American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

December 4, 2020

The Honorable Timothy J. Shea
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA–377

Re: Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017

Dear Acting Administrator Shea:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a proposed rule released by the Drug Enforcement Administration (DEA) that implements the "Protecting Patient Access to Emergency Medications Act of 2017" (the Act). ACEP commends the DEA for implementing this important piece of legislation. Overall, we agree with how the DEA has chosen to interpret many of the provisions included in the Act and believe that they support how emergency medical services (EMS) agencies treat patients across the country. However, we do have some technical and clarifying comments and questions that we request that the DEA address in the final rule.

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Registration for Emergency Medical Services Agencies

ACEP supports the DEA's proposal to implement the provision of the Act that creates a new registration category for EMS agencies under the Controlled Substances Act (CSA). The DEA is also appropriately allowing for three options for EMS agencies to transition their registration, including: (1) transitioning immediately on the effective date established by DEA; (2) transitioning at the expiration of current registration; or (3) transitioning three to six months prior to current renewal date.[1] ACEP recommends that with respect to the first option, the DEA should clarify what the "effective date" is in the final rule.

Designated Location of an Emergency Medical Services Agency

The Act authorizes EMS agencies to designate specific unregistered locations where controlled substances can be delivered for intended patient care and stored until patient encounters occur that require clinically necessary administration of allowed controlled substances. In the rule, the DEA specifies the types of locations that may be designated

[1] Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017 Proposed Rule, 85 Fed. Reg. 62,637 (October 5, 2020).

by an EMS agency. Specifically, the EMS states that only "stationhouses" can serve as "'designated locations."[2] Further, the rule defines stationhouse as "enclosed structures housing EMS agency vehicles within the state of the emergency medical services agency's registration, and which are actively and primarily being used for emergency response."[3] ACEP believes that the definition of stationhouse included in the rule is inadvertently confusing and not feasible in all situations. First, not all stationhouses are large enough to store every type of vehicle in an enclosed space. For example, it would be extremely challenging to store outdoor EMS vehicles such as helicopters and watercraft vehicles in enclosed spaces. We therefore recommend that the DEA broaden the definition of stationhouse to include appropriate accommodation for larger and outdoor vehicles.

The DEA also proposes that stationhouses cannot include locations that serve primarily as a residence (such as a house or apartment building), but must be a building that is actively serving "primarily to house the equipment of a county fire and rescue department."[4] While ACEP agrees that it is unusual for large, urban EMS systems to use apartment buildings or hotels as substations, there are some systems that do in fact use rental houses, apartments, and hotels as stations in order to improve their response times within certain communities. In some areas of the country, it may be unaffordable to use a dedicated building for emergency responses and the only realistic fiscal option available to EMS systems serving these areas is to rent a house or other similar structure. There could also be situations where stations are located in houses that could serve as both residences and as EMS response centers. In these cases, it would be difficult to ascertain whether that location "primarily" served as a place to "house the equipment of a county fire and rescue department." Therefore, we request that the DEA: 1) allow EMS systems to use structures that are not being primarily used for emergency responses as stationhouses in certain situations where it is not possible for EMS systems to obtain a dedicated building; and 2) clarify how it would define "primarily" if stationhouses serve both as residencies and as places that "house the equipment of a county fire and rescue department."

Under the Act, EMS agencies must provide notice to the DEA of designated locations and obtain a DEA registration for the registered location at which it receives controlled substances. The DEA is proposing that, after an EMS agency has been approved for a DEA registration, the EMS agency must wait 30 days after it notifies the DEA to deliver controlled substances to that designated location.[5] Although ACEP recognizes that the Act includes this waiting period requirement, we have concerns with how it would impact the continuity of operations for many EMS agencies. Waiting 30 days to begin to move controlled substances would create a burden to the EMS systems, as the units would need to come to the single registered location for distribution and/or restocking during this initial 30 days. For some systems, the distance could be greater than 50 miles. If EMS agencies have no convenient place to store controlled substances during this period, access to care could be jeopardized and it could be difficult for patients to receive the treatment they need in a timely manner. ACEP therefore requests that the DEA provide some more flexibility to EMS agencies to reduce their burden and continue to serve their communities and ensure that all the individuals they treat have access to the most appropriate medications.

Emergency Medical Services Vehicles

ACEP supports the DEA's proposal to allow EMS agencies to "store controlled substances in an EMS vehicle located at a registered location, a designated location, or in an EMS vehicle used by the agency that is traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency."[6] However, we would like to reiterate that EMS vehicles could include ground vehicles, aircrafts such as helicopters,

[2] 85 Fed. Reg. 62,637-38.
[3] 85 Fed. Reg. 62,638.
[4] Ibid.
[5] Ibid,
[6] Ibid.

and water vehicles, and therefore would like to confirm that controlled substances could be stored in any type of EMS vehicle. Since not all EMS vehicles are the same, and therefore may have different storage capabilities, the DEA should grant EMS agencies some degree of flexibility when deciding how to appropriately secure controlled substances in their vehicles.

