Wednesday, September 8, 2021

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Bipartisan Lawmakers Urge Creation of Non-Branded Specialty Formulary Tier

On August 25, Representatives Annie Kuster (D-NH) and David McKinley (R-WV) sent a letter to the Centers for Medicare & Medicaid Services (CMS) urging the agency to create a preferred formulary tier within Medicare Part D exclusively for generics and biosimilars that would not be open to branded drugs. **Read below.**

Medicare Trustees Report Finds Part A Reserves to be Exhausted by 2026

On August 31, the Medicare Board of Trustees released its annual report on the status of the program's finances, projecting that the Hospital Insurance Trust Fund (Part A) will be exhausted by 2026 - the same projection as last year. **Read below.**

Employers Could Save $14.1 Billion Annually by Shifting Care Away from Hospital Outpatient Departments

A new study from the Employment Benefit Research Institute found that employers and workers could save $14.1 billion annually if price differentials between hospital outpatient departments (HOPDs) and physician offices were eliminated for all physician-administered outpatient drugs (PAODs). **Read below.**

FULL STORIES

House Passes $3.5 Trillion Budget Resolution, Advancing Process for Expansive Reconciliation Bill

After a prolonged standoff between House Democratic leadership and a group of moderate members of the caucus, the House of Representatives advanced a $3.5 trillion budget resolution by a party line vote (220-212) on August 24. In a bid to secure the support of moderate members, House leadership agreed to hold a standalone vote on the bipartisan infrastructure bill – which passed the Senate in July – by September 27.

Attention now shifts to negotiations on the expansive budget reconciliation bill, through which Democrats are planning to pass the bulk of President Biden's first-term agenda, including health care priorities such as expanding Medicare to include hearing, vision and dental benefits, closing the Medicaid coverage gap, additional funding of paid sick and family leave, significant investments in home care and childcare programs, and making permanent the expanded Affordable Care Act subsidies.

Democrats are also working to include provisions allowing Medicare to directly negotiate prescription drug prices. The proposal could be modeled on the Elijah Cummings Lower Drug Costs Now Act – better known as H.R. 3 – that would use international reference pricing as the basis for Medicare drug price negotiations and apply those new prices to the private market. Other options have been floated, such as a measure to use "domestic reference pricing" that would use cost-effectiveness analyses and health technology assessments as the basis for price negotiations. An updated model from the Congressional Budget Office found that H.R. 3 would lead to two fewer new drugs in the first decade and 23 fewer over the next decade – a smaller impact on pharmaceutical industry innovation than what was projected in 2019.

Speaker Pelosi has instructed House committees to write, markup, and report their bills to the Budget Committee by September 15, though that timeline could slip. Democrats face an uphill challenge with a variety of industries coming out in opposition to proposals floated for the reconciliation bill. The Pharmaceutical Research and Manufacturers Association (PhRMA) has reportedly spent millions of dollars in a campaign against the drug negotiation proposals, and the U.S. Chamber of Commerce and the Business Roundtable are among several organizations preparing to fight proposed corporate tax increases. The timeline is further complicated by the other critical issues that need to be addressed by Congress this fall, such as funding the government, raising the debt ceiling, and the promised vote on the bipartisan infrastructure bill.

To view the new CBO report on drug development, CLICK HERE.

HHS to Establish Bureau to Oversee Pandemic Provider Relief

On August 31, the Biden Administration unveiled plans to reorganize the agency in charge of overseeing provider relief under the Health Resources and Services Administration (HRSA). In a plan published in the Federal Register, the new Provider Relief Bureau would absorb the Office of Provider Support's three divisions. While the divisions for customer support and data analytics/program integrity would remain unchanged, the old division of provider support will be replaced with the division of policy and program operations in order to better manage and distribute Provider Relief Funds (PRFs) appropriated by Congress in 2020.

The reorganization comes just days after it was reported that the Biden Administration hired several

independent contractors to help oversee and audit how PRFs are being distributed. According to reports, the auditing process will begin after September 30, when the first round of financial reports for the program are due. To date, the Department of Health and Human Services (HHS) has yet to distribute more than $50 billion – or roughly 25% of the total $187 billion appropriated by Congress – to help providers navigate the economic challenges of the COVID-19 public health emergency. Records show that the pace of funds has slowed in 2021, with the last major distribution occurring in October 2020.

With the Delta variant causing COVID-19 cases to once again skyrocket, providers and lawmakers are urging HHS to release its plan to distribute the remaining PRFs. On August 26, a bipartisan group of 43 Senators, led by Susan Collins (R-ME) and Jeanne Shaheen (D-NH) submitted a letter to HHS Secretary Xavier Becerra urging the department to clarify how it will spend the remaining funds that have been appropriated.

To view the HRSA notice about the reorganization in the Federal Register, CLICK HERE.

