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In This Issue

Spotlight Story: Opioid Abuse

Recent Actions to Tackle Ongoing Crisis

By some estimates, more than 100 people a day are dying from opioid abuse. Below are some recent efforts to address the crisis.

White House

President Trump on Thursday declared the opioid crisis a "public health emergency" which allows the federal government to waive some regulations, give states more flexibility in how they use federal funds and expand the use of telemedicine treatment. Meanwhile, the White House Opioid Commission, led by Gov. Chris Christie (R-NJ), is expected to issue recommendations next month to increase access to treatment, require prescriber education and offer model language for state legislatures to create standing orders for naloxone.

Capitol Hill

In addition to legislation that has been introduced in Congress this session to address the opioid crisis, the House Energy and Commerce Committee, chaired by Greg Walden (R-OR) held a full committee hearing on October 25th on federal efforts to combat the opioid crisis. The primary purpose was to receive testimony from federal agencies charged with implementing provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act (both enacted during the last Congress). Invited agency representatives were:

- Neil Doherty, DEA Deputy Assistant Administrator, Office of Diversion Control

- Dr. Scott Gottlieb, FDA Commissioner
- Dr. Elinore McCance-Katz, Assistant Secretary for Mental Health and Substance Abuse and Mental Health Services Administration
- Dr. Anne Schuchat, Prinicpal Deputy Director, Centers for Disease Control and Prevention (CDC)
- Dr. Nora Volkow, Director, National Institute on Drug Abuse at the National Institutes of Health

The hearing focused on ongoing concerns that the members had with a lack of response from the DEA on reports of "pill dumping" in West Virginia and the message that this "national emergency" needs an "all hands on deck approach." Democrats raised concerns about the perceived exclusion of the Centers for Medicare and Medicaid Services (CMS) from testifying at the hearing. They were vocal about the number of beneficiaries of programs being administered by CMS that are also impacted by this issue and wanted that population included in discussions. Questions also centered on the need for information on the impact of teens and children.

In addition, committee members inquired about what else was needed from Congress to assist agencies in addressing opioid abuse (agencies deferred to the Administration's agenda). Many questions were asked about quantifying the nature of the abuse, i.e., legal vs. illegal drug use. The consensus appeared to be that the legal abuse was far greater than the illegal abuse. Concerns were raised about the varying costs of naloxone and disparities in treatment options depending on factors of economic standing, race and location. Prescribing practices were in the crosshairs, with one member wanting to know if legislation is necessary to make excessive opioid prescribing illegal. Others raised the point that some patients leave the hospital addicted to opioids and that more prescriber training is needed.

More information can be found on the Committee's website including witness statements, hearing notices and background memos

Federal Agencies

The FDA announced that it is seeking public input on how the agency can or should use its authority to address the opioid crisis. This information will help the FDA understand areas of focus important to the public and identify and address opioid product and policy issues that need clarification. FDA is especially interested in hearing from interested parties in three key areas: (1) What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; (2) what steps can FDA take with respect to dispensing and packaging (e.g., unit of use) to facilitate consistency of and promote appropriate prescribing practice; and (3) should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented? Please submit feedback for consideration and inclusion in AMCP's comment letter to FDA to Soumi Saha, AMCP Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Dec. 15.

State Capitals

Between 2016 and 2017 more than 30 states considered at least 130 bills on opioids. Proposed legislation included statutory limits on prescribing, provider education and training requirements, access to naloxone and mandating use of abuse deterrent formulations. Most states have adjourned for 2017; however, these efforts will continue next year.

Federal Update

Advocacy Tip

Congressional Calendar

The first session of the 115th Congress aims to adjourn on Friday, December 15th. Between now and the target adjournment date, lawmakers are scheduled for approximately 15 work days in the House and 20 work days in the Senate.

CMMI Issues Request for Information on Patient-Centered Care Proposals

The Center for Medicare and Medicaid Innovation (CMMI) issued a request for information (RFI) seeking feedback on a new direction to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. In the RFI, CMMI outlines eight specific focus areas it is seeking feedback on which includes (1) Increased participation in Advanced Alternative Payment Models (APMs); (2) Consumer-Directed Care & Market-Based Innovation Models; (3) Physician Specialty Models; (4) Prescription Drug Models; (5) Medicare Advantage (MA) Innovation Models; (6) State-Based and Local Innovation, including Medicaid-focused Models; (7) Mental and Behavioral Health Models; and (8) Program Integrity. Please submit feedback for consideration and inclusion in AMCP's comment letter to Soumi Saha, AMCP Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Nov. 13.

FDA Releases Draft Guidance Seeking to Update REMS Format and Content

The FDA's Oct. 11 draft guidance titled "*Format and Content of a REMS Document*" aims to improve the REMS program by proposing a standardized format for REMS documents and supporting submission of REMS documents using Structured Product Labeling (SPL). AMCP has advocated for changes to the REMS program to create predictability, transparency, and consistency in the development, implementation, and assessment of REMS programs. AMCP is pleased to see the FDA take positive steps to create standardization with REMS documents and seeks member feedback on how the draft guidance document can be further improved. Please submit feedback for consideration and inclusion in AMCP's comment letter to FDA to Soumi Saha, AMCP Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Dec. 4.

