Health Policy Update – February 9, 2021

Congressional Democrats Push Forward with Budget Reconciliation to Pass Biden COVID Relief Package

On February 5, the Senate passed a budget resolution, the first step toward enacting President Biden's $1.9 trillion COVID-19 relief package. After nearly 15 hours of amendment debate, the Senate voted 51-50 along party lines to adopt the resolution, with Vice President Kamala Harris casting the tie-breaking vote. Congressional Democrats are aiming to use the budget reconciliation process to pass the legislation, which would enable the Senate to approve the measure with just 51 votes, instead of the 60- vote threshold typically required. The House passed the concurrent budget resolution later Friday, activating instructions to multiple committees tasked with writing the legislative text of the COVID relief package.

Biden's plan includes sending a new round of $1400 stimulus checks to Americans, increasing and extending the weekly federal unemployment benefit, and providing billions of dollars in aid to states, communities and schools. House Speaker Nancy Pelosi has laid out a timeline to pass the new relief bill by the end of the month, as current unemployment benefits expire on March 14.

Using the budget reconciliation process enables Democrats to pass the relief bill without buy-in from Republicans, who have said they prefer a smaller, more targeted package. Reconciliation has been used previously to pass the health care reform law in 2010 and the tax reform law in 2017.

To view the Biden Administration's COVID-19 relief proposal, CLICK HERE.

To view the text of the concurrent budget resolution, CLICK HERE.

President Biden Issues Executive Order to Re-Open Federal Health Insurance Exchanges

On January 28, President Biden signed an Executive Order re-opening federal health insurance exchanges. Under the EO, health insurance exchanges administered by healthcare.gov will open for a three-month enrollment period, beginning February 15, to help individuals who may have lost their employer-provided insurance as a consequence of the pandemic. Normally, individuals and families can only enroll during the six-week "open enrollment" period near the end of each year.

The EO does not affect state-run insurance marketplaces which currently exist in 15 states, though some have already opened their exchanges for a special enrollment period. The Biden Administration also directed federal agencies to re-examine Trump Administration policies related to Medicaid and the Affordable Care Act and determine whether changes are needed to make "high-quality healthcare accessible and affordable for every American."

To view the Executive Order, CLICK HERE.

To view a fact sheet on the Executive Order, CLICK HERE.

Medicare Part D Rebate Rule Delayed until 2023

On January 30, the U.S. District Court for the District of Columbia ordered HHS to postpone the effective date of the rebate rule to January 1, 2023. On January 12, 2021, the Pharmaceutical Care Management Association (PCMA) filed suit in the District Court, arguing that the federal government did not follow the Administrative Procedure Act by finalizing the rule in November 2020 after withdrawing the proposed rule in July 2019 and not providing a formal notice and comment period.

The PCMA had asked the court to strike down the rebate rule or to delay the 2022 implementation date. While the court delayed the rule pending review by the new administration, it did not rule on the provisions of the rebate rule itself. With the case now in abeyance, the court ordered HHS and the PCMA to submit a joint status report outlining whether and how the case should proceed by April 1.

The Part D Rebate Rule was originally proposed in January 2019 as part of the Trump Administration’s push to lower the cost of prescription drugs. At the time, HHS Secretary Alex Azar argued the rule would end a “shadowy system of kickbacks” and help deliver much-needed discounts to seniors directly. The Trump Administration later backed off the rule after it was projected to raise Medicare premiums and government spending but chose to finalize the rule after the 2020 election.

To read the January 30 court order, CLICK HERE..

To read the HHS November 2020 press release announcing the final rule, CLICK HERE.

Incoming Senate Finance Chairman Ron Wyden Talks Drug Pricing Reforms

In a call with reporters mid-January, Senator Ron Wyden (D-OR) said he would push for Medicare drug negotiations in his new role as chairman of the Senate Finance Committee.

Last Congress, Senator Wyden, then-ranking member of the Finance committee, authored a bipartisan bill, S. 2543, with then-Chairman Chuck Grassley (R-IA) that would have penalized drug makers for price increases above inflation and redesigned the Medicare Part D benefit to cap seniors’ out-of-pocket costs. While the bill passed the committee with the support of some Republicans, it was blocked from coming to the floor by then-Majority Leader Mitch McConnell (R-KY).

