

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

**February 3, 2015**

**To: Committee on Energy and Commerce Democratic Members and Staff**

**Fr: Committee on Energy and Commerce Democratic Staff**

**Re: Subcommittee on Health Markup of four health bills**

On Wednesday, February 4, 2015, at 2:00 p.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a markup of the following four bills: (1) *H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act*; (2) *H. R. 471, Ensuring Patient Access and Effective Drug Enforcement Act*; (3) *H.R. 648, Trauma Systems and Regionalization of Emergency Care Reauthorization Act*; and (4) *H.R. 647, Access to Life-Saving Trauma Care for All Americans Act*.

The Subcommittee held a legislative hearing on all of these bills on January 26, 2015.

**I. H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act**

This bill 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.

Last Congress, 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.

**II. H.R. 471, 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.

Senators Hatch and Whitehouse introduced legislation last Congress, S. 2862, the Regulatory Transparency, Patient Access, and Effective Drug Enforcement Act of 2014, that essentially melded H.R. 639 and H.R. 471. They currently are working to incorporate technical assistance from FDA and DEA. If they do so in time, the Wednesday markup may include a manager's amendment to reflect these changes. Otherwise, the new version may be marked up at full committee.

### **III. H.R. 648, 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, reauthorizes four trauma programs which were established or reauthorized in the Affordable Care Act.<sup>1</sup> This legislation reauthorizes the programs, detailed below, at \$24 million per year, from FY 2015 through FY 2020, and makes a number of technical changes. None of these trauma programs have been funded, however, in recent years.

- 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.<sup>2</sup>

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<sup>1</sup> The Affordable Care Act consists of two public health laws, Pub. L. No. 111-148 and Pub. L. No. 111-152.

<sup>2</sup> Health Resources and Services Administration, *Trauma-EMS Systems Program Report FY 2001-FY 2005* (online at [ask.hrsa.gov/detail\\_materials.cfm?ProdID=3752](http://ask.hrsa.gov/detail_materials.cfm?ProdID=3752)).

- 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 113<sup>th</sup> Congress, similar legislation (H.R.4080), passed the Committee by voice vote on April 3, 2014, and passed the House of Representatives on June 24, 2014.

#### **IV. H.R. 647, Access to Life-Saving Trauma Care for All Americans Act**

The Access to Life-Saving Trauma Care for All Americans Act, sponsored by Congressman Burgess and Congressman Green, reauthorizes additional trauma programs that are set to expire in FY 2015.

Part D of title XII 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.

Part H of title XII 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 ACA but has also never been funded.

The Access to Life-Saving Trauma Care for All Americans Act also moves the programs under part D and part H of title XII of the Public Health Service Act to the Office of the Assistant Secretary for Preparedness (ASPR), and makes a number of technical changes.