National Emergency Medical Services Advisory Council

DRAFT/INTERIM/FINAL

Advisory and Recommandations

Title: **Mitigating Medication, Supply, and Device Shortages.**

As prepared by the Subcommittee on **Equitable Patient Care**

A. Executive Summary

The National Emergency Services Advisory Council (NEMSAC) recognizes that Emergency Medical Services (EMS) clinicians must have equitable access to medications, medical supplies, and medical devices in order to protect the health and safety of the public. Unfortunately, many of the most critical medications, supplies, and devices are often in critically short supply for many reasons, including:

Healthcare Economic Pressures

Contrary to recent public debates on the high prices of medications, the majority of medications used by EMS are generic and, therefore, may not be commercially attractive for manufacturers. However, manufacturers must satisfy rigorous regulatory requirements that assure all products are safe to use. Given these constraints, there is no surprise that a limited number of companies devote limited resources (manufacturing sites, warehouses, production lines, etc.) to these medications, supplies, and devices.

Vulnerable Supply

These economic pressures create a vulnerable supply chain without excess capacity to mitigate the impact of disruptions. In the aftermath of Hurricane Maria (2017), common intravenous infusions were in critical shortage because a plant in Puerto Rico that manufactures the sterile bags that are filled with the infusions was heavily damaged. Similarly, a 2023 tornado in Rocky Mount, North Carolina damaged a pharmaceutical production site responsible for sterile injectable medications, and the largest manufacturer of intravenous solutions closed its Marion, North Carolina facility in the aftermath of

Hurricane Helene (2024). Due to the lack of redundancy in production facilities, isolated events result in the need for rationing of critical medications, supplies, and devices.

Unknown Demand, Preparedness, and Waste

While routine EMS patient care volumes can be somewhat stable over time, EMS must also be prepared to meet surging demand with little/no notice, for any type of response, for any length of time. A mass shooting my require significant hemorrhage control supplies in an isolated area, a chemical release may require mass treatment with seldom-used antidotes, and a global pandemic requires a seemingly infinite supply of personal protective equipment. To meet both known and unknown demand, EMS agencies frequently overstock medications, supplies, and devices in order to be prepared. Unfortunately, the cost of preparedness often translates into waste when medications, supplies, and devices expire or exceed shelf life.

Impact on All Aspects of Emergency Care

While critical shortages of medications are highly publicized, all aspects of emergency care are impacted. EMS agencies have faced difficulty in obtaining medical devices (ex: automated external defibrillators), supplies (ex: sterile saline flush, defibrillator batteries and pads), and emergency vehicles. Devices, supplies, and vehicles are just as critical as medications, and all are subject to economic pressures, supply chain vulnerabilities, and unknown demand.

Need for EMS-Tailored Solutions

EMS is not funded in the same manner as the rest of healthcare, with some of the most resource-intense responses receiving no reimbursement (ex: cardiac arrest resuscitation attempts without transport to the hospital). Strategies that may be feasible in a hospital or outpatient setting, such as development of a buffer stock or incentives that raise the cost of medications, will likely exacerbate the fragile economics of prehospital care.

Need for EMS Representation

The COVID-19 pandemic response highlighted many shortcomings in obtaining and maintaining adequate quantities of critical medications, medical devices, and medical supplies. Several Presidential Orders and Cabinet-level reports and policy suggestions attempt to address the issues. Hospitals and outpatient settings are frequently included, but

the voice and lens of EMS is frequently absent. Without representation, the unique challenges faced by EMS are unlikely to be addressed.

Increased attention to the crisis of medication, supply, and device shortages may be a silver-lining of the COVID-19 pandemic. Several opportunities to guarantee that EMS has access to these critical items have arisen, including:

- Improved understanding of demand, to assure that future supplies are adequate
- Improved visibility of pending shortages, to give enough time to update clinical protocols and educate EMS clinicians on necessary changes
- Improved understanding of the unique challenges faced by EMS, so that solutions for other aspects of the healthcare system do not paradoxically negatively impact prehospital care and operations

B. Recommendations

National Emergency Medical Services Advisory Council

Council recommendations to itself.

National Highway Traffic Safety Administration

Recommendation 1: Using the National Emergency Medical Services Information System (NEMSIS) to quantify actual medication usage, National Highway Traffic Safety Administration (NHTSA) should collaborate with the Federal Drug Administration (FDA) to create a dashboard of critical medications in order to detect signals of increased use that may translate to shortages. The dashboard must be available to EMS agencies (to plan mitigation strategies) and manufacturers (to inform production).

Recommendation 2: NHTSA should work with the National Emergency Medical Services Information System Technical Assistance Center (NEMSIS TAC) and the National Association of State EMS Officials (NASEMSO) to encourage state offices of EMS to create dashboards available to individual EMS agencies capable of tracking actual medication usage to avoid inadvertent overstocking and waste.

Recommendation 3: NHTSA should work with NASEMSO to encourage flexible model clinical guidelines that include alternatives or therapeutic interchanges for medications listed in individual protocols, in order to allow rapid medication substitutions based on availability.

