

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

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MEMORANDUM
January 24, 2015

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Examining Public Health Legislation to Help Patients and Local Communities”

On Tuesday, January 27, 2015, at 10:15 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Health will hold a legislative hearing entitled “Examining Public Health Legislation to Help Patients and Local Communities.” It will review six bills: (1) *Ensuring Patient Access and Effective Drug Enforcement Act*; (2) *Improving Regulatory Transparency for New Medical Therapies Act*; (3) *Veteran Emergency Medical Technician Support Act*; (4) *Trauma Systems and Regionalization of Emergency Care Reauthorization Act*; (5) *Access to Life-Saving Trauma Care for All Americans Act*; and (6) *National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act*.

I. Ensuring Patient Access and Effective Drug Enforcement Act

This bill, authored in the previous Congress, by Reps. Blackburn, Marino, Welch and Chu, would define Controlled Substances Act phrases, “consistent with the public health and safety” and “imminent danger.” It also would require the Drug Enforcement Administration (DEA) to permit registrants to submit an action plan to remedy statutory and regulatory violations severe enough that DEA is considering revoking or suspending the registrant’s controlled substances license. It would also require the Food & Drug Administration (FDA), in consultation with DEA, to submit a report to Congress one year after enactment regarding patient access to controlled substances medicines. Additional topics of coverage within the report are to include efforts to benefit patients and prevent diversion and abuse of controlled substances.

The bill, as H.R. 4709, passed the Committee by voice vote on June 10, 2014, and passed the House by voice vote under suspension of the rules on July 29, 2014.

II. Improving Regulatory Transparency for New Medical Therapies Act

This bill, authored in the previous Congress by Subcommittee Chairman Pitts and then-Subcommittee Ranking Member Pallone, would require the DEA to place a drug or substance into the controlled substances schedule recommended by the Food and Drug Administration (FDA) within 45 days of receiving the FDA recommendation. It also would require DEA to make final decisions on registration applications to manufacture or distribute a controlled substance to be used only in connection with a clinical trial within 180 days.

The bill, as H.R. 4299, passed the Committee by voice vote on June 10, 2014, and the Judiciary Committee on Sept. 10, 2014. It was placed on the Union Calendar on Sept. 19, 2014, but was never brought to the House floor.

III. Veteran Emergency Technician Support Act

The Veteran Emergency Medical Technician Support Act was introduced by Congresswoman Capps and Congressman Kinzinger in the 113th Congress. The bill authorizes a demonstration grant program for states. The demonstration program would inform government and other stakeholders on ways to streamline certification and licensure requirements for returning veterans with military emergency medical technician (EMT) training, to become emergency medical technicians in their states.

The Subcommittee held a legislative hearing entitled “Helping Veterans with Emergency Medical Training Transition to Civilian Service” on July 11, 2012.¹ During the 113th Congress, the bill, as H.R. 235, passed the Committee by voice vote on January 22, 2013, and passed the House on February 12, 2013.

IV. Trauma Systems and Regionalization of Emergency Care Reauthorization Act

The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, sponsored by Congressman Green and Congressman Burgess in the 113th Congress, reauthorized four trauma programs which were established or reauthorized in the Affordable Care Act.² The goals of these trauma programs are to provide grants to states for planning, implementing, and developing trauma care systems and establishing pilot projects to design, implement, and evaluate innovative models of regionalized emergency care and trauma systems. This legislation reauthorizes the programs, detailed below, at the currently-authorized level of \$24 million, each year from FY 2015 until FY 2019, and makes a number of technical changes. None of these trauma programs have been funded, however, in recent years.

¹ House Committee on Energy and Commerce, Subcommittee on Health, *Helping Veterans with Emergency Medical Training Transition to Civilian Service*, 112th Cong. (July 11, 2012).

² The Affordable Care Act consists of two public health laws, Pub. L. No. 111-148 and Pub. L. No. 111-152.

