

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

July 20, 2010

To: Members of the Subcommittee on Health

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Markup on July 22, 2010

On Thursday, July 22, 2010, at 3:00 p.m. in room 2123 Rayburn House Office Building, the Subcommittee on Health will meet in open markup session to consider the following bills:

- **H.R. 903**, “Dental Emergency Responder Act”
- **H.R. 1745**, “Family Health Care Accessibility Act”
- **H.R. 3199**, “Emergency Medic Transition (EMT) Act”
- **H.R. 5710**, “National All Schedules Prescription Electronic Reporting Reauthorization Act of 2010”
- **H.R. 5756**, To amend title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 to provide for grants and technical assistance to improve services rendered to children and adults with autism, and their families, and to expand the number of University Centers for Excellence in Developmental Disabilities Education, Research, and Service
- **H.R. ____**, “Safe Drug Disposal Act of 2010”

I. H.R. 903, DENTAL RESPONDER EMERGENCY ACT

Currently federal law deters states receiving federal emergency responder training grants from incorporating dental professionals and schools into their all-hazards emergency response plans. H.R. 903 allows states, at their option, to incorporate dentists and dental facilities into their planning.

H.R. 903 amends the Public Health Service Act to: (1) revise the National Health Security Strategy to include increasing the preparedness, response capabilities, and surge capacity of dental facilities and effective utilization of any available mobile dental assets;

and (2) provide that federal dental entities shall carry out activities under the public health and medical response training program. H.R. 903 amends the Homeland Security Act of 2002 to: (1) include dental personnel within the definition of “emergency response providers”; and (2) require the Chief Medical Officer of the Department of Homeland Security (DHS) to serve as the DHS’s primary point of contact for the dental community with respect to medical and public health matters related to natural disasters, acts of terrorism, and other man-made disasters. Finally, H.R. 903 amends the Post-Katrina Emergency Management Reform Act of 2006 to require operational plans developed by federal agencies with responsibilities under the National Response Plan to address the preparedness and deployment of dental resources.

II. H.R. 1745, FAMILY HEALTH CARE ACCESSIBILITY ACT

Currently, all medical professionals employed by health centers are covered under the Federal Tort Claims Act (FTCA) for medical malpractice. In order to receive this coverage, each health center must undergo extensive risk management training and have in place continuous oversight mechanisms to reduce the risk of malpractice.

Individuals seeking to volunteer at a health center must either have their own independent coverage or rely on the Volunteer Protection Act (VPA), which can complicate a health center’s risk management practices. Indeed, VPA coverage does not have the same malpractice coverage as FTCA.

H.R. 1745 amends the Public Health Service Act to deem volunteer practitioners at health centers as employees of the Public Health Service for purposes of any civil action that may arise due to providing services to patients at such health centers.

The bill defines “volunteer practitioner” as a licensed physician or licensed clinical psychologist who: (1) provides services to patients of a public or nonprofit entity receiving federal funds for serving medically underserved areas, at the request of the entity; (2) provides such service at a site at which the entity operates or at a site designated by the entity; and (3) does not receive any compensation for the provision of services.

III. H.R. 3199, EMERGENCY MEDIC TRANSITION (EMT) ACT

Military medics transitioning to the civilian corps – where their background could be put to work improving emergency response capabilities – often requires them to pay high fees and study entry-level curricula to receive certification.

The bill amends the Public Health Service Act to direct the Secretary of Health and Human Services (HHS) to award grants to state entities with jurisdiction over emergency medical personnel to provide for the expedited training and licensing, as emergency medical technicians, of veterans who received training as such a technician while serving in the Armed Forces.

The bill permits the use of grant funds to: (1) provide training; (2) provide reimbursement for costs associated with training, applying for licensure or certification; and (3) expedite the licensing or certification process.

In order for a state to be eligible for funds, it must demonstrate to HHS that it has a shortage of emergency medical technicians. The Secretary of HHS will also submit an annual report to Congress.

IV. H.R. 5710, NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION ACT OF 2010

The National All Schedules Prescription Electronic Reporting Act (NASPER), enacted in 2005, created an HHS grant program administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) for states to establish prescription drug monitoring programs (PDMPs).¹ PDMPs track drug prescriptions, with the goal of preventing overuse and illegal diversion. Approximately 40 states maintain PDMPs or have laws that authorize their establishment.² To be eligible for a NASPER grant, state programs must track drugs that fall under schedules II, III, and IV of the Controlled Substances Act, and must adhere to certain privacy, reporting, and interoperability requirements.

The law authorized \$15 million in each of fiscal years 2006 and 2007, and \$10 million each year for fiscal years 2008 through 2010. In FY2009 and in FY2010, Congress appropriated \$2 million to support NASPER grants in 13 states.

H.R. 5710 re-authorizes NASPER and provides funds to states to establish, improve, and maintain PDMPs. It ensures that appropriate law enforcement, regulatory, and state professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and errant prescriber/pharmacist prescribing and dispensing practices.