Recommendation 4: NHTSA should encourage NASEMSO to work with state boards on flexibility in drug licensing requirements to facilitate substitutions of specific medications (ex: different concentration, volume, or National Drug Code for the same medication or therapeutic interchanges) and the inter-agency transfer of medications, including controlled substances.

Federal Interagency Committee on Emergency Medical Services

Recommendation 1: The Federal Interagency Committee on Emergency Medical Services (FICEMS) should host stakeholder panels with EMS agencies and clinicians to understand their needs and identify possible solutions to address ongoing shortages. Pertinent FICEMS stakeholders include DoD, ASPR, HRSA, CDC, CMS, and IHS.

Recommendation 2: Using the healthcare preparedness program, ASPR should work with the FDA and the DoD Shelf-Life Extension Program to evaluate post-expiration use of drugs/supplies (ex: AED pads) and expedite extension of expiration dates whenever a shortage is identified or predicted; manufacturers should be required to set a minimum expiration period of 5 years for critical drugs and supplies.

Secretary of the Department of Transportation

Recommendation 1: The Secretary should advocate that EMS is specifically represented, as a critical stakeholder and distinct health care setting, in Interagency assessment and planning activities regarding critical shortages in medications, supplies, and devices.

Recommendation 2: The Secretary should host a listening session for the emergency response community (police, fire, and EMS) and vehicle manufacturers, with the goals of understanding how vehicle supply chain limitations impact preparedness and response and identifying solutions.

Agencies/Administrations within the Department of Transportation

On an ongoing basis, the Office of EMS should promote education on safe

medication practices (ex: 5 Rights of Medication Administration) to minimize risks associated with medication substitutions due to shortages.

C. Scope and Definition

EMS and the 9-1-1 system exist to provide timely, life-saving, and compassionate care outside of the hospital. Several time critical emergencies require immediate evaluation and treatment to maximize survival; delays in hemorrhage control after trauma, benzodiazepine administration for status epilepticus, epinephrine administration for anaphylaxis, and defibrillation for out of hospital cardiac arrest contribute to otherwise preventable death and disability. Even when lives are not at stake, delays in pain management are inhumane. Common sense dictates that EMS clinicians must have the appropriate medications, devices, and supplies to treat these time-sensitive conditions.

Clinical protocols, established at the state or local level, provide specific treatment guidance for care, and changing protocols is a time-consuming and administratively challenging process. Each EMS practitioner must be trained on any changes before protocol implementation, and this educational burden further delays implementation of any new or modified treatment recommendation. State pharmacy board policies vary, but many EMS agencies must obtain and maintain Terminal Distributor of Dangerous Drugs licenses that specifically list the name and concentration of medications available for administration as part of prehospital care; separate DEA licensure is needed for controlled substances. These licenses must be updated with any changes in clinical protocols before implementation.

Unfortunately, medication shortages are common, widespread, and long-lasting; all levels of prehospital care in every state, territory, and tribal region have been impacted for more than a decade. Multiple factors contribute to this ongoing crisis, including limited manufacturing, lack of financial incentives, and disruption of vulnerable supply chains by natural disasters and workforce issues. In 2023, the FDA reported 53 *new* and 98 *ongoing* medication shortages (FDA, Drug Shortages CY 2023, 2023). Medical device shortages have largely resolved, although the FDA Office of Supply Chain Resilience notes pertinent discontinuations, including

automated external defibrillators and personal protective equipment components (FDA, Medical Device Shortages List, n.d.).

D. Analysis

Issued in August 2020, Presidential Executive Order "Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States" calls for creating a list of essential medications and medical countermeasures, accelerating domestic production of those essential medications and medical countermeasures, and identifying vulnerabilities in supply chains (Trump, 2020). The FDA used several criteria in creating the list of essential medications and medical countermeasures, including medications for treating or stabilizing acute life-threatening conditions and devices that are always medically necessary to have in adequate supply (FDA, Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order (EO) 13944 , 2020). More than 300 medications and devices appear in the subsequent list (FDA, Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944, 2020).

Subsequent Presidential Executive Orders, issued January and February 2021, directed HHS ASPR, FDA, and other federal agencies to review and report on supply chain issues (Biden, Executive Order 14017 America's Supply Chains, 2021) (Biden, A Sustainable Public Health Supply Chain, 2021). The Departments of Defense, Health and Human Services, Homeland Security, and Veterans Affairs collaborated to create the National Strategy for a Resilient Supply Chain (Multiple, 2021). ASPR conducted interviews, surveys, workshops, desktop research, and solicited public feedback to draft the "Essential Medicines Supply Chain and Manufacturing Resilience Assessment" (ASPR, Essential Medicines Fact Sheet) (ASPR, Essential Medicines Supply Chain and Manufacturing Resilience Assessment, 2022). The broader FDA list of essential medications was pared down to a priority list of 86; of those pertinent to prehospital care, only 10 were not considered to be in shortage status by ASHP and/or the FDA, and some

have been in shortage since 2009. Select solution strategies include:

- Improving supply chain visibility to anticipate, prioritize, and respond to critical issues, demands, and disruptions;
- Improving data and information sharing across the supply chain;
- Promoting a diversified approach to capacity that avoids single points of failure;
- Leveraging the federal government's purchasing power;
- Regionalizing the Strategic National Stockpile for better positioning of essential medications;
- Proactively developing logistics plans for distribution of essential medications.

