprenorphine for opioid use disorders. This should increase the supply of community-based providers; and
- CMS's proposed Outpatient Prospective Payment System proposed rule, which would give a 5% pay increase to Rural Emergency Hospitals offering outpatient services, should further increase the availability of outpatient substance use disorder treatment. Should Rural Emergency Hospitals offer these services, emergency departments at these facilities could then refer patients to their own providers to continue treatment.

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[9] Yeboah-Sampong S, Weber E, Friedman S (2021). Emergency: Hospitals Can Violate Federal Law by Denying Necessary Care for Substance Use Disorders in Emergency Departments. Legal Action Center. https://www.lac.org/resource/emergency-hospitals-can-violate-federal-law-by-denying-necessary-care-for-substance-use-disorders-in-emergency-departments

[10] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_v_emerg.pdf

[11] https://www.dea.gov/press-releases/2022/03/23/deas-commitment-expanding-access-medication-assisted-treatment#:~:text=In%20response%20to%20the%20COVID,to%20make%20those%20regulations%20permanent.

Recommendations

In order to increase access to evidence-based care in emergency departments and save lives, CMS should:

1. Clearly state in the final rule that Rural Emergency Hospitals must meet the standard of care when treating patients with an opioid use disorder in emergency settings as a Condition of Participation in Medicare and Medicaid.

2. Update other documents, such as the guidance provided to state auditors, to clarify that this requirement applies to all emergency departments.

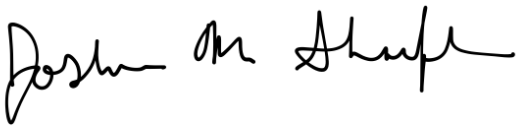
3. Warn facilities that failing to provide evidence-based care to people with substance use disorders may be a violation of federal laws, including EMTALA.

4. Facilitate the implementation of evidence-based practices for the treatment of opioid use disorder in emergency departments by providing examples of facilities that have implemented these practices and additional guidance.

Thank you for your consideration of these recommendations. Please do not hesitate to follow-up with Josh Rising at josh@rhstrategies.com with any questions.

Sincerely,

Josh Rising, MD
Principal
Rising Health Strategies



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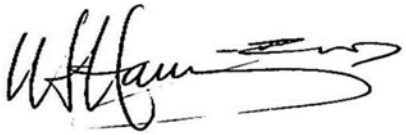

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