In December 2019, the House passed H.R. 3, which would have empowered the Medicare program to negotiate the price of up the 250 drugs that currently lack competition using an international pricing index as a basis for negotiations and penalizing drug makers who fail to participate. Those prices would then be extended to the commercial market. That legislation passed the House along a mostly party-line vote of 230-192 with only two Republicans voting in favor. The bill was a non-starter for the Republican-controlled Senate.

This time around, with a narrow Democratic majority in the House and an evenly divided Senate, Senator Wyden said, "I intend to start the agenda here with both what we did in the Senate Finance Committee and what the House is doing — a common sense change to change the rules so Medicare can use its leverage in the marketplace," Wyden told reporters. "It just defies common sense to not have the government do that."

While it would be difficult to pass significant drug pricing reforms with the 60-vote threshold in the Senate, it is possible Democrats may try to use the reconciliation process to pass such legislation with only a simple majority. “I think we’ve got to take bold action on prescription drug prices,” Wyden said. “We’re going to be looking at all the tools to get this done.”

To view a summary of H.R. 3, CLICK HERE.

To view a summary of the S. 2543, CLICK HERE.

CMS Issues Mid-Build Exception Determinations Under Site Neutral Law

On January 19, the Centers for Medicare & Medicaid Services (CMS) announced its determinations for “mid-build” exceptions to hospital outpatient departments (HOPDs) who applied for an exception from CMS’ site neutral payment policy. The decision means hospitals whose requests were rejected will face retroactive Medicare pay cuts for services that were billed at a higher rate but now fall under CMS’ site neutral payment policy.

Under the Bipartisan Budget Act of 2015, CMS was required to equalize reimbursement for some health care services provided in HOPDs, which bill Medicare under the Outpatient Prospective Payment System (OPPS), to match the Physician Fee Schedule (PFS) rates. But the changes only applied to newly built or newly acquired facilities. Existing HOPDs could continue to be paid as they were before the site neutral changes were implemented. The 21st Century Cures Act gave some providers the ability to claim an exception from the site neutral payment changes if they could demonstrate that the facility was “mid-build” at the time the site neutral payment changes were enacted.

The agency rejected more than 60% of requests for mid-build exceptions it received, totaling 202 out of 334.

Groups representing hospital stakeholders were critical of the decision, arguing that CMS’ review process was flawed and that it is unfair to penalize hospitals in the midst of the COVID-19 public health emergency. At a minimum, the hospitals argue that the payment cuts should not be retroactive, and that CMS should establish a clear and consistent process for reviewing mid-build exceptions.

To view a fact sheet from CMS outlining its mid-build exception determinations, CLICK HERE.

States Move Forward with Drug Importation, Reference Pricing Legislation

In recent weeks, several states have taken their first step to allowing for the importation of prescription drugs from Canada which was permitted by a rule finalized by the Trump Administration last year. In Florida, state officials are moving to outsource its drug importation plans to a private company to allow Canadian drugs to be used by state agencies including the Medicaid program and state-run correctional and mental health facilities. Meanwhile, state officials in Colorado aim to allow individuals to buy imported drugs at their local pharmacy and give health insurance plans the option to include imported drugs in their benefit designs.

Late last year, the Pharmaceutical Researchers and Manufacturers of America (PhRMA) filed a lawsuit challenging the drug importation rule. The Biden Administration has until March 30, 2021 to respond to the suit after having been granted an extension by U.S. District Court for the District of Columbia last week.

In addition, lawmakers in at least 5 states, including North Dakota, Oklahoma, Hawaii, Maine and Rhode Island introduced legislation to tie the prices of some prescription drugs to prices paid in Canada. The efforts are based on a model bill prepared by the National Academy of State Health Policy (NASHP) which would use internationally referenced rates to cap prices paid for the 250 most costly drugs to a level of the cheapest prices available among Canada’s four largest provinces.

The new prices would be made available to commercial payers, including employer-sponsored plans, people without insurance and Medicare Advantage plans. Medicaid and traditional Medicare would be excluded as they are federal programs.

To view the NASHP model legislation, CLICK HERE.