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# House Oversight & Reform Committee Announces Hearing on Drug Pricing Amid Continuing Government Shutdown

## FDA Grapples with Partial Lapses in Non-User Fee Funded Programs



Happy New Year and welcome to the first Legislative and Regulatory Briefing of 2019!

Congress has convened its first session of the new 116th Congress, with Democrats leading the House and Republicans controlling the Senate. As of Jan. 16th, the longest (partial) government shutdown marked its 26th day with no clear end in sight. Among other things, the shutdown has caused a partial lapse in non-user fee funded programs at the Food and Drug Administration (FDA). This has resulted in a hold on the FDA accepting new user fees for approval of new drugs and devices while it carries out critical functions for public health and

safety.

In Congress, the start of the year saw the introduction of a flurry of bills addressing drug costs. Sen. Bernie Sanders (I-VT) and Rep. Elijah Cummings (D-MD) announced three bills, currently without bill numbers or text, to combat the cost of pharmaceuticals, including a proposal to allow for drug importation from Canada. Sens. Chuck Grassley (R-IA) and Amy Klobuchar (D-MN) also introduced [Senate Bill 61](#) to allow for the personal importation of prescription drugs from approved pharmacies. AMCP does not support the importation of prescription drugs from other countries and you can read more about this in our ["Where We Stand"](#) document. In addition Rep. Cummings, who is Chairman of the House Committee on Oversight and Reform, [announced the committee](#) would launch one of the most wide-ranging investigations in decades into the prescription drug industry's pricing practices, and hold a Jan. 29 hearing on the topic.

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

## AMCP MANAGED CARE & SPECIALTY PHARMACY ANNUAL MEETING 2019

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### Eye on the States

#### Most State Legislatures Start 2019 Sessions

By Jan. 18, 44 states and the District of Columbia will have convened their legislatures for the year. AMCP expects to see the introduction of more bills similar to the one signed into law late last year in Ohio that permits health insurers to cover pharmacist-provided benefits ([S.B. 265](#)). AMCP has seen one thus far, [S.B. 108](#) in Indiana. State legislatures also have filed a myriad of legislation looking into drug pricing initiatives and the prevention and treatment of opioid use disorder at the state level. We will continue to watch and monitor state legislation which may impact the practice of managed care pharmacy.

#### AMCP to Increase Grassroots Advocacy Efforts

AMCP this year aims to build on the successful launch of its VoterVoice alert system for advocacy messaging. We encourage you to be informed about the issues affecting managed care pharmacy, and to follow your elected officials on print and social media, as well as 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 educated professionals with a wealth of experience and your elected officials can greatly benefit from your voice! AMCP also encourages you to take advantage and participate in these grassroots alerts as soon as you see them in your email. Remember that [AMCP Affiliates](#) and [State Advocacy Coordinators \(S.A.C.s\)](#) are an excellent resource too.

### Regulatory Update

#### AMCP Comments on CMS Advanced Notice of Proposed Rulemaking for IPI Model

AMCP submitted comments Dec. 31 to an [Advanced Notice of Proposed Rulemaking \(ANPRM\)](#) from CMS for a new potential International Pricing Index (IPI) Model for Medicare Part B Drugs. The IPI model is intended to lower expenditures for Part B drugs by implementing an international reference price to shift payments to a level that is comparable with prices in other countries. It also seeks to reform the current “buy and bill” system for Part B drugs and proposes alternatives to the current add-ons to the Average Sales Price (ASP)-based payments for physicians.

AMCP shares the Administration's concern about the rising costs of medications and the impact on patients, payers, and providers and, generally, we are supportive of CMS's efforts to lower prescription drug prices. However, AMCP voiced concern in our comments that some of the elements outlined in the ANPRM need further



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consideration to ensure that they are sustainable solutions for decreasing medication costs before making substantial changes to existing programs. AMCP urged CMS to consider our comments and others' comments before proposing a rule in the Spring. AMCP's final comments are available on the [AMCP website](#).

## AMCP Comments on CMS Proposed Rule for Medicare and Medicaid Programs

AMCP submitted comments Dec. 31 on a [new proposed rule](#) from CMS that would make policy and technical changes to the Medicare Advantage (MA or Part C) and the Medicare Prescription Drug Benefit (Part D) Programs. The proposed rule is intended to implement several provisions in the [Bipartisan Budget Act of 2018](#), improve program quality and accessibility, and strengthen program integrity. Proposed provisions are intended to reduce provider burden and promote flexibility and innovation that will provide MA and Part D sponsors with tools to improve quality of care and increase choice for MA and Part D enrollees.

AMCP supports CMS's efforts to provide additional telehealth benefits to beneficiaries and include telehealth as a basic benefit rather than a supplemental benefit in MA Plans. To enhance the benefit, AMCP strongly encouraged CMS to review and include pharmacists as healthcare providers under the Medicare Telehealth Benefit to enhance beneficiaries' ability to ensure optimal medication use and encouraged the use of Medication Therapy Management Services as part of telehealth benefits.

AMCP also supported CMS's proposal permitting PDP sponsors to use medical claims data to assist in care management of beneficiaries but disagreed with the proposed limitations on using these data for coverage determinations. Lastly, AMCP also supported CMS's efforts to increase transparency in the Star Ratings program to improve stability and predictability but supported CMS's alternative proposal of a three-percentage point cap instead of a five-percentage point cap for all measures, not just those measures that have been in the Part C and D Ratings program for more than three years. AMCP's final comments are available on the [AMCP website](#).

## Join AMCP's 2019 Policy and Advocacy Focus Areas Webinar on Feb. 5 at 2pm EST.

Learn more about where AMCP will focus its policy and advocacy efforts in 2019 by joining this webinar which is free to members! Tuesday, Feb. 5, 2-3pm EST. Register [here](#).



WEBINAR

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