Under current law, states adjacent to other states with NASPER grants must submit a plan for interoperability among the states' systems. H.R. 5710 specifies that state interoperability plans must include timelines for implementation, and directs HHS to monitor such efforts.

H.R. 5710 authorizes \$15 million for fiscal year 2011 and \$10 million for each of fiscal years 2012 through 2013.

¹ P.L. 109-60.

² Substance Abuse and Mental Health Services Administration, *SAMHSA FY2011 Congressional Budget Justification* (online at samhsa.gov/Budget/FY2011/SAMHSA_FY11CJ.pdf).

V. H.R. 5756, LEGISLATION TO IMPROVE SERVICES TO CHILDREN AND ADULTS WITH AUTISM AND THEIR FAMILIES

Individuals on the autism spectrum often need assistance in the areas of comprehensive early intervention, health, recreation, job training, employment, housing, transportation, and early, primary, secondary, and post-secondary education. There is a shortage of appropriately trained personnel across numerous important disciplines who are able to provide services and supports to children and adults with Autism Spectrum Disorders (ASD) and related developmental disabilities and their families.

The bill amends title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 to provide for grants and technical assistance to improve services rendered to children and adults with autism, and their families. Funding is authorized at \$17 million for each of fiscal years 2012 through 2016.

In addition, H.R. 5756 expands the number of University Centers for Excellence in Developmental Disabilities Education, Research, and Service and gives priority to applicants that demonstrate collaboration with minority institutions. Funding is authorized at \$2 million for each of fiscal years 2012 through 2016.

VI. H.R. ____, SAFE DRUG DISPOSAL ACT OF 2010

Drug take-back programs are one way to help address the growing problem of prescription drug abuse. A major factor in the increasing trend of prescription drug abuse is the availability of such drugs in the home. These programs provide a means by which patients can safely dispose of their unused medicines. Such programs also help the environment by decreasing the amount of pharmaceuticals that might otherwise enter waterways when they are flushed down the toilet.

Under current law, the Controlled Substances Act (CSA) creates a barrier for many drug take-back programs. The CSA regulates controlled substances³ through a closed registration system designed to prevent diversion.⁴ Under this system, any entity other than the “ultimate user” (i.e., the patient who is prescribed a controlled pharmaceutical) who receives or distributes a controlled substance must be registered with the Drug Enforcement Administration (DEA). In other words, although patients do not have to be registered with DEA in order to receive a controlled substance, they cannot lawfully deliver a controlled substance to another entity for any purpose, including disposal of the drug.⁵

³ Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include drugs that have a potential for abuse and physical and psychological dependence, such as narcotics, stimulants, depressants, anabolic steroids and hallucinogens.

⁴ Drug Enforcement Administration, *Testimony for the Special Committee on Aging Hearing on Drug Waste and Disposal: When Prescriptions Become Poison*, Statement of Joseph T. Rannazzisi, p. 3 (June 30, 2010) (hereinafter, “DEA Testimony”) (online at aging.senate.gov/events/hr223gk.pdf).

⁵ *Id.*

Under current law, the only entities authorized to take possession of expired or otherwise unwanted controlled substances for the purpose of disposal are known as “reverse distributors.” Other registrants, such as pharmacies, may dispose of controlled substances already in their possession (for instance, if they are expired, damaged, or contaminated), but may not accept controlled substances from patients or any other person solely for the purpose of disposal.⁶

In January 2009, in response to growing concerns raised by individuals, interest groups, the healthcare industry, and the law enforcement community, DEA solicited public comments on the disposal of controlled substances dispensed to individual patients, as well as to long-term care facilities. Although DEA received numerous comments during the public comment period, which ended on March 23, 2009, the agency has stated it cannot move forward with a regulatory proposal in the absence of authorizing legislation.⁷

H.R. ____ amends the Controlled Substances Act to allow people to deliver unused prescription drugs to an appropriate person for disposal purposes, as determined by the Attorney General. The Act also authorizes the Attorney General to issue regulations that will permit long-term care facilities to dispose of controlled substances on behalf of their patients.

The bill requires the Director of National Drug Control Policy (ONDCP,) in consultation with the Environmental Protection Agency (EPA), to carry out a public education and outreach campaign to increase awareness of drug take-back programs. It further requires a GAO report on the drug take back programs created through this legislation that includes findings and recommendations regarding the use, effectiveness, and accessibility of these disposal programs.

Finally, the bill requires the EPA administrator, in consultation with relevant state and local officials and other relevant experts, to examine the environmental impacts from disposal of controlled substances in existing disposal systems and make recommendations on the appropriate ways to dispose of prescription drugs. EPA will submit a report back to Congress on the result of such a study.

⁶ 21 CFR 1300.01(b)(41).

⁷ DEA Testimony, supra note 6, at 5.