Thursday, March 21, 2019

IPI Model Critics Express Concern with Patient, Stakeholder Impacts

Recent op-ed columns published in *Morning Consult* and *American Spectator* raise concerns with the administration's proposed International Pricing Index (IPI) model for Part B drugs. **Read below.**

Trump Administration Releases FY2020 Budget Proposal

The Trump Administration unveiled its fiscal year 2020 budget request to Congress. The $4.7 trillion spending proposal includes a number of healthcare-related provisions such as cuts to the Medicaid program as well as new funding to combat HIV/AIDS. **Read below.**

Alex Azar Testifies Before Congressional Committees

Over the past two weeks, Health and Human Services Secretary Alex Azar testified before the House Energy & Commerce, House Appropriations, and Senate Finance Committees on the Department's FY 2020 budget request. **Read below.**

MedPAC Releases March 2019 Report to Congress

On March 15, the Medicare Payment Advisory Commission (MedPAC) released the first of its two annual reports to Congress. **Read below.**

Ned Sharpless Appointed Acting FDA Commissioner

On March 12, the Trump Administration announced that Ned Sharpless, the current director of the National Cancer Institute (NCI) would serve as the acting commissioner of the Food and Drug Administration starting in April. **Read below.**

Bipartisan Lawmakers Urge HHS to Maintain Protected Drug Classes

On March 13, a bipartisan group of over 70 lawmakers submitted a letter to Department of Health & Human Services (HHS) Secretary Alex Azar expressing opposition to HHS' proposal to weaken coverage protections in six classes of drugs—particularly for HIV drugs. **Read below.**

CMS Releases Updated Drug Pricing Data

On March 14, the Centers for Medicare & Medicaid Services (CMS) released new data on drug prices in the U.S. The research shows the biggest spending increases in Medicare and Medicaid occurred for drugs for which there is only one manufacturer. **Read below.**

IPI Model Critics Express Concern with Patient, Stakeholder Impacts

Recent op-ed columns published in *Morning Consult* and *American Spectator* raise concerns with the administration's proposed International Pricing Index (IPI) model for Part B drugs.

A March 21 column by The Network's Lucy Langer, MD published in *Morning Consult*, "For Oncologists, Trump's Medicare Part B Plan Makes Treating Cancer Harder," states that while the goals of the IPI Model are well-intended, it will result in unintended consequences for patients without lowering drug costs. She further encourages the adoption of more patient and physician centered approaches to lowering drug costs over mandatory demonstration programs.

A March 18 column in *American Spectator*, "Part B Drug Reforms Do Not Put American Patients First," points out that the model, if implemented as proposed, would put American patients second to bureaucratic drug price controls of foreign governments and healthcare decision making of third-parties.

To read the *Morning Consult* op-ed, CLICK HERE.

To read the *American Spectator* op-ed, CLICK HERE.

Administration Releases 2020 Budget Proposal

The Trump Administration released its budget plan for FY 2020. The budget details legislative and regulatory priorities for next year including policies under the Department of Health and Human Services (HHS) designed to reduce the cost of prescription drugs, lower Medicare spending and increase funding for the Food and Drug Administration (FDA). HHS Secretary Alex Azar will testify before three key congressional committees this week to discuss the proposed budget. Here are the highlights:

Medicare Payment Policy

- Pay all off-campus hospital outpatient departments at the physician office rate
- Pay on-campus hospital outpatient departments at the physician office rate for certain services
- Create a risk-adjusted monthly Medicare Priority Care payment for primary care providers by reducing payments for all non-E/M services and procedures

Drug Pricing Policy

- Establish an inflation limit for reimbursement of Medicare Part B drugs
- Authorize the HHS Secretary to consolidate certain drugs covered under Part B into Part D
- Reduce payment for innovator drugs from ASP plus 6 percent to ASP minus 33 percent when a manufacturer takes anti-competitive action post-primary patent expiration or market exclusivity period expiration

- Allow CMS to apply savings from a reduction in payment to hospitals for drugs purchased under the 340B Drug Pricing Program to hospitals that provide a certain amount of charity care
- Grant broad regulatory authority for the 340B Drug Pricing Program to set enforceable standards of program participation and requires all covered entities to report on use of program savings
- Establish a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase
- Provide demonstration authority for up to five States to test drug coverage and financing reforms in their Medicaid programs

HHS, NIH and FDA Funding

- Includes $87.5 billion in funding for HHS, a $11.9 billion decrease over FY19 levels
- Includes $33.7 billion in funding for NIH, a $4.5 billion decrease over FY19 levels
- Includes $6.1 billion in funding for FDA, a $643 million increase over FY19 levels
- The President's budget is largely a messaging activity to highlight policy areas of interest for the Administration and would require additional regulations or legislation before being enacted.

To view the HHS FY 2020 Budget, CLICK HERE.