To view the new Provider Relief Bureau's website, CLICK HERE.

To read the bipartisan Senate letter to HHS Secretary Becerra, CLICK HERE.

CMS Delays Enforcement of Insurer Transparency Rules by 6 Months, Chamber of Commerce Drops Lawsuit

On August 20, the Centers for Medicare & Medicaid Services (CMS) released new guidance on how it will implement the insurer price transparency rule scheduled to go into effect on January 1, 2022. According to the guidance, the department will delay enforcement of the Transparency in Coverage final rule by an additional six months (until July 1, 2022) to give health plans additional time to comply. Recognizing that it will take significant resources and time for stakeholders to create publicly available, machine-readable files detailing rates, the department will also hold off on enforcing the first requirement for reporting until December 27, 2022. Additionally, HHS also indefinitely delayed the enforcement of the requirements that plans disclose prescription drug prices pending new rule making.

After CMS made the announcement to delay enforcement, the U.S. Chamber and the Tyler Area Chamber of Commerce (TX) dropped their lawsuits challenging the rule. The now withdrawn suit had argued that the requirement to disclose prices in machine-readable files is burdensome, can lead to higher healthcare costs and goes beyond federal regulatory authority.

To read the new guidance released by CMS on the price transparency rule, CLICK HERE.

Bipartisan Lawmakers Urge Creation of Non-Branded Specialty Formulary Tier

On August 25, Representatives Annie Kuster (D-NH) and David McKinley (R-WV) sent a letter to Centers for Medicare & Medicaid Services (CMS) urging the agency to create a preferred formulary tier within Medicare Part D exclusively for generics and biosimilars that would not be open to branded drugs. The policy builds on a recent CMS rule, the Contract Year 2022 Medicare Advantage (MA) and Part D Final Rule, that lets MA and Part D plans use a second, preferred specialty tier to increase their leverage with drug manufacturers in price negotiations.

“It is critical that CMS increases Medicare savings and addresses the abusive gaming tactics that are keeping lower-cost generic and biosimilar medicines out of patients’ hands,” the Members said in a press release accompanying the letter. “Most importantly, these solutions will ensure that millions of Medicare beneficiaries are able to fully realize the benefits from lower-cost generic and biosimilar medicines.”

The lawmakers also propose CMS set a coinsurance percentage for the new specialty tier that is significantly lower than the co-insurance for the non-preferred specialty tier.

To view the Kuster-McKinley letter, CLICK HERE.

To read more about the CY2022 MA and Part D Final Rule, CLICK HERE.

Medicare Trustees Report Finds Part A Reserves to be Exhausted by 2026

On August 31, the Medicare Board of Trustees released its annual report on the status of the program’s finances, projecting that the Hospital Insurance Trust Fund (Part A) will be exhausted by 2026 – the same projection as last year.

The impact of the COVID-19 pandemic apparently overall had a limited net impact on the program’s expenses. Though the initial surge in layoffs at the start of the public health emergency – which lowered payroll tax collections – coupled with increased expenses tied to COVID-19 hospitalizations, testing and vaccines for Medicare enrollees had a negative impact on the program’s solvency, these effects were mostly offset by a significant decline in non-COVID care and especially elective procedures.

The report also provided insight into demographic changes that occurred as a result of the pandemic. U.S. mortality rates are expected to be elevated by 15 percent over pre-pandemic norms in 2021 and not return to normal levels until 2023. Further, lower immigration and depressed fertility rates will also have a significant effect on the trust fund in the short term – though the long-term effects on the Medicare system remains unclear as the pandemic still appears far from over.

To read the Medicare Trustees report, CLICK HERE

Employers Could Save $14.1 Billion Annually by Shifting Care Away from Hospital Outpatient Departments

A new study from the Employment Benefit Research Institute found that employers and workers could save $14.1 billion annually if price differentials between hospital outpatient departments (HOPDs) and physician offices were eliminated for all physician-administered outpatient drugs (PAODs).

The authors note that waste from site-of-service price differentials is being compounded by two other trends: the shifting of care from physician offices to more costly HOPDs and the fact that HOPD prices are growing faster than physician office prices.

- Just over one-half of PAODs were administered in HOPDs. One-third were administered in a physician’s office (PO), and 9 percent were received in other settings, such as a patient's home.
- On average, plan payments to HOPDs were triple what plan payments were to POs for the same unit of medication. In the aggregate, employers and workers would collectively save

$10.3 billion annually if price differentials between HOPDs and POs were eliminated for the 72 PAODs examined in this analysis. If the savings is extended to all PAODs, aggregate savings would be $14.1 billion each year.

- On a per-member, per-year basis, savings would be $80.21 for the 72 drugs examined in this analysis and $110.03 for all PAODs if price differentials between HOPDs and POs were eliminated.

To read the full study, CLICK HERE.