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ACT FOR PATIENTS

Emergency/Critical/Trauma Care Controlled Substances in Short Supply
Improving Access for Patients to Life-Saving Drug Therapies

The field emergency medical services (EMS) and critical care transport (CCT) communities are facing an unprecedented crisis in access to life-saving drugs for patients with acute, life-threatening conditions and traumatic injuries. Field EMS and CCT practitioners utilize a variety of pharmaceuticals in caring for their patients: 1) critical life-saving, 2) pain management, and 3) seizure and sedation control. Some drugs used for patients with emergency or critical conditions are controlled substances, such as the benzodiazepine class of drugs for seizures and sedation, and morphine and fentanyl for pain management. Our community has serious concerns about ongoing challenges with the application of Drug Enforcement Administration (DEA) oversight of controlled substances in the pre-hospital and interfacility patient care environment. In the context of the progressively worsening drug shortage crisis in field EMS and CCT medicine, those challenges are exacerbated in a manner that is negatively impacting the ability of our physicians and practitioners to mitigate the drug shortage crisis, maintain patient safety and avoid medical errors.

Background:

The underlying DEA regulations governing the distribution, transfer, administration and disposal of controlled substances do not recognize the unique nature of emergency medical and critical care provided in the field EMS/CCT transportation setting. These regulations were designed for licensed mid-level practitioners (e.g. nurse practitioners and physician assistants), and not field EMS practitioners providing care under the medical oversight of physician EMS and CCT medical directors.

Further, there is a lack of specific and consistent guidance for the field EMS/CCT community on how to interpret the current regulations and apply them in the medical transport environment. Field EMS/CCT physician medical directors report inconsistent and contradictory application of DEA regulations among regional offices and even within field offices. Such varying interpretations include whether individual field EMS stations require separate DEA registrations, whether specific field EMS registrations should be as practitioner or distributor, and what locking mechanism(s) and inventory practices are required for controlled substances.

Waste and Inability to Share Controlled Substances in Short Supply:

The challenges posed by the inapplicability and inconsistent application of the DEA regulations to the field EMS setting have now been exacerbated by the drug shortage crisis, posing serious risk to patient safety and the provision of life-saving care. At a time when it is most imperative to best utilize the limited quantities of life-saving drugs used for patients with emergency and critical conditions, including traumatic injuries, the regulations and their inconsistent application impede the ability of physicians and field EMS and CCT practitioners to mitigate drugs in shortage for the benefit of their patients.

Sharing of Drugs in Short Supply: Practitioners are subject to stringent rules regarding the movement of drugs from hospitals to field EMS and CCT practitioners and between service locations/bases within provider field EMS and CCT agencies. At least some field EMS and CCT agencies have been told that they are prohibited from moving more than 5% of their annual allocation of controlled substances without becoming a "distributor." This impedes the ability of sharing life-saving controlled substances in short

supply between practitioners, and even among bases within one field EMS/CCT agency to best distribute very limited quantities to where they are most needed for patients.

Disposal/Waste: Paramedics and nurses in field EMS/CCT are trained to administer certain formulations and concentrations of controlled substances. When a drug is in short supply and only a larger quantity than the normal formulation can be obtained, several problems emerge. First, field EMS/CCT practitioners are required to dispose of unused amounts. They cannot repackage the remaining unused portion of the drug in shortage, which results in waste of a critical drug in short supply. Second, the operational procedures for the disposal of the remainder of the drug are subject to vastly varying interpretations by DEA personnel. Some DEA officials have begun requiring "reverse distribution" rather than disposal with extraordinary associated bureaucratic forms, paperwork and expense to ensure compliance. Third, the production of drugs in short supply by pharmaceutical manufacturers in aliquots of larger volumes or different concentrations than traditionally used or needed by field EMS and CCT practitioners increases waste of the scarce medication as well as the risk of drug diversion. Fourth, changes in drug formulations or concentrations are difficult to manage in the medical transport environment and substantially increase the risk of medical error. This is especially problematic with regard to patients receiving controlled substances for whom an inadvertent error in dosing can result in a substantial and potentially permanent adverse outcome.

