January 2018

In This Issue

House E&C Subcommittee on Health Approves H.R. 2026 'Pharmaceutical Information Exchange (PIE) Act of 2017'

AMCP-Supported Legislation Now Goes Before Full Energy and Commerce Committee

AMCP applauds the U.S. House Energy and Commerce Committee's Subcommittee on Health for its approval Jan. 17 of H.R. 2026, the "Pharmaceutical Information Exchange (PIE) Act of 2017." The approved bill, which clarified some definitions, now goes to the full Energy and Commerce Committee for consideration.

"The Academy is very pleased with Wednesday's approval of H.R. 2026," said AMCP CEO Susan A. Cantrell, RPh, CAE. "We thank bill sponsor Rep. Brett Guthrie (R-KY) for his leadership on this important issue. The thrust of H.R. 2026 is to give health plans the economic and scientific information they need to make coverage determinations more quickly on medications in the pipeline — so that upon FDA approval patients can get access to innovative therapies sooner. For patients waiting for breakthrough medicines, every minute counts."

Cantrell also noted the bill contains requirements that communications be "truthful, nonmisleading, and based on competent and reliable scientific evidence." This, along with safeguards that communications take place only between sophisticated parties such as health plans and formulary committees ensures that such exchanges will be responsible, she added.

"The PIE Act will allow AMCP's 8,000 members — who manage pharmacy benefits for more than 270 million Americans — to more accurately forecast and make coverage decisions sooner on these emerging

products. AMCP is proud to have led on this issue on behalf of our members," Cantrell said.

AMCP in fall 2016 led a multi-stakeholder effort to develop recommendations on allowing pre-approval information exchange. H.R. 2026 closely aligns with these recommendations. For more information on AMCP's recommendations allowing pre-approval information exchange, read "Enabling the Exchange of Clinical and Economic Information Pre-FDA Approval."

Read Cantrell's Jan. 17 letter to Subcommittee Chairman Michael C. Burgess (R-TX) and Ranking Member Gene Green (D-TX).

Oversight Subcommittee Hearing: 'The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse'

House Ways and Means Oversight Subcommittee held a Jan. 17 hearing on the current condition of the opioid crisis and efforts by Centers for Medicare and Medicaid Services (CMS) to prevent opioid abuse. The hearing focused on the tools in place to collect data and the utilization of that data by CMS to take appropriate action. Current recommendations from the Office of the Inspector General (OIG) and the Government Accountability Office (GAO) were discussed with regards to improvement and impact. A summary of the hearing prepared for AMCP is located here. For more information, visit the Committee website.

AMCP To Increase Managed Care Pharmacy's Voice on Capitol Hill, State Legislatures

AMCP urges you to be ready for this Midterm Election year. This year, all 435 seats in the U.S. House of Representatives and 33 of the 100 seats in the U.S. Senate will be up for reelection. In addition, certain states will hold special elections to fill Congressional district vacancies. On the state front, 39 governorships will be up for election and 87 of the 89 state legislative chambers will hold regularly scheduled elections. In some states, elections will only be held for the lower house. In addition many states will hold primaries prior to the general election.

Every level of government will consider legislation on issues of importance to managed care pharmacy and the patient populations that you serve. AMCP encourages you to be informed about those issues and follow your elected officials on print and social media, participate in town halls and respond to surveys and opinion polls. In other words, use every available opportunity to be engaged in the legislative process. You are highly education professionals with a wealth of experience and your elected officials can greatly benefit from your voice.

This year, AMCP will increase our grassroots efforts through our VoterVoice alert system, primarily on the national level but there will be state efforts as well. We encourage you to take advantage of those grassroots efforts as soon as you see the request in your inbox. Also

Advocacy Tip

It is important to acknowledge you can be a resource for information to a legislator. At the state level, many legislators have a large number and scope of bills to consider, on many topics. Make sure you are concise and bring factual evidence to the legislator as a way of educating them on the topic and identifying yourself as a potential resource for them.

remember that the AMCP Affiliates are an excellent resource. For more information on the AMCP Affiliates, visit our website.