FDA Issues New Educational Materials on Biosimilars for Health Care Professionals

The FDA recently released new educational materials for health care professionals about biosimilar and interchangeable products. The materials include four fact sheets and graphics for health care professionals that:

- Provide the basic definitions of terms like: biological drugs, reference products, biosimilar, interchangeable; and other

November's upcoming elections are on the horizon. According to the National Conference of State Legislatures (NCSL), New Jersey and Virginia will be voting on governors and legislative seats, nine states have special elections for legislative seats and voters in seven states will vote on statewide ballot measures: Maine, New Jersey, New York, Ohio, Pennsylvania, Texas and Washington. NCSL has commentary on these elections and also a blog that might be of interest.

terms to facilitate understanding the relationship between biosimilars and their reference products;
- Describe the rigorous standards any biosimilar must meet prior to approval and explain how the FDA approval pathway works for these products;
- Contain details about the data and information FDA reviews to determine biosimilarity, and how to find more information; and
- Provide information about prescribing biosimilar and interchangeable products.

AMCP's Biosimilars Resource Center also contains a wide range of educational materials for health care providers and stakeholders. Visit www.biosimilarsresourcecenter.org.

Healthy People 2030 Draft Framework

AMCP submitted comments to the Office of Disease Prevention and Health Promotion (ODPHP) on the Healthy People 2030 Draft Framework, supporting Foundational Principle #2 which states: *Achieving the full potential for health and well-being for all provides valuable benefits to society, including lower health care costs and more prosperous and engaged individuals and communities.* ODPHP is a division within the U.S. Department of Health and Human Services that leads disease prevention and health promotion efforts in the U.S. AMCP also provided specific policy areas and laws that should be updated to meet Foundational Principle #2 including support for a competitive marketplace, inclusion of pharmacists as members of health care teams, and interoperable IT systems.

Upcoming Comment Periods

AMCP is seeking stakeholder feedback on the following proposals that are open for comment. Please respond via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments. All of AMCP's final comment letters are available on the AMCP website here.

Topic	***Feedback Due to AMCP***	***Comments Due***
USP – Drug Classification System	Oct. 27	Oct. 30
FDA—Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements	Nov. 13	Nov. 20
CMS - Innovation Center New Direction	Nov. 13	Nov. 20
FDA - Statistical Approaches to Evaluate Analytical Similarity Guidance for Industry	Nov. 13	Nov. 21
FTC - Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics	Dec. 1	Dec. 8
FDA - Format and Content of a REMS	Dec. 4	Dec. 11

Document		
FDA - Opioid Policy Steering Committee	Dec. 15	Dec. 28

AMCP In Action

AMCP Supports Pharmacy Service Billing Codes for Team Based Care

AMCP staff member Tricia Lee Wilkins, Director of Pharmacy Affairs, was recently selected to represent the Pharmacy Health IT Collaborative at the American Medical Association's CPT Editorial Panel Meetings. The Pharmacy Health IT Collaborative was founded by several pharmacy associations, including AMCP, to promote the effective use of medications through information technology as well as to strengthen the role of pharmacists as care providers within an interoperable health system. Through the Pharmacy Health IT Collaborative, AMCP is supporting the role of pharmacists as members of the clinical care team. The availability of pharmacy service billing codes will facilitate roles for pharmacists within emerging models of team-based and value-based care.

AMCP Supports Innovation in Marketplace With Webinar on Value Based Contracting

AMCP hosted a well-attended Oct. 11 webinar, "Advancing Value-Based Contracting: AMCP Partnership Forum Proceedings," as a follow up to the Academy's Value-Based Contracting Partnership Forum in June. Featured speakers were Amy Duhig, Senior Director for Global Health Economics and Outcomes Research at Xcenda, and Robin Turpin, Value Evidence Lead at Takeda. The webinar described the creation of a consensus definition and guiding principles for value-based contracts; strategies for evaluating, implementing and monitoring value-based contracts; and recommendations for mitigating legal and regulatory barriers to the new contracting model. An archived recording of the webinar can be found here. For more information on the Forum, please visit here. A link to the Forum Proceedings may be found here. AMCP will continue to work with members and interested stakeholders to advance the adoption and expansion of VBCs. AMCP is looking for feedback on ways to promote adoption of VBCs and provide resources to AMCP members and stakeholders If you would like to be involved or have suggestions on ways AMCP can promote VBCs please contact Tricia Lee Wilkins at tlwilkins@amcp.org.

AMCP Legislative and Regulatory Priority Setting Survey for 2018

Thank you for taking the time to complete the member survey. Two lucky members received a gift card for participating in the drawing. The survey results were shared during the Joint Priority Setting meeting at AMCP Nexus 2017. The Board will be reviewing the results and the priorities will be announced in January. AMCP will have a hold a webinar in late January to discuss the priorities.

State Update

AMCP Comments on Arkansas Biosimilars Interchangeability Provisions

AMCP submitted comments to the Arkansas State Board of Pharmacy on proposed regulatory changes pertinent to biosimilars. AMCP supported proposed changes that would update several definitions, including biological product, biosimilar, and biosimilar product, to align with the FDA definitions of these terms. AMCP also supported proposed changes would permit the dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted, which is consistent with the Biologics Price Competition and Innovation Act (BPCIA). AMCP also recommended some technical amendments to maintain consistency with federal regulations and minimize any potential confusion or misinterpretation.

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