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Health Policy Update – June 15, 2021

President's Budget Hearings, FDA Approval of Alzheimer's Drug Aduhelm Stir Up Drug Pricing Debate

Biden Administration officials took to Capitol Hill last week for a series of hearings on the president's budget request. The noticeable absence of any drug pricing proposals in the budget prompted questions from lawmakers about policies the administration supports and the path forward. In a hearing of the Senate Finance Committee, several Democratic members asked if the President supports Medicare negotiating drug prices directly. HHS Secretary Xavier Becerra reiterated the administration's desire to lower drug prices and work with Congress on specific reforms, including direct negotiation.

Congressional Democrats, including Speaker Nancy Pelosi (D-CA), have been outspoken in their desire to include drug pricing measures as part of the President's domestic priorities, including the American Jobs Plan and the American Families Plan. As the White House continues bipartisan negotiations on infrastructure – the subject of the American Jobs Plan – the American Families Plan is looking like an increasingly attractive vehicle for drug pricing. Since the Families Plan contains some controversial provisions, most Democrats expect it to advance under the budget reconciliation process. This lengthy process, which allows compliant legislation to pass the Senate with a simple majority vote, would not likely begin until July at the earliest.

The slim Democrat majorities in both the House and the Senate further complicate the path forward on drug pricing reform. H.R. 3, a measure that would allow the federal government to directly negotiate the prices of hundreds of high-priced Medicare drugs, passed the House in 2019, but it is unclear whether the votes exist to pass it again now. In the Senate, a group of senators led by Finance Committee Chairman Ron Wyden (D-OR) are revisiting a bipartisan proposal from last Congress that excluded drug price negotiation. Separately, Finance Committee ranking Republican Chuck Grassley (R-IA) is scheduled to meet with a group of 10 moderate House Democrats to try and forge a bipartisan, bicameral consensus on the path forward.

Perpetuating the drug pricing debate is the FDA's recent decision to approve Biogen's controversial Alzheimer's treatment, Aduhelm (aducanumab), which some argue lacks sufficient evidence of clinical efficacy. Additionally, concerns have been raised whether the new drug – priced at $56,000 annually – would or should be easily accessible to patients. A spokesperson from CMS confirmed to Inside Health Policy that the agency is still reviewing the FDA's decision and had yet to announce reimbursement plans, which could come in the form of a national coverage determination (NCD).

The Institute for Clinical and Economic Review (ICER), among others, have criticized the FDA's decision on the grounds that there is insufficient evidence to demonstrate Aduhelm's effectiveness in slowing disease progression and that the current price tag is too high given the uncertainties of the drug's benefits.

To view the Senate Finance hearing on the president's budget, CLICK HERE.

To view the House Ways and Means hearing on the president's budget, CLICK HERE..

To view ICER's statement on Aduhelm, CLICK HERE.

HHS Provides Additional Guidance on Terms and Conditions Associated with Provider Relief Funds

On June 11, HHS posted revised guidance for healthcare providers receiving Coronavirus-related Provider Relief Funds (PRF). Congress first authorized the PRF in March 2020 as part of the CARES Act, distributing funds in tranches as available. Under the original terms and conditions of the program, healthcare providers accepting funds must use them by June 30, 2021, or return any surplus. Considering some providers only recently received PRF dollars, a number of stakeholders requested an extended deadline to use the provided funds.

Friday's revised guidance adjusts use-of-fund deadlines depending on when providers first received their PRF payment(s). For providers receiving PRFs prior to June 30, 2020, their deadline to use funds remains unchanged – June 30, 2021. For providers receiving PRFs between July 1, 2020-December 31, 2020, their deadline to use funds is pushed back an additional 6 months, to December 31, 2021. Providers receiving funds in the first 6 months of 2021 can continue to use funds until June 30, 2022, and any future PRF payments made after July 1, 2021 must be used or returned by December 31, 2022.

The guidance also updates the associated PRF reporting timelines.

To read the HHS press release on the revised PRF timelines, CLICK HERE.

To read the updated HHS guidance on the PRF, CLICK HERE.

CMMI Director Fowler Discusses Mandatory Payment Models, Public Option, Drug Pricing Reform

On June 3, Center for Medicare and Medicaid Innovation (CMMI) Director Liz Fowler gave extensive insight into the Biden Administration's healthcare agenda during an interview with *Health Affairs*. Her hour-long remarks covered a wide variety of topics including mandatory payment models, the potential of a public option health plan, and the Trump Administration's Most Favored Nation Model for Medicare Part B drugs.

In discussing the need to implement advanced payment systems that are value-based, Fowler said it's too "comfortable [for providers] to remain" in Medicare fee-for-service. Moving forward, Fowler expressed support for expanding mandatory payment models in order to eliminate the biases and risk selection of voluntary models. Mandatory value-based models represent an idea that was also

supported by CMMI directors under the Trump Administration. Though Fowler recognized there are some disadvantages to the mandatory approach, she expressed optimism that they would improve quality for patients and result in cost-savings for the Medicare and Medicaid programs.