Field EMS/CCT practitioners believe that it is crucial to ensure the quality and efficacy of drugs during transport, and to ensure patient safety, drug security and avoid diversion. However, remaining concerns exist with regard to how to comply with DEA rules not designed for the medical transport environment and disparate application of those rules when seeking to mitigate life-saving drugs in short supply.

Request:

The EMS community applauds the work of both Committees in seeking to address these essential issues for patients lacking access to essential drugs and we generally support the approaches taken by the Committees. More specifically, our community supports the House Energy & Commerce Committee's approach in addressing quotas of controlled substances in short supply. The EMS community also supports the Senate HELP Committee's discussion draft approach with regard to the FDA reviewing regulations that may be contributing to or exacerbating the drug shortage crisis for certain controlled substances. The EMS community further believes that the same approach should be taken with regard to the DEA in making the following reviews, critical savings and solutions to best enable practitioners to serve their patients with life-threatening illnesses or injuries. Thus, in addition to other changes suggested by a number of organizations in the EMS community with regard to improvements regarding FDA notification that will help to better address the adverse impact of drug shortages on field EMS and CCT patients, we also suggest these additional amendments below, which more specifically address the issues surrounding controlled substances provided to patients in the field EMS and CCT settings.

1. DEA regulations should be reviewed in light of the drug shortage crisis so as to improve and mitigate access to a limited supply of life-saving controlled substances for patients with emergency and critical illnesses and injuries including by: 1) improving DEA regulatory applicability to the field EMS/CCT setting; 2) addressing inconsistencies in the field EMS/CCT transport environment so that DEA rules are communicated in a clear and consistent manner nationwide; and 3) removing impediments to the mitigation of drug shortages for patients whose lives hang in the balance (please see suggested language below).

2. Require more specific reporting of changes in substantial drug formulation and concentration by pharmaceutical manufacturers for drugs anticipated to be in short supply to enable provider mitigation and operational procedures to avoid wastage, prevent drug administration errors, ensure patient safety, and to combat and anticipate drug shortages.
3. Require a GAO study on the issues that have not yet been fully analyzed with regard to mitigation of the drug shortages in the following areas:
    a. Impediments to mitigation by providers and practitioners to access life-saving drugs for their patients and recommended solutions, including controlled substances that are used for patients with emergency medical, critical or life-threatening conditions or traumatic injuries;
    b. Patient populations particularly at serious risk of death or disability or medical errors due to the drug shortage crisis; and
    c. Implementing affordable shelf-life extension programs based on the current military model for non-military EMS settings.

SUGGESTED LANGUAGE REGARDING DEA REVIEW OF REGULATIONS/GUIDANCES

Internal Review – Not later than six months after the date of enactment of this Act, the Attorney General shall –

(1) analyze and review the regulations promulgated under the Controlled Substances Act, the guidances or policies issued under such Act related to drugs intended for human use or biological products as defined by Section 351 of the Public Health Services Act, and the practices of the Drug Enforcement Administration regarding enforcing such Act related to proper ordering, storing, supplying, administering, transferring and disposal of such drugs, to identify any such regulations, guidances, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) which are also controlled substances, including as they relate to the provision of emergency medical and critical care by hospitals, physicians, physician medical directors, and field emergency medical services and critical care transport practitioners and providers; and
(2) determine --
    a. how regulations, guidances, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce, prevent or mitigate such drug shortages, taking into consideration the effect of any changes on the public health; and
    b. whether regulations should be developed or modified specifically to address the unique environment of emergency medical services medicine and whether additional guidance should be provided to ensure consistency in the application of existing or new regulations governing controlled substances utilized in the provision of emergency medical and critical care in the pre-hospital and interfacility settings.

SUGGESTED CHANGES REGARDING REPORTING CHANGES IN DRUG FORMULATION OR CONCENTRATION

Senate HELP Committee Discussion Draft: page 2, line 15 and House Energy & Commerce Committee Discussion Draft: page 193, line 20 -- after the word "manufacture", insert "or substantial changes in the drug formulation or concentration" before the word "of".