- Section 1202 of the Public Health Service Act authorizes a competitive grant program for improving trauma care in rural areas. This program permits the Secretary of Health and Human Services (HHS) to make grants to public and nonprofit private entities for the purposes of conducting research and establishing demonstration projects to improve the availability and quality of emergency medical services in rural areas.
- Section 1203 of the Public Health Service Act authorizes a competitive grant program for improving or enhancing the development of trauma care systems. This program received federal funding from 1992-1994 and 2001-2005. During that time, grants were awarded to all 50 states, the District of Columbia, and the territories for activities such as designating a state agency to lead the administration of a trauma system; developing plans for state and regional trauma systems; and training emergency medical services personnel in trauma assessment and triage protocols.³
- Section 1204 of the Public Health Service Act authorizes a competitive grant program for regionalized systems for emergency care and trauma response. This program directs the Secretary of HHS to award grants and contracts to states, partnerships of one or more states and one or more local governments, Indian tribes, or partnerships of one or more Indian tribes to establish pilot projects to design, implement, and evaluate regionalized emergency care and trauma models.
- Part B of title XII of the Public Health Service Act authorizes formula grants to states in order to improve access to high-quality trauma care. When these programs were last funded, states and territories used the funds to develop, implement, and monitor modifications to the trauma care component of the state plan for the provision of emergency medical services.

During the 113th Congress, the bill, as H.R.4080, passed the Committee by voice vote on April 3, 2014, and passed the House of Representatives on June 24, 2014.

V. Access to Life-Saving Trauma Care for All Americans Act

We expect legislation to be introduced by Congressman Burgess and Congressman Green to reauthorize three additional trauma programs:

- Section 1241 of the Public Health Service Act authorizes grant programs to trauma centers to assist with uncompensated care costs; advances centers' core missions by supporting patient stabilization and transfer, education and outreach, coordination with other trauma systems, and essential personnel and services; and provide emergency funds to centers at risk of closing or reducing services. These programs were reauthorized in the ACA, but have not received funding.

³ Health Resources and Services Administration, *Trauma-EMS Systems Program Report FY 2001-FY 2005* (online at ask.hrsa.gov/detail_materials.cfm?ProdID=3752).

- Section 1261 of the Public Health Service Act established an interagency program for basic and clinical trauma research, led by the National Institutes of Health.
- Section 1281 of the Public Health Service Act authorizes grants to states to improve the availability of trauma center care services and trauma-related physician specialties. The program was first authorized in the Affordable Care Act but has never been funded.

VI. National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act

The National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act was sponsored by Congressman Whitfield and then-Subcommittee on Health Ranking Member Pallone in the 113th Congress. This bill would reauthorize the prescription drug monitoring program (PDMP) first authorized in 2005, and administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). Among other provisions, the NASPER Reauthorization Act seeks to strengthen the interoperability of SAMHSA-supported PDMPs.

In 2012, approximately 6.8 million individuals in the United States were prescription drug users for nonmedical purposes.⁴ PDMPs can help prescribers, pharmacists, and law enforcement officials track the misuse of prescription drugs, and 49 states now have laws authorizing these programs.⁵

The Subcommittee on Health held a legislative hearing on this legislation, as H.R. 3528, on November 20, 2013.⁶ The Subcommittee also held a hearing on prescription drug abuse on June 14, 2013, and the Subcommittee on Oversight and Investigations held a hearing on prescription drug and heroin abuse on April 29, 2014.⁷

⁴ National Institute on Drug Abuse, *Drug Facts: Nationwide Trends* (Jan. 2014) (online at www.drugabuse.gov/publications/drugfacts/nationwide-trends).

⁵ Testimony of Michael Botticelli, Acting Director of the Office of National Drug Control Policy, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, 113th Cong. (April 29, 2014).

⁶ House Committee on Energy and Commerce, Subcommittee on Health, *Examining Public Health Legislation to Help Local Communities*, 113th Cong. (Nov. 18, 2013).

⁷ House Committee on Energy and Commerce, Subcommittee on Health, *Examining the Federal Government's Response to the Prescription Drug Abuse Crisis*, 113th Cong. (June 14, 2013); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, 113th Cong. (April 29, 2014).

VII. Witnesses

Mr. D. Linden Barber

Partner and Director of DEA Compliance Operations
Quarles & Brady

Dr. Nathan B. Fountain

Chair, Medical Advisory Board
Epilepsy Foundation

Mr. Ben D. Chlapek

Chair, Military Relations Committee
National Association of Emergency Medical Technicians

Dr. Blaine Enderson

Chair, Trauma Center Association of America
Professor of Surgery and Medical Advisor for Trauma, Emergency and Critical Care
University of Tennessee Medical Center

Mr. John L. Eadie

Director
Prescription Drug Monitoring Program (PDMP) Center of Excellence, Brandeis University