

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

July 8, 2016

To: Subcommittee on Health Democratic Members and Staff
Fr: Committee on Energy and Commerce Democratic Staff
Re: Hearing on “Strengthening our National Trauma System”

On **Tuesday, July 12, 2016 at 10:00 a.m., in Room 2322 of the Rayburn House Office Building**, the Subcommittee will hold a legislative hearing titled “Strengthening our National Trauma System.” The legislative measures under review at the hearing include H.R. 4365, “Protecting Patient Access to Emergency Medications Act of 2016” and a discussion draft of H.R. ____, the “Military, Civilian, and Mass Casualty Trauma Readiness Partnership Act.”

I. H.R. 4365, THE “PROTECTING PATIENT ACCESS TO EMERGENCY MEDICATIONS ACT OF 2016”

A. Background

It is current standard practice of emergency medical service (EMS) personnel to administer necessary drugs during a medical emergency under a standing order. A standing order is a protocol issued by an EMS medical director that details how and when EMS practitioners can administer or dispense a controlled substance to a patient during time-sensitive emergency situations without first seeking approval of the EMS medical director.

In 2011, in response to a question submitted by a Kentucky paramedic, the Drug Enforcement Agency (DEA) issued a letter stating that, per the requirements of the Controlled Substances Act (CSA) (21 U.S.C. § 801 et seq.)¹ and its implementing regulations, for the administration or dispensing of a controlled substance to be valid, EMS personnel must have a

¹ Enacted in 1970, the Controlled Substances Act outlines federal policy relating to the manufacture, importation, possession, use, and distribution of several categories of drugs (referred to as “scheduled” drugs in the Act).

patient- and issue-specific order from the EMS medical director.² Therefore, dispensing a controlled substance under a standing order is not valid. Currently, DEA is not enforcing this interpretation of the CSA and standing orders are used nationwide by EMS personnel when administering controlled substances in emergency situations.

EMS providers and organizations are concerned that DEA will begin to enforce the policy articulated in its 2011 letter relating to standing orders. EMS providers assert, however, that this would adversely affect their ability to treat patients during emergency situations. EMS providers state that, in an emergency situation, they may not have enough information about the patient to seek a patient- and issue-specific order. EMS providers assert further that during a medical emergency there is often not time to contact a medical director for a patient- and issue-specific order.

DEA has expressed its willingness to work with Congress and stakeholder groups to address this issue in a way that balances key interests in protecting against diversion of controlled substances with the unique circumstances associated with emergency medical care.

B. Summary of H.R. 4365

H.R. 4365, sponsored by Reps. Hudson (R-NC) and Butterfield (D-NC) would:

- Codify the use of standing orders to allow EMS personnel to administer and deliver controlled substances without patient- or issue-specific orders;
- Allow an EMS agency to have one registration per state, rather than a separate registration for each location of the EMS agency; and,
- Make an EMS agency, and not individual medical directors, liable for receiving, storing, and tracking controlled substances (similar to the liability currently imposed on hospitals).

II. REPORT ON “A NATIONAL TRAUMA SYSTEM: INTEGRATING MILITARY AND CIVILIAN TRAUMA SYSTEMS TO ACHIEVE ZERO PREVENTABLE DEATHS AFTER INJURY”

A. Background

On June 17, 2016, the National Academies of Sciences, Engineering, and Medicine released the report, *A National Trauma System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury*. This report was completed by the Committee on Military Trauma Care’s Learning System and its Translation to the Civilian Sector of the National Academies, which was established through funding from three federal agencies and five professional organizations. The three federal agencies include the Department of

² Letter from John W. Partridge, Chief, Liason and Policy Section, Office of Diversion Control, Drug Enforcement Administration, to Jeremy R. Urekew, Paramedic, Anchorage Fire & Ambulance Districts (December 19, 2011).

Defense's Medical Research and Material Command, the Department of Homeland Security's Office of Health Affairs, and the U.S. Department of Transportation's National Highway Traffic Safety Administration. The five professional organizations include the American College of Emergency Physicians, American College of Surgeons, National Association of Emergency Medical Technicians, National Association of EMS Physicians, and Trauma Center Association of America.

