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Congressional Committees Focus Initial Hearings of 2019 on Pharmaceutical Pricing

Drug costs have been a focus of key lawmakers and committees on Capitol Hill in recent weeks. On Jan. 29, Rep. Elijah Cummings (D-MD), Chairman of the House Committee on Oversight and Reform, held a hearing titled “Examining the Actions of Drug Companies in Raising Prescription Drug Prices,” which featured witnesses representing academia, patients and other consumers. On Feb. 12, the House Ways and Means Committee held a hearing titled “The Cost of Rising Prescription Drug Prices,” which examined similar territory. AMCP submitted [formal comments](#) to be entered into the Congressional record on the House Ways and Means hearings.

Meanwhile, a bipartisan group of lawmakers on Feb. 5 reintroduced the “Creating and Restoring Equal Access to Equivalent Samples Act” (CREATES Act) as a sensible, efficient, market-based way for generic drug and biosimilar manufacturers to address the current tactics which delay development of generics and biosimilars. The bill, which AMCP supports, would promote the timely entry of generic and biosimilar products and increase competition in the prescription drug market by stopping activities that block access to samples. AMCP recent delivered its [own letter](#) of support to Senate leaders, and has signed onto a [joint letter](#) of 50 organizations, including AARP and AHIP, representing patients, providers and hospitals.

AMCP will actively monitor all pertinent developments on Capitol Hill and will advocate for policies and legislation that advance managed care pharmacy positions.



Eye on the States

Advocacy Tip

AMCP Monitors State Legislation Affecting Managed Care Pharmacy

As states move further into their legislative seasons, a familiar set of pharmacy and pharmaceutical-related bills are being introduced and debated.

- 25 states have introduced bills that would address practices of pharmacy benefit managers (PBMs), such as gag clauses, licensure requirements and pharmacy reimbursement rates.
- 12 states have proposed importation legislation, but any state program allowing for importation would first have to be approved by the Trump Administration.
- 14 states have introduced 25 bills addressing transparency, including legislation requiring the reporting by manufacturers or health plans on drug price increases, or the most expensive drugs a plan pays for. Drug-price reporting proposals vary on the timeline and whether they are based on a percentage increase over WAC or over a certain dollar amount.
- 26 states have introduced legislation covering a range of managed care pharmacy techniques, including formulary management restrictions (IN S.B. 585) and how prior authorizations are handled, such as by requiring Electronic Prior Authorization (IL H.B. 2160).

AMCP will continue to monitor state legislation pertinent to managed care pharmacists. While many bills may be introduced in a session, few go through the process of committee hearings, and still fewer proceed to full votes as originally drafted and without any amendments. AMCP looks to see where we can have the most impact in the legislative process to educate lawmakers on the benefits of managed care pharmacy strategies.

Regulatory Update

AMCP Comments to OCR on Modifying HIPAA Rules to Improve Coordinated Care

On Feb. 12, AMCP submitted comments to an Office for Civil Rights (OCR) [Request for Information on Modifying HIPAA Rules to Improve Coordinated Care](#). The goal of the RFI is to seek public input on ways to modify the HIPAA Rules to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination and/or case management and to promote the transformation to value-based health care, while preserving the privacy and security of protected health information (PHI).

In comments, AMCP supports Privacy Rule revisions to encourage care coordination and implementation of value-based care models by managed care organizations. AMCP noted that managed care organizations are establishing and implementing value-based care but are limited by lack of available PHI for operational, treatment and payment decisions and encouraged OCR to maintain flexibility in PHI disclosure requirements. Additionally, AMCP emphasized the negative impact CFR 42 Part 2 has had on the ability to coordinate care for patients with substance use disorders and voiced our support for the need for codification of these provisions into the HIPAA statute. AMCP's [final comments are available here](#).

CMS Issues Draft Call Letter, Proposal to Eliminate Safe Harbor for Rebates

Stay current with all of AMCP's many comments to lawmakers and regulators at our [letters and statements page](#).

AMCP MANAGED CARE &
SPECIALTY PHARMACY
ANNUAL MEETING
MARCH 25-28, 2019



The Centers for Medicare and Medicaid Services (CMS) recently issued two proposals of interest to AMCP members: (1) the annual Draft Call Letter of proposed changes to Medicare Part D in the upcoming contract year, and (2) a proposal to eliminate safe harbor protections for negotiated rebates under Part D and managed Medicaid. The AMCP regulatory affairs team strongly encourages members to share their thoughts and concerns on these proposals, which outlined below, to help inform AMCP's formal responses to CMS. The proposals are:

CMS Issues Advanced Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter

On Jan. 30, CMS released its [Draft Call Letter](#) outlining requirements for plan sponsors to participate in the Medicare Part C and D programs for the upcoming contract year. For contract year 2020, CMS proposes numerous provisions around opioids and efforts to ensure beneficiaries are receiving appropriate pain management therapy. CMS also proposes numerous updates, changes and potential new measure concepts for the Star Ratings Program. In addition, CMS is considering changing policies and is accepting comments relating to its tier composition policy for generics and specialty medications in Part D, among other provisions. AMCP has prepared a [summary of proposed provisions](#) of interest to AMCP members on the [AMCP website](#). Comments to CMS on the Draft Call Letter are due March 1.

CMS Issues Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

On Feb. 1, CMS released a [proposed rule](#) that would eliminate the safe harbor protection for rebates that exists in the federal Anti-Kickback Statute (AKS) under Medicare Part D and Medicaid programs. The proposal would also replace these protections with a proposed new safe harbor that allows for price reductions for point-of-sale discounts to beneficiaries and for manufacturer-paid service fees to PBMs. AMCP has prepared a [summary and analysis of CMS's proposal](#). Comments to CMS on this proposal are due April 8.

NOTE: Please submit feedback to AMCP on the Call Letter by Friday, Feb. 22 and removal of safe harbor proposal by Friday, March 22. You may provide feedback via email to Afton Wagner, AMCP Director of Regulatory Affairs, at awagner@amcp.org. In addition: Both topics will be discussed in educational programming during the AMCP 2019 Annual Meeting that will be held March 25-28 in San Diego, CA. Please visit: www.amcpmeetings.org.

See You at AMCP Annual Meeting 2019, March 25-28 in San Diego!

Get an update on State and Federal Legislation and Regulation at L1: Federal and State Legislative and Regulatory Update! [Register here](#).