HHS released the white paper "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States" that details administrative actions in response to the ongoing medication shortage crisis (HHS). These steps include:

- Creation of a new Supply Chain Resilience and Shortage Coordinator that works across HHS divisions;
- FDA's response uses multiple information sources to determine if a shortage exists or is expected in order to plan mitigation strategies;
- ASPR's creation of an essential medication list detailed above;
- A presidential memorandum allows HHS, under the Defense Production Act, to expand manufacturing capacity and flexibility and strengthen public-private partnerships
    - ASPR is exploring how this authorization can increase domestic production of essential medications
- CMS is considering processes to support hospital access to a buffer stock of essential medications.

Other proposed solutions include requiring drug manufacturers to notify the FDA of increasing demand or interruption or discontinuation of production and allowing ASPR to fund large-scale manufacturing of critical medications, either in The response to a specific event or to support stockpiling.

Many of these proposed solutions are not new. The FDA's 2019 report "Drug Shortages: Root Causes and Potential Solutions" also recommended improved data sharing, requiring risk management plans for manufacturers, lengthened expiration dates of medications facing shortage, predictive modeling (recommended in a 2014 GAO report), and tracking of manufacturer inventories of essential medications (FDA, Report | Drug Shortages: Root Causes and Potential Solutions, 2019) (GAO, 2014). While these solutions have not been implemented, others have been, including improved FDA collaboration with HHS ASPR and DARPA, creation of a list of essential medications, and tracking of medical device shortages.

The NEMSAC notes that the Department of Transportation, as the federal home of EMS, was largely absent in creating these assessments, strategies, and policy considerations.

Recently, several professional organizations have called attention to the special circumstances faced by EMS. Ten stakeholder groups, including the NASEMSO, National Association of EMS Educators (NAEMSE), National Association of Emergency Medical Technicians (NAEMT), and the National Association of EMS Physicians (NAEMSP), sent a joint letter to the Senate Finance Committee highlighting aspects of the shortage crisis that are unique to EMS and that shortages in EMS must be prioritized and addressed differently. Specifically, scope of practice issues, the lack of economic leverage of small EMS agencies, and the lack of resources may limit the effectiveness of strategies suggested in the reports above (Appendix 1).

NAEMT, the International Association of Fire Fighters (IAFF), the International Association of Fire Chiefs (IAFC), and the American Ambulance Association (AAA) highlight the challenges of acquiring new emergency vehicles due to supply chain issues. In a joint letter to the Secretary of Transportation sent August 2022, the groups note that the expected acquisition time for a new ambulance has ballooned from 2 months to an unacceptable 2 years (Appendix 2). There are similar delays in acquiring new fire apparatus, and the ability to respond to emergencies—including priorities in the National Roadway Safety Strategy—is challenged. In the letter, stakeholders point to decreased vehicles chassis production; the Department of Commerce (DOC) notes a "fragile" semiconductor supply chain with demand that "far outstrips supply,"

and this shortage likely exacerbates vehicle production problems (DOC, 2022). These issues are further detailed in the EMSWorld e-book "The Ambulance Shortage—Problems and Solutions" (EMSWorld). Contributors to the e-book received a statement from the Department of Transportation that the joint letter had been received and "we intend to convene relevant stakeholders in the industry to identify potential actions to address it."

E. Strategic Vision

Ensure that EMS has reliable access to essential medications, medical devices, and medical supplies in order to fulfill the mission of improving health, reducing morbidity and mortality, and relieving suffering in the prehospital setting.

F. Strategic Goals

(1) Within one year, the Secretary of Transportation will request that EMS is specifically represented in all aspects related to the assessment of, or solutions to, shortages in medications, medical supplies, and medical devices.

(2) Within two years, NHTSA, through NEMSIS and relevant partners, will create dashboards to track actual usage of medications.

(3) Within two years, the Department of Transportation will convene stakeholder listening sessions regarding prolonged acquisition times for emergency vehicles.

G. Crosswalks

Previous NEMSAC advisories relevant to this issue include:

- Implementing the National EMS Culture of Safety Strategy (2014)
- EMS Utilization of Controlled Substances (2017)
- EMS Resource Allocation and Distribution During Disaster (2021)
- Impact of Public Law 115-83 on EMS Providers: Protecting Patient Access to Emergency Medications Act of 2017 (2024)
- Biennial State of EMS Systems Funding (2023)

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I. Appendices

Appendix 1: NAEMSP Joint EMS Response to Senate Finance on Drug Shortages

Appendix 2: IAFF Joint Letter to DOT on Ambulance Shortages