The committee's charge was to define the components of a learning health system necessary to enable continued improvement in trauma care in both the civilian and military sectors, and to provide recommendations for ensuring that lessons learned over the past decade from the military's experiences in combat are sustained and built upon for future combat operations as well as translated to the civilian health care system.³ For the purpose of this report, trauma care is defined as "integrated and coordinating emergency medical services and trauma care systems; point of injury or tactical care; en-route care or care during transport; initial resuscitation including care at small facilities prior to trauma center; care at the trauma center including emergency medicine, trauma surgery and specialty surgical care, anesthesia, and critical care; and transition to but not inclusive of rehabilitation and recovery."⁴

III. RELEVANT RECOMMENDATIONS OF THE COMMITTEE

In concluding that "military and civilian trauma care will be optimized together or not at all,"⁵ the committee issued 11 recommendations to achieve that goal. These recommendations can be categorized into three broad categories: the aim, the role of leadership, and an integrated military-civilian framework for learning to advance trauma care. The recommendations relevant to the Energy and Commerce Committee are included below, broken out by category.

A. The Aim

Recommendation #1: The White House should set a national aim of achieving zero preventable deaths after injury and minimizing trauma-related disability.

B. The Role of Leadership

Recommendation #2: The White House should lead the integration of military and civilian trauma care to establish a national trauma care system. This initiative would include assigning a locus of accountability and responsibility that would ensure the development of common best practices, data that would ensure the development of common best practices, data standards, research, and workflow across the continuum of trauma care.

³ National Academies of Sciences, Engineering, and Medicine, *A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury* (June 17, 2016).

⁴ *Id.*

⁵ *Id.*

Recommendation #4: The Secretary of Health and Human Services (HHS) should designate and fully support a locus of responsibility and authority within HHS for leading a sustained effort to achieve the national aim of zero preventable deaths after injury and minimizing disability. This leadership role should include coordination with governmental (federal, state, and local) academic, and private-sector partners and should address care from the point of injury to rehabilitation and post-acute care.

C. An Integrated Military-Civilian Framework for Learning to Advance Trauma Care

Recommendation #5: The Secretary of Health and Human Services and the Secretary of Defense, together with their governmental, private, and academic partners, should work jointly to ensure that military and civilian trauma systems collect and share common data spanning the entire continuum of care. Within that integrated data network, measures related to prevention, mortality, disability, mental health, patient experience, and other intermediate and final clinical and cost outcomes should be made readily accessible and useful to all relevant providers and agencies.

Recommendation #6: To support the development, continuous refinement, and dissemination of best practices, the designated leaders of the recommended national trauma care system should establish processes for real-time access to patient-level data from across the continuum of care and just-in-time access to high-quality knowledge for trauma care teams and those who support them.

Recommendation #7: To strengthen trauma research and ensure that the resources available for this research are commensurate with the importance of injury and the potential for improvement in patient outcomes, the White House should issue an executive order mandating the establishment of a National Trauma Research Action Plan requiring a resourced, coordinated, joint approach to trauma care research across the U.S. Department of Defense, the U.S. Department of Health and Human Services (National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, U.S. Food and Drug Administration, Patient-Centered Outcomes Research Institute), the U.S. Department of Transportation, the U.S. Department of Veterans Affairs, and others (academic institutions, professional societies, foundations).

Recommendation #8: To accelerate progress toward the aim of zero preventable deaths after injury and minimizing disability, regulatory agencies should revise research regulations and reduce misinterpretation of the regulation through policy statements (i.e., guidance documents).

Recommendation #9: All military and civilian trauma systems should participate in a structured trauma quality improvement process.

Recommendation #10: Congress, in consultation with the U.S. Department of Health and Human Services should identify, evaluate, and implement mechanisms that ensure the inclusion of pre-hospital care (e.g., emergency medical services) as a seamless component of health care delivery rather than merely a transport mechanism.

Recommendation #11: To ensure readiness and to save lives through the delivery of optimal combat casualty care, the Secretary of Defense should direct the development of career paths for trauma care (e.g., foster leadership development, create joint clinical and senior leadership positions, remove any relevant career barriers, and attract and retain a cadre of military trauma experts with financial incentives for trauma relevant specialties). Furthermore, the Secretary of Defense should direct the Military Health System to pursue the development of integrated, permanent joint civilian and military trauma system training platforms to create and sustain an expert trauma workforce.

IV. DISCUSSION DRAFT OF H.R. _____, THE “MILITARY, CIVILIAN, AND MASS CASUALTY TRAUMA READINESS PARTNERSHIP ACT”

The discussion draft is intended to respond to Recommendation #11 by providing financial support to civilian trauma centers that integrate military trauma personnel and teams as part of their care delivery workforce.

The discussion draft would create a grant program that awards grants to those trauma centers that allow military trauma care providers to provide trauma care and related care to offset the costs to the trauma center of integrating such teams or personnel. The discussion draft would also require the Department of Health and Human Services to submit a report to Congress related to payment to trauma centers with respect to traumatic injuries under Medicare, Medicaid, and the Children’s Health Insurance Program.

V. WITNESSES

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