

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

September 12, 2016

To: Committee on Energy and Commerce Democratic Members and Staff
Fr: Committee on Energy and Commerce Democratic Staff
Re: Subcommittee on Health Markup of five health bills

On **Monday, September 12, at 5:30 p.m., or 10 minutes after the conclusion of the Subcommittee on Communications and Technology markup, whichever is later, in room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a markup of the following five bills: (1) *H.R. 4365, Protecting Patient Access to Emergency Medications Act of 2016*; (2) *H.R. 1192, National Diabetes Clinical Care Commission Act*, (3) *H.R. 1209, Improving Access to Maternity Care Act*, (4) *H.R. 1877, Mental Health First Aid Act of 2015*, and (5) *H.R. 2713, Title VIII Nursing Workforce Reauthorization Act of 2015*. The Committee will reconvene on **Tuesday, September 13 at 2:00 p.m. in 2322 of the Rayburn House Office Building**.

All of the bills are bipartisan measures.

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

A. Overview

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.) and its implementing regulations,¹ for the administration or dispensing of a controlled substance to be valid, EMS personnel must have a 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.

Representatives Hudson (R-NC), Butterfield (D-NC), and others introduced H.R. 4365 on January 12, 2016. The bill would amend the CSA to clarify that EMS personnel can administer controlled substances under a standing order from an EMS medical director who oversees emergency care. This amendment would codify what is current practice across the U.S. and help ensure that patients have ready access to important, and often life-saving, drugs in an emergency situation. H.R. 4365 would also streamline the emergency medical services registration process to allow for a single registration for a state EMS agency, rather than requiring registration by each EMS medical director or each EMS agency location. To help safeguard against diversion, the bill would hold EMS agencies responsible for receiving, storing, and tracking controlled substances.

The markup will consider an amendment in the nature of a substitute (AINS) to H.R. 4365.

B. Changes Made by the AINS to H.R. 4365

The AINS makes several important technical changes to H.R. 4365 to clarify requirements under the Act, ensure consistency with the CSA, limit disruptions to state EMS agencies, and ensure DEA has necessary information to conduct oversight. A summary of these changes include:

- Replacing “practitioner” with “professional” throughout the bill as the term practitioner is currently defined in the CSA at 21 USC § 802(21) to include entities that have independent authority to, among other things, distribute, dispense, or administer controlled substances in the course of professional practice. Many EMS professionals do not have such independent authority and therefore would be precluded from administering controlled substances under a standing order. The intent of the legislation is to remove barriers to administration during times of emergency and permit any state licensed or certified EMS professional to dispense a controlled substance pursuant to a standing order.
- Requiring an EMS agency to notify DEA 30 days before delivering or storing a controlled substance at any designated location. This will help ensure DEA has information

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).

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

on where an EMS agency is delivering or storing controlled substances while retaining the single registration requirement.

- Revising to make clear that an EMS agency may use a standing order that was adopted, but not issued, by the EMS medical director to permit the current practice of some EMS agencies that use regional standing orders developed by external qualified medical bodies.
- Clarifying that it is the responsibility of the registered EMS agency to ensure all EMS professionals comply with requirements of the Act, maintain required records (including specifying when an EMS agency or any designated location is required to physically maintain such records), and comply with physical security requirements established in DEA regulations.
- Revising to eliminate redundancy with current requirements of the CSA and ensure terminology aligns with existing CSA definitions.

II. H.R. 1192, NATIONAL DIABETES CLINICAL CARE COMMISSION ACT

A. Overview

Representative Olson (R-TX) introduced H.R. 1192 on March 2, 2015. The bill would create the National Diabetes Clinical Care Commission to improve the clinical care for individuals with diabetes and associated conditions. The Commission would be composed of governmental and nongovernmental members and charged with duties and responsibility to improve federal efforts related to diabetes and its associated conditions. Under this bill, the Commission is directed to issue a final report not later than three years after the date of the Commission's first meeting.

The markup will consider an AINS to H.R. 1192.

B. Changes made by the AINS to H.R. 1192

The AINS would create the National Clinical Care Commission to improve clinical care for individuals with a complex metabolic or autoimmune disease, a disease resulting from insulin deficiency or insulin resistance, or complications caused by any such disease. The AINS would require the Secretary of HHS rather than the Comptroller General to appoint the categorical members of the Committee. The AINS adds safety net providers as an additional category of the type of members the Secretary must appoint to the Commission. This category was added because safety net populations are disproportionately burdened by morbidity and mortality from the conditions that the Commission will focus on. Finally, the AINS strikes the section allowing for appropriations otherwise made available to HHS to be redirected to the Commission.

III. H.R. 1209, IMPROVING ACCESS TO MATERNITY CARE ACT

A. Overview

Representatives Burgess (R-TX), Capps (D-CA), and Duckworth (D-IL) introduced H.R. 1209 on March 3, 2015. The goal of this legislation is to expand access to maternity care services by better identifying areas with maternity care shortage. The legislation would create a

new Health Professional Shortage Area (HPSA) designation to specifically designate communities that have a shortage of maternity care providers.

The markup will consider an AINS to H.R. 1209.

B. Changes made by the AINS to H.R. 1209

The AINS would amend the legislation to require the Health Resources and Services Administration (HRSA) to identify what constitutes a shortage of providers of full scope maternity services and identify geographic areas within the existing Primary Care Health Professional Shortage Areas designation rather than create a new HPSA designation.

IV. H.R. 1877, MENTAL HEALTH FIRST AID ACT OF 2015

A. Overview

Representatives Jenkins (R-KS) and Matsui (D-CA) introduced H.R. 1877 on April 16, 2015 which would authorize grants for mental health first aid training programs. The purpose of those programs is to train certain categories of individuals on the safe de-escalation of crisis situations, recognition of the signs and symptoms of mental illness, and the timely referral to mental health services in the early stages of developing mental disorders. The legislation would authorize \$20 million for fiscal year 2016 and such sums as may be necessary for fiscal years 2017 and 2018.

The markup will consider an AINS to H.R. 1877

B. Changes made by the AINS to H.R. 1877

The AINS would amend an authorized mental illness awareness training grant program to be consistent with the mental health first aid training program requirements included in the introduced version of H.R. 1877. It also changes the authorization levels to \$14,963,000 for each of fiscal years 2017 through 2021.

V. H.R. 2713, TITLE VIII NURSING WORKFORCE REAUTHORIZATION ACT OF 2015

A. Overview

H.R. 2713 was introduced by Rep. Lois Capps (D-CA) and Rep. David Joyce (R-OH) on June 10, 2015. This legislation would reauthorize Title VIII nursing workforce programs through 2020. H.R. 2713 would also make technical changes to the statute to reflect advancements in the field of nursing. The legislation would add the definition of nurse-managed health clinic to the Title VIII statute. The legislation would also amend the Advanced Education Nursing Grants and the National Advisory Council on Nurse Education and Practice to include clinical nurse specialists. Finally, the legislation would further amend the Advanced Education

Nursing Grants to include clinical nurse leaders in order to incorporate advance education programs into the grant program.

An amendment may be considered at markup to make technical changes to H.R. 2713.