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## Spotlight Story: Opioid Epidemic

### White House Declares Opioid Crisis a National Emergency

President Trump on Aug. 10 declared the opioid crisis a national emergency, the Administration's strongest action so far to address the epidemic. The declaration came days after the White House Opioid Commission, led by Gov. Chris Christie (R-NJ), recommended the action as a means to direct congressional efforts. While no specific steps have been outlined, the President stated that a lot of time effort and money will be spent on the crisis. The White House Opioid Commission did, however, make several recommendations including increasing access to treatment, requiring prescriber education and model language for state legislatures to create standing orders for naloxone.

AMCP has been monitoring the actions of federal agencies working to address the crisis. In [remarks](#) made on July 10, FDA Commissioner Scott Gottlieb announced plans to expand the Risk Evaluation and Mitigation Strategy (REMS) on extended release opioid analgesics to include immediate release opioids. The new REMS program will include education on pain management for providers including nurses and pharmacists. Although specific timing for the new immediate release opioid REMS was not given, Commissioner Gottlieb stated that the FDA will work to minimize any additional burden to industry and is open to adjusting the new REMS as necessary.

The Commissioner also announced efforts to focus on post market evaluation of product safety and a new provider survey to understand beliefs and attitude on abuse deterrent formulations. AMCP will continue to monitor developments to keep members updated on this and other federal actions.

## Federal Legislative Updates

### Senate Goes on Summer Recess Leaving Affordable Care Act (ACA) Unchanged

The Senate held three floor votes during the week of July 24 to repeal and replace the Affordable Care Act (ACA). In a final vote on July 28th, Senators narrowly rejected the third proposal called the Health Care Freedom Act, also known as the “skinny” repeal amendment. That Act would have repealed mandates that most individuals have health insurance and that large employers cover their employees, among other provisions. Following that last vote, the Senate prepared for recess and will return on Sept. 5th.

### AMCP Supports Introduction of the CREATES Act

On July 27, AMCP sent a letter in advance of a hearing scheduled by the House Judiciary Subcommittee on Regulatory Reform, Commercial & Antitrust Law, in support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212). This bipartisan legislation is designed to increase competition and patient access to safe and affordable generic and biosimilar medicines. Subcommittee Chair Tom Marino (R-PA) read into the hearing record names of organizations, including AMCP, sending [letters](#) of support.

### AMCP Supports The Overdose Prevention and Patient Safety Act (H.R. 3545)

The Academy supports the Overdose Prevention and Patient Safety Act (H.R. 3545), which was introduced July 28 by Rep. Tim Murphy (R-PA) with bipartisan support. H.R. 3545 is designed to align the law enacted in 1970 for disclosure of substance use disorder records with the Health Insurance Portability and Accountability Act (HIPAA) which was enacted in 1996. [H.R. 3545](#) will allow appropriate access to patient information that is essential for providing whole-person coordinated care and it also strengthens protections for a patient's substance use disorder records. Giving health care providers access to a patient's entire health history will help prevent overdoses and harmful drug-to-drug interactions.

AMCP is a member of the Partnership to Amend 42 CFR Part 2 (Part 2 is the regulation adopted under the 1970 law referenced above). The Partnership has over 30 health care organizations committed to modernizing the privacy laws as one of the ways to combat the opioid epidemic. AMCP joined Partnership members in expressing [support](#) for this important legislation. The Partnership website is an excellent resource for additional information: [www.helpendopioidcrisis.org/](http://www.helpendopioidcrisis.org/)

**Action Alert:** AMCP sent an Aug. 16 action alert requesting members to contact their representative in Congress and seek their support as a cosponsor of H.R. 3545. So far, more than 70 members of the House have heard from AMCP members. If you have not had a chance to respond to the alert, please do so now. Also if you have not seen the alert please check your spam folder. AMCP alerts are powered by Voter Voice.

## Advocacy Tip

During the congressional August recess, AMCP encourages you to seek opportunities to meet your lawmakers (i.e., in town hall meetings) and share your experiences on the value of managed care pharmacy.

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## Congress Passes FDA Reauthorization Act of 2017 (FDARA)

The Senate on Aug. 3 passed H.R. 2430, which amends the Federal Food, Drug, and Cosmetic Act to revise and extend user-fee programs for prescription drugs, medical devices, generic drugs and biosimilar biological products. The Senate's 94 to 1 voice vote, without amendments, follows the House's July 12 passage of the bill. Sen. Bernie Sanders (I-VT) was the only "nay" vote, as he sought to include his amendments on importation, and without those amendments he was not willing to support the bill. The bill was presented to the President on Aug 7. As of today, the bill remains unsigned.

**Note:** AMCP held an Aug. 15 webinar: *Implications for Managed Care Pharmacy from the FDA Reauthorization Act*, to discuss the key provisions of FDARA and their implications to managed care pharmacy. The recording of that webinar will be available at <http://amcp.org/webinars/> in the next few days.

### Upcoming Comment Periods

AMCP is seeking stakeholder feedback on the following proposals that are currently open for comment. Please provide feedback via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at [ssaha@amcp.org](mailto:ssaha@amcp.org) by the dates listed for incorporation into AMCP's comments on the matter. All of AMCP's final comment letters are available on the AMCP website and also included in the Legislative-Regulatory Briefing.

Topic	Feedback Due to AMCP	Comments Due
ICER – <a href="#">Tentative 2018 Research Agenda</a>	Aug. 24	Aug. 29
CMS - <a href="#">Calendar Year 2018 Proposed Physician Fee Schedule Rule</a>	Aug. 24	Sept. 11
FDA - <a href="#">Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting</a>	Sept. 11	Sept. 18
ODPHP – <a href="#">Healthy People 2030 Proposed Framework</a>	Sept. 22	Sept. 29

### State Regulatory Updates

#### Washington State Rx Program Finalizes Substitution Requirements for Interchangeable Biological Products

Effective Sept. 1, the Washington State Prescription Drug Program will require dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted. AMCP submitted [comments](#) in support and urged Washington state to finalize the rule as proposed as AMCP supports

the automatic substitution, without additional restrictions or recordkeeping requirements, of interchangeable biological products that are licensed by the Food and Drug Administration (FDA) and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4). For more information on the final rule, please click [here](#).

## Eye on State Legislatures

Only six states are still in session: California, Ohio, Massachusetts, Michigan, New Jersey and Wisconsin. Current state bills that AMCP is tracking may be accessed [here](#). AMCP's letters can be accessed at [Letters, Statements and Analysis](#).

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