In This Issue

Spotlight Story: Opioid Crisis Part II

White House and Congress Continue Work on Opioid Abuse Crisis

The White House and Congress continued their efforts to address the national opoid abuse epidemic. The following are some recent developments:

Administration

The President's Commission on Combating Drug Addiction and the Opioid Crisis issued its final report on Nov. 1. The report included 56 recommendations in the following categories: Federal funding and programs, Opioid Addiction Prevention, Prescribing Guidelines, Regulations and Education, PDMP Enhancements, Supply Reduction and Enforcement Strategies, Opioid Addiction Treatment, Overdose Reversal and Recovery and Research and Development.

Under Prescribing Guidelines, the recommendations included:

- That HHS, the Department of Labor (DOL), VA/DOD, FDA, and ONDCP should work with stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain.
- That HHS coordinate the development of a national curriculum and standard of care for opioid prescribers. An updated set of guidelines for prescription pain medications should be established by an expert committee composed of various specialty practices to supplement the CDC guidelines that are specifically targeted to primary care physicians.

- That federal agencies work to collect participation data. Data on prescribing patterns should be matched with participation in continuing medical education data to determine program effectiveness and such analytics shared with clinicians and stakeholders such as state licensing boards.
- That the Administration develop a model training program to be disseminated to all levels of medical education (including all prescribers) on screening for substance use and mental health status to identify at risk patients.
- That the Administration work with Congress to amend the Controlled Substances Act to allow the DEA to require that all prescribers desiring to be relicensed to prescribe opioids show participation in an approved continuing medical education program on opioid prescribing.
- That HHS, DOJ/DEA, ONDCP, and pharmacy associations train pharmacists on best practices to evaluate legitimacy of opioid prescriptions, and not penalize pharmacists for denying inappropriate prescriptions.

Under PDMP enhancements, recommendations included:

- That the Administration support the Prescription Drug Monitoring (PDMP) Act to mandate states that receive grant funds to comply with PDMP requirements, including data sharing. This Act directs DOJ to fund the establishment and maintenance of a data-sharing hub.
- That PDMP data integration with electronic health records, overdose episodes, and SUD-related decision support tools for providers is necessary to increase effectiveness.
- That ONDCP and DEA increase electronic prescribing to prevent diversion and forgery. The DEA should revise regulations regarding electronic prescribing for controlled substances.
- That the Federal Government work with states to remove legal barriers and ensure PDMPs incorporate available overdose/naloxone deployment data, including the Department of Transportation's (DOT) Emergency Medical Technician (EMT) overdose database.

The Commission included Chairman Gov. Chris Christie (R-NJ), Gov. Charlie Baker (R-MA), Gov. Roy Cooper (D-NC), and Rep. Patrick J. Kennedy (D-MA), Professor Bertha Madras, PhD, and Florida Attorney General Pam Bondi (R).

Congress

The Opioid Network, led by the Center for Popular Democracy, was formed to advocate for Congressional funding to address the opioid epidemic, including treatment and overdose prevention. The White House declaration last month of the opioid crisis as a "public health emergency" did not include a specified funding request to Congress.

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.

Congressional Calendar

The first session of the 115th Congress remains scheduled to adjourn on Friday, Dec. 15th. The primary focus now is enacting a tax plan. The Senate has included language to repeal the Affordable Care Act's individual mandate in version; however the House version does not have a similar provision. Details will have to be resolved during conference committee discussions. Between now and the target adjournment date, lawmakers are scheduled for approximately 13 work days in the House and 16 work days in the Senate.

Regulatory Update

CMS Adopts New Coding & Reimbursement Policy for Biosimilars in Medicare Part B

On Nov 2, CMS released the final rule Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018. In the final rule, CMS reverses its previous coding and payment policy for biosimilars in Medicare Part B and adopts a new policy that provides for separate coding and payment for each biosimilar. Effective January 1, 2018, newly approved biosimilar products with a common reference product will no longer be grouped into the same HCPCS code. CMS will issue detailed guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers. Completion of these changes, which will require changes to the claims processing systems, is planned to occur as soon as feasible, but should not be expected to be complete by January 1, 2018. CMS anticipates that this will be done by mid-2018 and plans to issue instructions using subregulatory means, such as change requests/transmittals to contractors and the ASP website.

CMS notes that the change in coding and payment policy for biosimilars in Medicare Part B is necessary at this time to foster a robust, and competitive marketplace and encourage the innovation that is necessary to bring more of these products to the marketplace. CMS also notes that it will continue to monitor Part B biosimilar payment and utilization, particularly as they relate to access, to determine if future changes to coding and payment are warranted.