Regulatory Updates

AMCP Submits Comments to CMS on Medicare Advantage, Part D Proposed Rule

AMCP submitted comments on Jan. 16 to CMS on the proposed rule that amends regulations for Medicare Part C and Medicare Part D to implement provisions of the Comprehensive Addiction and Recovery Act (CARA), the 21st Century Cures Act, and also makes changes to improve program quality, accessibility, and affordability. AMCP's comments focused on the following major provisions:

- *Drug Management Programs* (also referred to as "lock-in programs") - AMCP believes that the drug management program provisions require significant revisions prior to finalization and that CMS should carefully consider whether implementation for CY 2019 is feasible.
- *Medication Therapy Management* - AMCP strongly supports the inclusion of MTM programs in the medical loss ratio (MLR) as quality improving activities.
- *Benefit Design & Utilization Management* – AMCP supports the classification of biosimilars as applicable drugs under Medicare Part D for non-LIS catastrophic cost sharing and LIS cost sharing and encourages CMS to work with Congress to address the classification of biosimilars as non-applicable drugs during the "donut hole." AMCP supports increased flexibility for sponsors to implement midyear formulary changes and recommends that CMS include interchangeable biosimilars as eligible for midyear formulary changes. AMCP does not support the any willing provider provisions due to quality and fraud, waste, and abuse concerns and recommends that CMS withdraw its proposal.
- *Health IT* – AMCP supports adoption of the updated NCPDP SCRIPT standard for e-prescribing and recommends CMS also adopt the NCPDP ePA standard to improve efficiencies in the prior authorization process, improve patient outcomes, reduce POS rejections, and improve the Medicare Part D member experience.
- *Fraud, Waste, and Abuse* - AMCP supports the inclusion of fraud prevention expenditures in incurred claims for Medical Loss Ratio (MLR) reporting purposes.

AMCP's full comments are available here.

Regulatory Actions on Opioid Epidemic

AMCP Submits Comments to FDA on Focus Areas for Opioid Policy Steering Committee

AMCP submitted comments Dec. 28, 2017, to the Food and Drug Administration (FDA) with recommendations on key focus areas of the newly established Opioid Policy Steering Committee (OPSC). Among other things, AMCP recommends the FDA ensure a robust body of evidence is available prior to proposing policy and regulatory changes for opioids; updates to labeling and packaging requirements to minimize risk of abuse and diversion; a comprehensive education strategy for health care providers and patients; and broad adoption of electronic prescribing of controlled substances. AMCP also recommended changes to federal regulations and legislation to provide Managed Care Organizations access to Prescription Drug Monitoring Programs. The full comment letter may be viewed here. Please send any questions to tlwilkins@amcp.org.

AMCP to Present at FDA Public Meeting This Month on Opioid Policy and Strategy

FDA recently announced that it plans to hold a meeting, *Opioid Policy Steering Committee - Prescribing Information - Exploring a Strategy for Implementation*, on Jan. 30 to consider steps to combat the opioid crisis. Some of the "steps" under consideration include requiring sponsors to create a nationwide prescription drug monitoring program, mandating additional prescriber documentation when prescribing opioids above a certain threshold, potentially imposing additional requirements to improve patient storage and handling of opioids and requiring sponsors to create mandatory opioid take-back programs. AMCP will be providing oral testimony during the hearing. The FDA is also accepting written comments through March 16. To learn more about the meeting or watch a live or archived telecast, visit here.

SAMHSA Releases Final Part 2 Rule and Announces Public Listening Session

The Substance Abuse and Mental Health Services Administration (SAMHSA) released a final rule of 42 CFR Part 2 on Jan. 2 to: facilitate the sharing of substance use disorder patient information for health care operations and payment purposes with patient consent; support audit and evaluation activities; and permit use of an abbreviated notice of prohibition of redisclosure that may assist users of electronic health records in which text fields and space are limited. While the proposed rule is a step in the right direction, AMCP remains concerned that the rules governing the sharing of substance use disorder records do not align with HIPPA and therefore will continue to work with SAMHSA, Congress, and stakeholders to ensure alignment to allow for disclosures for treatment and care coordination purposes.

In addition, SAMHSA announced it will hold a public listening session for 42 CFR Part 2 on Jan. 31. A requirement of 21 Century Cures, SAMHSA describes the listening session as "an opportunity to provide input concerning the effect of 42 CFR Part 2 on patient care, health outcomes, and patient privacy as well as potential regulatory changes and future subregulatory guidance." AMCP will attend the listening session along with a representative from the Partnership to Amend 42

CFR Part 2, of which AMCP is a member. The Partnership will submit comments to SAMHSA. Deadline for written comments is Feb. 28.

