

Health Policy Update – April 4, 2019

Azar to Reconsider IPI Drug Pricing Model

This week, four members of the House of Representatives sent letters to Health and Human Services (HHS) Secretary Alex Azar urging his department to withdraw the Administration's International Pricing Index (IPI) drug pricing model and instead work with Congress to develop market-based reforms to address prescription drug costs.

The letters, which were authored by Representatives George Holding (NC-02), Mark Walker (NC-06), Adrian Smith (NE-03), and Tom McClintock (CA-04), warned against the risks of implementing foreign price controls, arguing that doing so could jeopardize patient access to innovative therapies. Congressmen Holding and Walker also expressed opposition to the use of the Center for Medicare and Medicaid Innovation to implement the mandatory payment model.

To view the letter from Reps. Holding and Walker, [CLICK HERE](#).

To view the letter from Rep. McClintock, [CLICK HERE](#).

To view the letter from Rep. Smith, [CLICK HERE](#).

Alliance for Site Neutral Payment Reform Hosts Capitol Hill Briefing

On March 21, the Alliance for Site Neutral Payment Reform hosted a Capitol Hill briefing to outline opportunities for expanding site neutral payment policy to lower costs for patients, Medicare and taxpayers.

During the briefing, speakers representing the Alliance, Avalere and the American Academy of Family Physicians provided an overview of the Medicare payment process, discussed the real-world implications for patient and healthcare costs, and highlighted opportunities for congressional and regulatory action.

Following the briefing, representatives from the Alliance had the opportunity to speak to the *New York Times* about site neutral reforms and opportunities for cutting costs without threatening patient access to care. The resulting editorial specifically reviews provisions included in the Administration's 2020 budget proposal and the potential savings resulting from equalized payments across settings.

To read the *New York Times* editorial, [CLICK HERE](#).

To view the Alliance press release, [CLICK HERE](#).

McKesson's Ben Jones Discusses Cancer Care Policies with AJMC

In a video interview with the American Journal of Managed Care, McKesson Specialty Provider's Vice President for Government Relations and Public Policy outlined some of the most significant issues affecting community oncology

care this year. In particular, Jones highlights site neutral payments, changes to the 340B drug discount program, step therapy in Medicare Advantage plans and the Administration's International Pricing Index (IPI) drug pricing plan.

To view the full interview, [CLICK HERE](#).

Department of Justice Argues Court Should Strike Down Entire ACA

On March 25, the Department of Justice submitted a legal filing that urges the U.S. Court of Appeals for the Fifth Circuit to uphold the district court's ruling that the Affordable Care Act (ACA) – including its protections for people with preexisting conditions – should be invalidated.

In December, a federal judge found the ACA should be declared unconstitutional in its entirety, which was the position argued by the Republican attorneys general who brought the suit.

The case is currently pending before the U.S. Court of Appeals for the Fifth Circuit and may make its way to the Supreme Court.

To read the Administration's legal filing, [CLICK HERE](#).

Federal Court Strikes Down Association Health Plan Rule

On March 28, Judge John Bates of the U.S. District Court for the District of Columbia issued a ruling that rejects the Trump Administration's attempts to expand access to association health plans. The federal judge found the Trump Administration's final rule allowing associations and employers to band together to create association health plans (AHPs) goes beyond its authority under the Employee Retirement Income Security Act (ERISA).

After the Trump Administration issued its final rule to allow the creation of AHP, eleven states and the District of Columbia sued the federal government to block the rule, arguing it would weaken coverage under the Affordable Care Act.

In his ruling, Judge Bates found the final rule ran counter to "Congress's clear intent that ERISA cover benefits arising out of employment relationships." The Administration is expected to appeal.

To read the U.S. District Court for the District of Columbia's opinion, [CLICK HERE](#).

House Energy & Commerce Committee Advances Drug Pricing Bills

On March 27, the House Energy & Commerce Subcommittee on Health considered a series of bills intended to speed up competition amongst generic drug manufacturers, including the Creating and Restoring Equal Access To Equivalent Samples (CREATES) Act ([H.R. 965](#)). During the markup session, committee Republicans sought

amendments to lessen penalties against brand-drug makers and strengthen brands' defense against lawsuits, and they tried to eliminate a measure in a bill banning pay-for-delay deals that would make past settlements illegal.

Ultimately, the Democrats on the subcommittee could not secure the commitment of Republicans to vote for pay-for-delay legislation (The Protecting Consumer Access to Generic Drugs – [H.R. 1499](#)) even if it were amended. Republican amendments to both CREATES and the pay-for-delay bills were voted down along party lines.

Four other bills were passed out of the subcommittee with bipartisan support, including the Payment Commission Data Act of 2019 ([H.R. 1781](#)) to boost MedPAC's access to pricing and rebate data; the Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics Act of 2019 ([H.R. 938](#)) to limit first-approved generic makers' ability to delay rivals; and the Purple Book Continuity Act of 2019 ([H.R. 1520](#)) and the Orange Book Transparency Act of 2019 ([H.R. 1503](#)) to provide drug makers with more information on brand patents through FDA databases.

On April 3, the full House Energy and Commerce Committee advanced the six drug pricing bills to the full House including H.R. 965, H.R. 1499, H.R. 938, H.R. 1520, H.R. 1503, and H.R. 1781. All passed the committee by a voice vote.

To read more on the subcommittee mark-up, [CLICK HERE](#).

To read Chairman Pallone's memorandum to the committee, [CLICK HERE](#).

Energy & Commerce Subcommittee Chair: No Plans for 340B Oversight Hearings

On March 26, House Energy & Commerce Subcommittee on Oversight and Investigations Chair Diana DeGette (CO-01) announced the subcommittee does not intend to hold oversight hearings about the 340B drug discount program during this session of Congress. Her comments echo similar remarks made by Health Subcommittee Chair Anna Eshoo (CA-18).

During the last Congress, in which Republicans controlled the House of Representatives, lawmakers held multiple hearings on the 340B program. Administration officials and advocacy organizations, including the Pharmaceutical Research and Manufacturers of America, have indicated that 340B reform is still a priority.