FTC Workshop Examines Competition Issues Related to Prescription Drug Markets

On Nov. 8, the Federal Trade Commission (FTC) hosted a workshop titled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" to examine competition issues related to prescription drug markets, specifically obstacles to generic entry into the marketplace. The goal of the workshop was for the FTC to better understand challenges within the current marketplace to help inform future policy and actions to help increase generic entry into the marketplace.

Advocacy Tip

Midterm elections are set for Nov. 6, 2018. All 435 seats in the U.S. House of Representatives and 33 of the 100 seats in the Senate will be on the ballot. In addition, 39 state and territorial governorships and numerous other state and local seats are up for grabs. Visit the candidates' websites to get to know their positions on health care and other important issues facing the country.

During the keynote address, FDA Commissioner Scott Gottlieb noted that FDA is concerned about public health when patients are unable to access a generic medication. Gottlieb noted that while the FDA appreciates the need to reward innovation, they also appreciate the need to honor the framework of Hatch-Waxman. Gottlieb also spoke about steps that the FDA is taking to address current challenges to generic entry into the marketplace including new initiatives that will be announced in the coming weeks to make the generic drug approval process more efficient, contacting pharmaceutical supply chain intermediaries to inform them of the FDA's interest in making sure that generic firms can gain access to the doses they need to run bioequivalence studies, and providing guidance on the FDA's intent to waive the single shared REMS system.

In addition to the workshop, the FTC is seeking public comment through Dec. 8 on the following questions:

1. Do generic drug manufacturers have sufficient incentives to enter markets where the brand drug is off-patent? Do policymakers or market participants have a role in providing incentives to encourage entry decisions that better align with the public interest?

2. Some report strategies to reduce generic drug competition when the branded drug is off-patent. Are these reports accurate? If so, what steps are taken to reduce competition? If not, are there other reasons why generic entry is not seen as robust? What can be done?

3. What role do intermediaries, such as pharmacy benefit managers and group purchasing organizations play in prescription drug pricing, consumer access, and quality? What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?

4. How do companies assess the benefits, costs, and risks of contracting with intermediaries? How well do consumers understand intermediaries' roles? Is more information necessary?

5. How should stakeholders evaluate proposals to reduce drug prices and increase consumer access in prescription drug markets? What role can the FTC play in addressing these issues?

CMS's 2019 Proposed Payment Notice for Exchanges Calls for Major Changes to EHBs

CMS's Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, released Oct. 27, proposes giving states additional flexibility in the definition of essential health benefits (EHBs), which includes a comprehensive pharmacy benefit. The aim is to increase affordability of health insurance in the individual and small group markets. Beginning in 2019, the proposed rule would give states additional flexibility to define their EHB benchmark plan and do so on an annual basis. CMS outlines four proposed options for states to select an EHB benchmark plan:

- **Maintain their current 2017 EHB-benchmark plan.** States could do so without taking any action.
- **Select *another* state's 2017 EHB-benchmark plan.** States could select any one of the 50 EHB benchmark plans used for the 2017 plan year by another state. CMS would defer to the selecting state's implementation of EHB-benchmark plan benefits and limits, such as converting benefits with dollar limits to non-dollar limits. This would be true even when the selecting state's implementation of EHB standards is different from the originating state's implementation.
- **Replace *one or more EHB categories* from another state's 2017 EHB-benchmark plan.** States could replace any of the 10 required EHB categories in its 2017 EHB benchmark plan with the same category or categories of benefits from another state's 2017 EHB benchmark plan. For example, a state could select the prescription drug category from one state's EHB benchmark plan and the hospitalization category from another state's EHB benchmark plan.
- **Select a *new EHB-benchmark plan* so long as the plan is equal in scope to a typical employer plan and is no more generous than the most generous comparison plan.** These comparison plans are the state's 2017 EHB benchmark plan and the state's three largest small group health plans by enrollment (identified during the 2017 EHB benchmark selection process). The state, based on an actuarial analysis and certification, would decide whether the proposed EHB benchmark plan is equal in scope of benefits provided under a typical employer plan and meets the generosity standard.

AMCP is analyzing the proposal and its potential impact to patients, as well as its potential downstream impact on the comprehensive pharmacy benefit. Comments are due to CMS by Nov. 27.

