Statement of

Craig Manifold, D.O., F.A.C.E.P.

American College of Emergency Physicians (ACEP)
Chairman
EMS Committee

EMS Medical Director
San Antonio, Texas

Assistant Professor
University of Texas Health Science Center
San Antonio, Texas

Joint Surgeon
Texas National Guard

Before the
House Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

Hearing on

"Strengthening our National Trauma System"

Presented
June 24, 2016

I. Introduction

Thank you Mr. Chairman. My name is Craig Manifold, D.O., F.A.C.E.P., and I am an EMS Medical Director in San Antonio, Texas, and the current chairman of the American College of Emergency Physicians' (ACEP) EMS Committee. On behalf of the 35,000 members of the ACEP, I would like to thank you for this opportunity to testify today about H.R. 4365, the "Protecting Patient Access to Emergency Medications Act of 2016," sponsored by Representatives Richard Hudson (R-NC) and G.K. Butterfield (D-NC), and why it's imperative that this legislation be enacted as soon as possible.

The current practice of Emergency Medical Services (EMS) medicine is of significant importance to the nation's health and public safety. Thousands of physicians serving as EMS medical directors provide medical oversight to tens of thousands of EMS professionals who respond to calls for help 24 hours a day, seven days a week, 365 days a year. Most of my EMS medical director colleagues voluntarily fill these vital roles and it is through their physician licenses that these individuals are able to provide health care services in their communities.

One of the most critical components of this care is the ability of paramedics to administer controlled substances to patients when they follow our medical protocols, more commonly referred to as "standing orders," set forth by the EMS medical director. However, patients' access to these life-saving medications is in jeopardy and Congress must take action quickly to codify the use of standing orders in the pre-hospital setting.

II. Controlled Substances Act

The U.S. Congress enacted the Controlled Substances Act (CSA) in 1970 to establish federal drug policy under which the manufacture, importation, possession, use, and distribution of certain substances is regulated. The law created five Schedules to classify various narcotics, drugs and other substances based on their medical use and potential for abuse. Over the years, the Drug Enforcement Administration (DEA) has promulgated a number of rules to update the regulations associated with the CSA. However, they tend to focus on the types of facilities and services that were available in 1970 rather than for all aspects of the modern health care system, in particular the mobile nature of EMS.

The practice of EMS medicine and its supporting technology and medications have evolved substantially since the CSA was enacted. One significant improvement in patient care has been the use of controlled substance medications by paramedics to abate life-threatening conditions such as seizures and treating pain from traumatic injuries, such as fractures, burns and amputations. Administration of these controlled substances follows strict protocols set forth by the EMS medical director so that these drugs will be available when and where they are needed. These standing orders dictate the circumstances under which various controlled substances may be used without directly seeking the medical director's assent prior to their administration because appropriate, and sometimes life-saving, care demands immediate action.

Take, for instance, the EMS response to a child who is undergoing a long convulsive seizure. On this occasion, the paramedic only has minutes to act or the patient can suffer permanent injuries or even death. This is not the time for them to seek permission for a time-sensitive treatment, but

rather to follow their training and the medical director's standing orders for the administration of the anti-seizure medication (benzodiazepine). Unfortunately, this is the type of care that is at immediate risk if the DEA promulgates a rule that explicitly bans the use of standing orders because the orders are not "patient specific."

DEA Ruling on Standing Orders

In 2011, a paramedic within the Anchorage Fire & Ambulance Districts in Louisville, Kentucky asked the DEA what their policy was pertaining to EMS and the administration of controlled substances to patients prior to arrival at a hospital. The paramedic stated in his letter that they currently had to obtain oral permission from a physician to administer a narcotic to any patient, but they were hoping to revise their protocols to allow the use of non-patient specific standing orders for patients meeting predefined criteria.

In response, the DEA Office of Diversion Control stated that under the terms of the CSA and its implementing regulations the administering or dispensing of a controlled substance would only be valid if it was patient and issue specific. They also said a practitioner may not delegate this responsibility. Therefore, the dispensing of a controlled substance in response to a standing order would not be valid.

While this letter was in response to a specific question raised by a specific EMS agency, it established the formal position of the DEA with regard to the use of standing orders. For several years, DEA was content not to enforce this ruling because standing orders are necessary to protect and provide appropriate care for patients. However, this was starting to change and

several of my EMS medical director colleagues were notified by their regional DEA representatives that they intended to start imposing the ban on standing orders.

DEA Rule to Ban Standing Orders

Until recently, these were regional decisions and pronouncements. In October 2014, the DEA sent representatives to ACEP's annual (Scientific Assembly) meeting in Chicago to notify us they intended to promulgate a rule that would explicitly ban the use of standing orders. As you may imagine, this news was quite shocking and not well received by my EMS medical director colleagues.

A few months later, the DEA attended the National Association of EMS Physicians (NAEMSP) annual meeting in New Orleans where the issue was once again discussed, but no suitable resolution achieved. The DEA representatives reiterated their position that the CSA requires each prescription be associated with a written order and a single patient.

This is not only an impossible standard for EMS medical directors to meet, but it would absolutely devastate our ability to provide the necessary, emergent treatments for severely ill or injured patients. When an ambulance is called to a medical emergency, there is no way to know in advance the name and address of the individual(s) who will need to be treated and explicit oral authorization (even with this information) is not always available. There are too many instances when a patient is incapable of sharing this information with us or communication between the paramedic and the medical director is impractical or even unfeasible.