To view the FY 2020 fact sheet on Lowering Drug Prices, CLICK HERE.

To read the Alliance for Site Neutral Payment Reform's statement, CLICK HERE.

Alex Azar Testifies Before Congressional Committees

Over the past two weeks, Health and Human Services (HHS) Secretary Alex Azar testified before the House Energy & Commerce, House Appropriations, and Senate Finance Committees on the Department's FY 2020 budget request. In all three hearings, lawmakers questioned Azar about a variety of healthcare issues, including HHS' various proposals to lower prescription drug prices.

Azar faced questions about the possibility of Medicare negotiating drug prices in Part D, which he rejected, saying such a move would require a national formulary which raises access questions. He also defended the Administration's proposal to create exceptions to the protected class drug policy in Part D, asserting that plans currently do not have negotiation power on such drugs.

To view the Energy & Commerce Committee hearing, CLICK HERE.

To view the House Appropriations Committee heating, CLICK HERE.

To view the Senate Finance Committee hearing, CLICK HERE and HERE.

MedPAC Releases March 2019 Report to Congress

On March 15, the Medicare Payment Advisory Commission (MedPAC) released the first of its two annual reports to Congress. The report includes MedPAC's analyses of payment adequacy in fee-for-service (FFS) Medicare and reviews the status of Medicare Advantage (MA) and the prescription drug benefit, Part D. Following tradition, the commission will hold a public meeting next month to discuss the report's recommendations to Medicare's payment policy.

In the report, MedPAC expressed concern that last year's update to the Medicare Part D donut hole policy which now mandates that drug makers cover 70 percent of drug costs, while lowering the amount that insurance companies must cover from 20 percent to 5 percent. MedPAC is concerned the policy is actually creating incentives for insurance plans to get patients to the coverage gap as quickly as possible, fueling higher prices for Medicare and beneficiaries. MedPAC found that Medicare's spending in the catastrophic phase is growing at a rate of nearly 17 percent annually — faster than any other segment of Medicare Part D. More than 360,000 beneficiaries spent more than $5,000 on a single prescription in 2016, a tenfold increase from 2010.

Though MedPAC didn't adopt a specific policy recommendation for Congress to address drug prices, several members of the commission expressed support for a drug arbitration process. The system that they envision will empower a neutral agent to decide on a price for drugs purchased under Medicare Part B if they meet certain criteria.

To read MedPAC's March 2019 report to Congress, CLICK HERE.

To read more about the upcoming MedPAC meeting, CLICK HERE.

Ned Sharpless Appointed Acting FDA Commissioner

On March 12, the Trump Administration announced that Ned Sharpless, the current director of the National Cancer Institute (NCI) would serve as the acting commissioner of the Food and Drug Administration starting in April. The announcement came a week after FDA Director Scott Gottlieb unexpectedly decided to step down from the agency.

Sharpless has an extensive background in science and medicine, serving as head of the Lineberger Comprehensive Cancer Center at the University of North Carolina before taking the reins at NCI in October 2017. He also co-founded two early-stage biotech companies: G1 Therapeutics, a developer of cancer drugs that raised $108.6 million in a 2017 initial public offering, and HealthSpan Diagnostics, a developer of blood tests.

Bipartisan Lawmakers Urge HHS to Maintain Protected Drug Classes

On March 13, a bipartisan group of more than 70 lawmakers submitted a letter to Department of Health & Human Services (HHS) Secretary, Alex Azar, expressing opposition to HHS' proposal to weaken coverage protections in six classes of drugs—particularly for HIV drugs.

The letter, spearheaded by Representatives Barbara Lee (D-CA) and Will Hurd (R-TX), expressed concern that prior authorization and step therapy requirements could adversely affect patients and public health. The lawmakers worry that patients will be forced to take less-effective drugs, which could lead to significant complexity, pain, and side effects. Finally, the lawmakers informed Secretary Azar that the HHS proposal could exacerbate health disparities in low-income and minority communities.

To read the full text of the letter, CLICK HERE.

CMS Releases Updated Drug Pricing Data

On March 14, the Centers for Medicare & Medicaid Services (CMS) released new data on drug prices in the U.S. The research shows the biggest spending increases in Medicare and Medicaid occurred for drugs for which there is only one manufacturer. Even when a range of treatments are available for a particular disease like cancer, the lack of price competition for branded drugs is a driver of higher prices.

According to CMS, physician-administered drugs in Medicare Part B with the largest dollar change in annual spending tended to be single-source drugs. Furthermore, over 120 Medicare Part D drugs—all but one are manufactured by just one company—had an increase in average unit price of at least $35 dollars between 2016 and 2017. Part D spending jumped by hundreds of dollars per dose for dozens of products, with a handful going up by more than $1,000.

To view the new drug pricing data, CLICK HERE.