Proposed Changes to Recordkeeping Requirements

Overall, ACEP supports the DEA's proposed policies regarding recordkeeping requirements, as they directly align with provisions in the Act. We also believe that EMS physician medical directors should have ultimate control over all records and should be the ones who are responsible for ensuring compliance with all recordkeeping requirements.

However, we are concerned about the burden associated with some of the requirements. The DEA outlines a long list of records that must be kept for each dose of controlled substances administered or disposed of in the course of providing emergency medical services.[7] This includes initials of the medical director or authorizing medical professional issuing the standing or verbal order and the people who administered and disposed of the controlled substance. ACEP believes that the DEA must allow for electronic signatures from physician medical directors. Further, we note that it will be incredibly challenging to have the physician medical director's or authorized medical provider's initials entered into a standardized controlled substance log for every verbal order. The jurisdiction of physician medical directors can cover many miles, and it would be logistically impossible for their initials to be entered into a log for each dose of controlled substances that is disposed of or administered. We therefore recommend that the DEA provide additional flexibility around the initialing requirements in the final rule. To ensure compliance by EMS personnel with standing and verbal orders, the DEA could consider requiring that the administration of controlled substances be included in EMS agencies' quality assurance or improvement programs.

Proposed Changes for Security Requirements

In accordance with the Act, the DEA is proposing that EMS personnel be allowed to administer controlled substances in the event of an emergency through standing orders issued by EMS medical directors.[8] ACEP agrees with this proposed policy but acknowledges that the implementation of standing orders may vary by state. As the DEA notes in the rule, "standing orders that are developed by a state authority may be issued and adopted by the medical director of an EMS agency."[9] While some states have these types of policies in place and others do not, we support the proposal to allow the EMS physician medical director to have the ultimate authority to issue standing orders regardless of state policy.

The DEA is also proposing that an EMS professional may administer a controlled substance outside of the presence of a practitioner if the administration is authorized by State law and is pursuant to a verbal order.[10] A medical director or authorizing medical professional must issue the verbal order in response to a request by the EMS professional with respect to a specific patient, either in the case of a mass casualty incident, or to ensure the proper care and treatment of a specific patient.[11] While we support this policy, we note that the DEA does not address a common situation where verbal orders from the mobile intensive care nurse (MICN) are relayed from the base station (typically a hospital base) physician. We ask that the DEA discuss how EMS agencies should handle such a scenario in the final rule.

[7] 85 Fed. Reg. 62,647.
[8] 85 Fed. Reg. 62,640.
[9] Ibid.
[10] Ibid.
[11] Ibid.

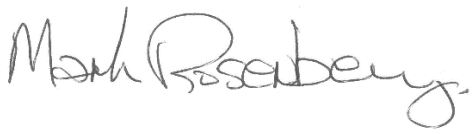
In addition, the DEA proposes that EMS agencies must contact the Special Agent in Charge (SAC) for the area or DEA Headquarters Diversion Control Division for approval of shortages, public health emergencies, or mass casualty events.[12] We have serious concerns about the practicality of having to contact the local SAC or DEA Headquarters Diversion Control Division in these situations. First, we are uncertain about what exactly EMS agencies should be seeking approval of from the DEA. If there is a mass causality event, we want to better understand what specific role the DEA would play in making that determination. It is also unclear whether EMS professionals are allowed to appropriately administer controlled substances before obtaining this "approval." If EMS professionals must wait until they hear back from the DEA, then any delay could seriously jeopardize their ability to treat individuals experiencing medical emergencies. Finally, it is not realistic to assume that EMS agencies would be able to expeditiously contact the DEA in these situations. Given our numerous questions and concerns about the practicality of this requirement, the DEA should clarify exactly what it means by seeking "approval of shortages, public health emergencies, or mass casualty events" in the final rule and provide additional flexibility to EMS agencies to treat individuals experiencing emergencies.

Definition of Hospital-based EMS Agency

In the rule, the DEA proposes to define "hospital-based emergency medical services agency" as an agency that is "covered by the registration of the hospital."[13] This definition seems to imply that a single EMS agency can only be registered, and thus have a contract with, one hospital. However, in some cases, EMS agencies have broader contractual relationships with hospitals. Virginia, for example, has regional councils in place, which are essentially a coalition of agencies and hospitals. Through these councils, collaborative agreements have been established between all the EMS agencies and all hospitals for the exchange of medications. ACEP therefore requests that the DEA expand this definition of "hospital-based emergency medical services agency" in the final rule to allow for these types of contractual arrangements.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,



Mark S. Rosenberg, DO, MBA, FACEP
ACEP President

[12] 85 Fed. Reg. 62,641.
[13] 85 Fed. Reg. 62,648.