It should be noted that we collect this information for the official medical record after the care is provided and we follow local, state and federal regulations regarding the maintenance of those patient records.

Legislative Solution

We tried to reach an administration solution to this dilemma, but were unable to do so. When that effort failed, ACEP, NAEMSP and the National Association of EMTs (NAEMT) decided we would need to seek a legislative solution that would explicitly allow the use of standing orders in an effort to maintain appropriate patient care. As with most laws, legislative and regulatory updates are often necessary to keep the law relevant and consistent with current needs and practices.

It took some time, but our negotiations finally led to the introduction of H.R. 4365 and we are tremendously thankful to the bill's sponsors, Representatives Hudson and Butterfield, as well as the other original co-sponsors, Representatives Steve Cohen (D-TN), Blake Farenthold (R-TX), Joe Heck (R-NV) and Raul Ruiz (D-CA), for their support. As of Monday, the bill had 117 bi-partisan co-sponsors.

While codifying the use of standing orders for EMS personnel is essential, we also wanted this legislation to advance policies that would provide uniformity, clarity and certainty for EMS agencies and their medical directors around the country. Not only will these provisions greatly improve EMS medical direction and patient care, they will establish even better controls to prevent EMS drug diversion.

DEA Registration

One of the easiest solutions to reduce confusion and duplicity with regard to the primary point of contact between the EMS agency and the DEA is to simplify the registration process. Currently, most EMS medical directors, rather than the EMS agency itself, register with the DEA and then their agency obtains and administers controlled substances through their medical director's individual DEA number. That places a tremendous burden on these volunteers because of the potential liability for the medical director if the ambulance service experiences a drug diversion.

Many of my colleagues and I believe it makes sense for the EMS agency to be registered with the DEA. It should be an agency, not an individual, which assumes the responsibility for ordering, storing, disbursing, and administering controlled substances. EMS agency registration would also allow for the entire organization to be united under one enrollment, thereby streamlining the process and reducing administrative costs while still preserving accountability. Maintaining a separate registration for individual locations and vehicles under the purview of the EMS agency is extremely time-consuming and expensive.

Medical Direction

Another common-sense provision in this bill is a requirement that each EMS agency have at least one medical director who is responsible for the oversight of all medical services provided by the agency. This individual must be a physician licensed in the state where they practice and where the EMS agency is located.

The EMS medical director would be responsible for patient transportation decisions; establishing medical protocols (including standing orders); overseeing all aspects of patient care provided by EMS personnel; establishing drug formularies for the agency; dispensing and administration of all medications and controlled substances to patients; training EMS personnel; and overseeing quality improvement for the agency. In short, the medical director should oversee all aspects of the medical services being provided and the EMS agency should be responsible for the administrative services.

Oversight of Controlled Substances/Diversion

One of the most important responsibilities of the EMS medical director is his/her work to prevent the misuse or unintended use of medications and controlled substances that are available on EMS vehicles. EMS medical directors and the associated management staff work diligently to oversee the implementation, administration and monitoring of controlled substances within their agencies. My colleagues and I take this responsibility very seriously and we believe the provisions in H.R. 4365 will actually reduce opportunities for drug diversion, although diversion is not a common occurrence in EMS. In fact, one recent survey of large EMS agencies in the U.S. showed less than 20 diversions or investigations for nearly 70,000 doses of controlled substance administered.

As I previously mentioned, many EMS agencies rely on their medical director's DEA license to order, transport and administer controlled substances. These medications can only be delivered to the address associated with your registration. In the recent past, that meant these controlled substances had to be delivered to my house. Alternatively, I could have waited for address

changes and ordering processes to be updated but this would have placed patient care in jeopardy and I was not willing to do that. I can assure you I have had more than one conversation with my wife and children about the types of substances that are arriving at our home with my name on them. Clearly, it makes more sense for these substances to be delivered to a central location operated by the EMS agency, where there would be direct supervision of these medications at all times.

It is also vital that the EMS agency has the ability to freely transfer controlled substances within its own organization. A colleague in Houston, Texas has had to have over one hundred DEA registrations due to the requirement of needing a specific DEA registration with every brick and mortar facility (fire station) where medications are stored. Completing a "distributorship" registration requires complex procedures, expense and increased potential for diversion. The ability for an EMS agency to track and monitor the movement of controlled substances within the agency will improve the efficiency and delivery of medical care to ill or injured patients.

Conclusion

If the DEA prohibits the use of standing orders in EMS, patients will needlessly suffer and die. Thankfully, the DEA has given us time to pursue legislative solutions that will codify the use of standing orders and make other common-sense changes that will improve the delivery of care in the pre-hospital setting. However, I do not believe this grace period is unlimited. Congress must take action quickly to ensure millions of Americans who require emergency medical services each year are not prohibited from receiving these life-saving medications.

In addition to those Members of Congress who have supported H.R. 4365, I would like to thank our coalition partners who have helped advance this legislation. I would especially like to thank NAEMT for their work to add this critical issue to today's hearing. Finally, I would like to thank the members of this committee for the opportunity to testify today about how essential the provisions of H.R. 4365 are to optimal patient care.