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 – Revisions to Medicare Part D Manual Chapter 13	Jan. 24	Jan. 31
CMS - Revisions to Medicare Part D Manual Chapter 14	Jan. 24	Jan. 31
NIH – All of Us Research Input	Feb. 1	Feb. 9
FDA – Packaging, Storage, and Disposal of Opioids	Feb. 5	Feb. 12
OIG – Solicitation of New Safe Harbors	Feb. 19	Feb. 26
SAMHSA – Confidentiality of Substance Use Disorder Patient Records	Feb. 21	Feb. 28
CMS – CY2019 Call Letter (to be released ~ Feb. 2)	Feb. 21	Mar. 2 (anticipated)
FDA – Opioid Policy & Strategy	Feb. 26	Mar. 16

Eye on States

State Legislative Activity

By next month, 46 States and the District of Columbia will have convened their 2018 Legislative sessions, with Louisiana joining in March. Montana, Nevada, North Dakota, and Texas are not scheduled to meet in 2018 unless special sessions are called. AMCP already has seen a continuation of legislation dealing with biosimilars/interchangables, medication synchronization, and PBM legislation dealing with mandated audit policies and contract provisions carried over from 2017 sessions. Drug pricing and transparency remain key issues focused on at the state level in 2018, with 8 states to date looking at Maximum Allowable Cost (MAC) pricing and "price gouging" on essential generic drugs in legislation. Legislation focused on the need to address Opioids includes prescribing limits and guidelines. AMCP continues to follow these issues and others which impact managed care pharmacy. AMCP will

communicate the principles and strategies of managed care pharmacy that are available as solutions to legislative areas of concern.

Focus on Biosimilars — To date, Alaska, Iowa, Kansas, Michigan, New Hampshire, South Carolina, and Vermont have proposed legislation or carry over proposals from the 2017 legislative sessions. Generally, these bills have similar language. AMCP is encouraged that they generally acknowledge pharmacists have the authority to substitute an interchangeable biological product, which is consistent with the Biologics Price Competition Innovation Act (BPCIA). Additionally, the language usually indicates the ability of pharmacists to substitute for a less expensive biologic/interchangeable product. However, burdensome provisions contained in the 2017 legislation proposals persist, such as additional notice and record keeping requirements not required for any other class of FDA approved drugs, as well as no requirement that prescribers maintain records, and defining drugs that are not approved as interchangeable but are considered "therapeutically equivalent" as substitutable for a biologic. AMCP will continue to advocate for amendments to these bills to address those areas of concern. Biosimilars State Tracking Chart

Upcoming AMCP Webinars

AMCP Policy & Advocacy Focus Areas in 2018

Tuesday, Jan. 30, 2pm EST

Registration

Please join us for an introduction and discussion of AMCP's Policy and Advocacy Focus Areas for 2018. This webinar will identify those focus areas, provide background on the decision making process and an overview of preliminary efforts to take "action" on this agenda.

The key issues identified as priorities for AMCP are:

- ***The Rising Cost of Medications:*** This priority will focus on how managed care pharmacy professionals improve value and outcomes for patients.
- ***Shift from Fee-for-Service to Value-Based Care:*** In this area, AMCP will advocate for legislative and regulatory initiatives that focus on shifting away from traditional payment systems to policies that provide incentives to improve outcomes. AMCP will also examine practices in value-based contracts to disseminate best practices.
- ***Opioid Management:*** In this priority area, AMCP will continue its work in key areas of opioid management, including drug management programs or lock-ins for Medicare Part D; promoting health plan and pharmacy benefit manager access to prescription drug monitoring programs; and promoting managed care pharmacy strategies that promote the appropriate use of opioids for pain and also access to medications for addiction treatment.

We will be seeking your input for ways for AMCP to make an impact in those areas as well as your commitment to participate in AMCP advocacy efforts during the year.

The webinar will be hosted by:

Public Policy Committee – Vice Chair
Brian Lehman, MHA, MBA, RPh
Strategic Consultant – Pharmacy Professional Affairs
Humana

Legislative and Regulatory Action Committee – Vice Chair
Abby Stoddard, PharmD, MBA
Government Affairs Consultant Principal
Prime Therapeutics

Implications for Managed Care Pharmacy from 2019 Part D Call Letter, Star Ratings

Tuesday, Feb. 27, 2pm EST

Registration

Join AMCP for a first look at the provisions contained in the draft 2019 CMS Medicare Part D Call Letter that is scheduled to be released by the Centers for Medicare and Medicaid Services (CMS) on February 2, 2018. This webinar will deep dive the policy provisions of importance to managed care pharmacy including medication therapy management, opioid management, specialty pharmacy, and Star Ratings for 2019 and beyond. Be one of the first to know and help inform AMCP's comments to CMS!

Speakers:

Babette Edgar, PharmD, MBA, FAMCP
AMCP Immediate Past President, 2016-2017
Principal, BluePeak Advisors

Mitzi Wasik, PharmD, BCPS, FAMCP, FCCP
AMCP President Elect, 2018-2019
Lead Business Strategy Consultant Southeast Region, Aetna

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