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***
CMS - Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019	Nov. 20	Nov. 27
FTC - Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics	Dec. 1	Dec. 8
FDA - Format and Content of a REMS Document	Dec. 4	Dec. 11
FDA - Opioid Policy Steering Committee	Dec. 15	Dec. 28

AMCP In Action

AMCP Nominated to MAP Medicaid Adult Workgroup and Medicaid Child Workgroup

On Nov. 7, the Governance Committee of the National Quality Forum's Board of Directors recommended AMCP for the Measure Application Partnership (MAP) Medicaid Adult Workgroup and Medicaid Child Workgroup for 2018. Through statutory authority under the Affordable Care Act, the Department of Health And Human Services is required to seek input from a consensus based entity on measure development. The MAP was created through collaboration to provide input on the selection of quality measures for public reporting, payment, and other programs. The nomination is provisional pending public comment and final approval by the Board of Directors on Dec. 4.

AMCP Participates in National Quality Partners Opioid Stewardship Meeting

On Nov. 14, AMCP Staff participated in the National Quality Partners Opioid Stewardship In-Person Forum. The Forum was organized by The National Quality Forum (NQF) with the following objectives: to provide practical guidance to advance opioid stewardship; identify solutions and resources for barriers to successful implementation of opioid stewardship; and identify policy levers and measurement approaches to support opioid stewardship. Corresponding with the NQF Annual Meeting, in March 2018, the National Quality Partners will release an Opioid Stewardship Playbook documenting the recommendations of participating experts and stakeholders on a national approach to opioid stewardship. In addition to AMCP, other participating organizations included the American Society of Health-System Pharmacists, the Pharmacy Quality Alliance, the US Pharmacopeial Convention and URAC.

AMCP's Susan Cantrell Joins PQA Board of Directors Along With Other AMCP Members

On Nov. 14, the Pharmacy Quality Alliance (PQA) announced that AMCP CEO Susan A. Cantrell RPh, CAE, had been appointed to the PQA Board of Directors for 2018-2019. Other AMCP members appointed to the board include former AMCP President Cynthia Pigg, BS Pharm, MHA, FAMCP, Senior Vice President and Chief Pharmacy Officer at Gateway Health Plan; and Sharon Jhawar, Pharm D, MBA,CGP, Chief Pharmacy Officer at SCAN Health Plan, who is a member of AMCP's Legislative and Regulatory Action Committee. The mission of PQA is to optimize health by advancing the quality of medication use. PQA members are active in developing and promoting the use of quality metrics which provide meaningful evaluation of medication use. Additionally, PQA provides education on methods for pharmacist-led and team based quality improvement.

State Legislative Update

State Biosimilar Legislation

New York Gov. Andrew Cuomo (D) on Oct. 23 signed into law AB 7509, which directs a pharmacist to substitute a less-expensive biological product for a prescribed biologic product provided that certain conditions are met, including that the product is an interchangeable biological product, and that the pharmacist communicates to the prescriber specific details about the substitution within five days. The law also requires the prescriber to inform the patient when an interchangeable biological product is prescribed. The New York law increases the number of states with laws on biosimilars to 37, along with Puerto Rico. Michigan (H.B. 4472) and Wyoming (LSO 257) still have legislation pending for 2017.

Upcoming AMCP Webinars

Value-Based Health Care for Patients, Providers & Payers: Summary from AMCP Foundation Research Symposium

Thursday, Nov. 30, 2pm EST
Registration

This webinar will discuss highlights from the half-day event on "Value-Based Health Care: Identifying Benefits for Patients, Providers and Payers." Select experts from the 7th Annual Research Symposium will revisit their views on identifying and utilizing value to improve care. The perspectives of patients, employers and payers will be explored and the summary report will be released. Visit the AMCP Foundation website for more information.

Speakers:

- Moderator – John Doyle, SVP, IQVIA
- Employer/Payer Perspective – Ruth Daniel, Sr. Analyst, Southwest Airlines
- Plan/Provider Perspective – Cliff Goodman, SVP, Lewin Group
- Patient Perspective – Alan Balch, CEO, Patient Advocate Foundation

Where Does the ACA Stand Heading into 2018?

Tuesday, Dec. 5, 2pm EST
Registration

2017 has been a tumultuous year for the Affordable Care Act, and there is still uncertainty surrounding the status of the Marketplaces as we head into 2018. This session will give you an update on ACA hot topics such as cost-sharing reduction payments and state waivers. With open enrollment almost over, we will take a look at enrollment numbers from the first month and see what we can deduce about the 2018 risk pools. In addition, we will examine proposed rules for plans in 2019.

Speaker:

- Moderator – Mary Jo Carden, VP of Government and Pharmacy Affairs, AMCP

- Melissa Andel, MPP, Health Policy Director, Applied Policy

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