



National Association of EMS Physicians®
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September 11, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1786-P

Dear Administrator Brooks-LaSure:

The National Association of EMS Physicians® (NAEMSP®) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the request for comment on potential payments for the cost of maintaining access to essential medicines included in the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule.

NAEMSP® is a domestic membership organization of over 2,000 physicians, paramedics, nurses, administrators, educators, and researchers dedicated to providing quality prehospital emergency services. NAEMSP® represents thousands of physician EMS medical directors and Chief Medical Officers who are committed to ensuring that the citizens in their communities have fair and equal access to needed emergency medical care.

The NAEMSP® applauds the Agency's leadership in addressing the critical issue of maintaining access to essential medications. NAEMSP® has long been concerned about chronic and increasing drug shortages in the prehospital setting that seriously affect patient safety and quality of care. While the request for comment focuses on establishing additional payments to hospitals for maintaining access to essential medicines, access to medications is a problem plaguing healthcare providers across the United States, and prehospital emergency medical services (EMS) systems have not been immune.

Critical Medication Shortages Remain a Problem for Many EMS Systems

EMS drug shortages can have substantial adverse impacts through treatment delays, the use of inferior alternative products, and an increased risk of medication errors. Addressing the problem of drug shortages should focus on buffer stocks and the underlying factors that lead to periods of shortage in the prescription drug market, particularly the underlying market factors that have contributed to the current shortages for EMS.

From dextrose to epinephrine to saline, many common drugs found in an ambulance have been in short supply the last few years, forcing agencies to adjust protocols and find alternatives based on what drugs

and concentrations they can secure. Paramedics must quickly adapt to alternative medications or the same medication but in different concentrations, significantly increasing the risk of medication errors in a fast-paced environment in which time is of the essence for patients.

Rebuild the Supply Chain in a Sustainable Way – Revised Stockpiling Approach

NAEMSP® supports efforts to subsidize hospitals in establishing and maintaining access to buffer stock; however, we have concerns that the requirement of a three-month supply could have the unintended effect of impacting supplies to EMS in the prehospital setting. Stockpiling drugs can cause a facility to be left with excess inventory, which is costly and might not be absorbed if the shortage is averted or is not as severe as anticipated. Further, drugs have a limited shelf life, and holding excess inventory could exacerbate shortages in other critical care settings outside the hospital. Accordingly, we recommend rebuilding the supply chain in a sustainable way that will not adversely impact providers outside of the hospital setting by advancing a glide path for buffer stock that begins within two - weeks and gradually increases to a three-month buffer stock supply as production capacity improves. This approach will help allocate medicines to locations most needed while in shortage.

Bolster Access to Address EMS Drug Shortages

The medications used in EMS are critical to saving lives before and during transport to a hospital. Many EMS agencies lack the buying power of large hospital systems, especially among smaller and volunteer EMS agencies in rural areas. EMS agencies also need different concentrations than hospitals and need them consistently to avoid switching medications and doses to prevent medical errors.

Accordingly, as CMS examines establishing additional payments to hospitals to maintain access to essential medicines, the Agency should also extend an add-on payment category for ambulance payments for critical medications, such as those listed below. If only hospitals had an add-on payment, it would inhibit the ability of ambulance agencies to secure life-saving medications for prehospital care.

Life-saving Medicines Critical for EMS

The medications listed below, identified by EMS Medical Director leaders, are critical to protecting individual patients with emergent or acute life-threatening emergency medical conditions. These medications are all excellent candidates for buffer inventory in the ambulance setting as their unavailability can lead to immediate and significant adverse health outcomes and those for which supply chains are vulnerable.

The list below was developed through an NAEMSP® survey of EMS Medical Directors. The list includes the nine medications that are most critical to the practice of prehospital emergency medicine. Some of these are included in the ASPR Essential Medicines report. This list should be reexamined consistently by establishing an Advisory Committee on Critical Medications to identify which EMS medications are most needed daily and in a public health emergency.

Epinephrine (aka “Adrenaline”) – Restart the heart, stabilize rhythms

First-line antidote in severe, potentially fatal allergic reactions (anaphylactic shock). Life-saving medication for asthmatics and those with emphysema who cannot breathe. Improves blood pressure in severe heart failure (cardiogenic shock). First-line medicine in cardiac arrest to help restart the heart. Used to increase heart rate when the heart’s pacemaker fails (symptomatic bradycardia).

Lidocaine

Primary medicine is used to stabilize or reverse lethal abnormal heart rhythms. It is an anesthetic and is also used by EMS to blunt the pain of painful procedures.

Calcium

A first-line antidote to stabilize the heart from lethally high levels of potassium is often seen in dialysis patients and victims of crush syndrome seen in the aftermath of tornados, earthquakes, and hurricanes where building collapse occurs. First-line antidote to reversal of potentially deadly overdoses of a common class of prescribed medications (calcium channel blockers).

Intravenous Fluids

Advanced Life Support (ALS) EMS saves lives and decreases morbidity by administering IV fluids to critically ill patients to stabilize blood pressure in shock states.

0.9% saline (aka "normal saline") First-line intervention for sepsis and septic shock (severe infections) with or without low blood pressure. First-line intervention for low blood pressure due to dehydration (nausea, vomiting, diarrhea, heat exhaustion/stroke).

- Lactated Ringers Solution (aka "Ringers Lactate")

First-line intervention for sepsis and septic shock (severe infections) with or without low blood pressure. First-line intervention for low blood pressure due to dehydration (nausea, vomiting, diarrhea, heat exhaustion/stroke). Has buffering properties that are desirable in some disease states.

Albuterol - Treat life-threatening breathing problems

First-line breathing medication in asthma, chronic bronchitis, and/or emphysema patients. Also used in children with wheezing from bronchiolitis, respiratory syncytial virus (RSV) infection, and other causes of airway passage constriction. Also used as a treatment for dangerously high levels of potassium, often seen in dialysis patients, crush syndrome patients, and those taking certain diuretics ("water pills").

Midazolam - Treat life-threatening, prolonged seizures

First-line antidote for seizures in children and adults.

Often, a first-line sedative is used to expedite the placement of a breathing tube in people who stop breathing. It is an excellent sedative for people suffering from panic attacks and overwhelming anxiety. Helps sedate patients being transferred from one hospital to another on a ventilator.

10% dextrose solution (aka IV glucose) - Reverse life-threatening low blood sugar

First-line medication for life-threatening drop in blood sugar levels. Much safer than 50% dextrose formulations. 5% dextrose is suitable for use as a carrier for many other medications but too dilute to be of practical use in low blood sugar emergencies.

Fentanyl - Treat severe pain

Often, the preferred prehospital medicine for the treatment of sudden or acute pain given its rapid onset (faster relief for the patient) and rapid offset (allows the hospital to assess pain shortly after arrival). This has fewer adverse side effects (low blood pressure, itching) than morphine.

Used as a sedative for patients transported on a ventilator (breathing machine). Also suitable for kidney failure patients as it is processed mostly in the liver.

Conclusion

NAEMSP® thanks you for your interest and consideration of our thoughts and recommendations. We appreciate your leadership on this important issue and look forward to working together to strengthen the supply chain for providers and patients. If you have any questions regarding these comments, please contact Miranda.Franco@hklaw.com or 202-469-5259.