Director Fowler also said that the Biden Administration will continue to prioritize the creation of a public option health plan, though she left unanswered questions about how or when such a policy would be designed and implemented – instead stressing the need for Congress and state governments to work through issues such as how to set reimbursement rates and how to ensure a healthy level of competition in the healthcare marketplace.

Finally, Fowler provided some additional insight into the Biden Administration's thinking on potential drug pricing models, including the Most Favored Nation Model that was proposed by the Trump Administration late last year, which has since been blocked by federal courts. Her remarks suggested that the Biden Administration will first try to work with Congress on drug pricing solutions before considering options under CMMI's authority.

"Let's see what Congress can do because it's a lot easier to make progress on this issue there," she said. "But if that's not possible, I think we stand ready to work with them and look and see how far we can get."

To watch Liz Fowler's interview with *Health Affairs*, CLICK HERE.

Lawmakers Send Letter to CMMI Director Fowler Urging Improved Transparency, Stakeholder Engagement

A bipartisan group of lawmakers sent a letter last week to CMMI Director Liz Fowler, urging her to provide more transparency around the development and refinement of its payment models and improve engagement with stakeholder groups.

"As we look towards the future of CMMI, we believe it will be stronger with greater transparency and increased participation from stakeholders," the letter reads. "We believe in greater use of real-time data to immediately understand the impact of models on healthcare providers and patients so that decisions can be made quickly about the value of a demonstration."

The letter, which was led by Representatives Terri Sewell (D-AL) and Adrian Smith (R-NE), along with 24 other co-signers, suggested that CMMI needs to revert to its intended mission of carrying out demonstration projects of limited scope and duration to test new payment and delivery concepts. The letter asks that the agency reveal the modeling data and assumptions that inform its decision making, making such information available to stakeholders beforehand.

It also noted that CMMI tends to produce models that have been "biased towards savings rather than improving beneficiary health or addressing health disparities."

To read the letter, CLICK HERE.

340B Update: Biden Administration Asks Congress for More Resources to Audit Drug Discount Program

Included in the Biden Administration's budget proposal unveiled on May 28 is an important request related to the 340B Drug Pricing Program. The proposal calls for appropriating $17 million in 2022 for operations and oversight of the 340B program, a $7 million increase over 2021 levels. In addition, the administration's budget asks Congress to grant HHS the power to audit hospitals' records to understand how savings from the program have been spent and calls for increasing expenditures to set up a 340B dispute resolution process, which is currently the subject of litigation.

On the same day the President's budget proposal was released, the American Hospital Association (AHA) filed a brief in their petition asking the U.S. Supreme Court to reverse an appeals court decision related to the 340B program. The petition seeks to overturn a ruling that upheld HHS' statutory authority to impose significant reimbursement cuts to hospitals participating in the 340B Drug Pricing Program. The Supreme Court is expected to soon decide whether or not it will take up the case, along with a separate AHA case regarding site-neutral reimbursements for hospital provider-based departments ((PBDs).

In related news, several drug manufacturers filed motions to delay a deadline to respond to HHS' demand that they resume drug discounts to low-income health providers while lawsuits against the government play out. On May 27, the U.S. District Court for the Southern District of Indiana extended the compliance deadline for Eli Lilly. On June 1, the U.S. District Court for the District of New Jersey rejected similar motions filed by Sanofi and Novo Nordisk. If the Health Resources and Services Administration (HRSA) determines that a drug company has sold a product to an entity at an incorrect price, it may be subject to civil monetary penalties.

In a budget hearing last week, HHS Secretary Xavier Becerra, asked about pharmaceutical manufacturers found noncompliant with the 340B program said, "you violate the law, you pay the consequences." He also urged Congress to further clarify the program's statutory language.

To read the FY2022 HRSA budget justification, CLICK HERE.

To view the AHA's two reply briefs, CLICK HERE.and HERE.

To read the motion filed by Eli Lilly, CLICK HERE.

ICER Announces New Project to Study Insurer Drug Coverage Policies

The Institute for Clinical and Economic Review (ICER) recently announced that it plans to study health plan utilization management practices. According to its announcement, the project will focus on cost sharing, clinical eligibility, restrictions on prescriber qualifications and step therapy. ICER has historically focused its analyses on pharmaceutical products and whether they are cost-effective and fairly priced for patients, but now will be devoting more attention to whether health insurance coverage provides fair access to those drugs.

Last year, ICER published new criteria for using cost-sharing and prior authorization. The forthcoming report will apply these criteria to coverage policies for 28 different drugs. In May, ICER published a protocol outlining how it will conduct its first assessment of how well insurer coverage policies align with a set of fair access standards developed with the input of patient advocates, clinicians, specialty societies, payors and pharmaceutical manufacturers. The first annual assessment is expected in October 2021.

To view ICER's protocol for fair access assessment, CLICK HERE.

To view ICER's plan and full timeline for the project, CLICK HERE.