UnityPoint Health Federal Update – January 2022

December 17, 2021 – January 14, 2022

December 17, 2021

Congress

Senate Committees Release BBB Text, as Negotiations and Meetings with Parliamentarian and Continue. This week, Congress completed action on its final "must pass" items of the year, including raising the debt limit and finalizing the annual defense authorization bill. At the same time, all eyes remained on the Senate to see whether Democrats would act on the Build Back Better (BBB) Act before the end of the year.

Since the House approved its version of BBB on November 19, Senate Democrats have been working with the Senate Parliamentarian on issues related to the so-called "Byrd Rule," which dictates what types of provisions can advance in legislation considered under the budget reconciliation process. In addition, negotiations have been ongoing among the President, Democratic leaders and Senator Joe Manchin (D-WV) regarding his concerns with the size and scope of the legislation as well as particular provisions.

On December 11, key Senate committees unveiled their draft BBB texts, including the Finance Committee and Health, Education, Labor and Pensions (HELP) Committee (drafts found here and here, respectively). When compared with the House-passed bill there were notable health-related changes in the Finance and HELP drafts. Some highlights of health care changes include, but are not limited to:

- Removing the House bill's 12.5% cut to disproportionate share hospital (DSH) payments to hospitals in non-Medicaid expansion states.
- Eliminating regulatory requirements related to skilled nursing facility (SNF) staff-to-patient ratios that were included in the House bill.
- On Home and Community Based Services (HCBS) in Medicaid, removing many of the cited limitations for the use of funds and changes improvement plan requirements to be defined by the Secretary of Health and Human Services (HHS) and adding an additional $3 million in funds to the House's already allocated $22 million, for purposes of developing HCBS quality measures.
- Changing the permanent expansion of the Money Follows the Person demonstration to begin in 2022, rather than 2023 as passed by the House.
- Regarding Medicaid postpartum coverage, removing several of the House-passed version's state reporting requirements.
- Protecting low income people who gain coverage in 2025 (and didn't have other coverage for their health expenses) by requiring qualified health plans to cover up to three months of services prior to enrollment and requiring HHS to reimburse plans for those costs.
- Notable drug pricing provisions include the following: Regarding Medicare drug price negotiation, the Senate Finance committee text clarifies how the maximum fair price for a prescription drug covered by Medicare Part B or D will be determined, with additional specifications for the maximum fair price calculation of insulin products. The updated text also makes modifications to the timeline and baseline to determine how the inflation-based rebates for prescription drugs under Part B and D will

be calculated. Finally, it specifies that generic prescription drugs could be exempted from inflation-based rebates if they experience supply chain disruptions or create access issues.

It is important to note that the draft Senate text is subject to further changes before a BBB package reaches the Senate floor, given the aforementioned negotiations with Senator Manchin—or any other Democratic senators who raise concerns with particular provisions—along with forthcoming rulings from the Parliamentarian.

Negotiations are ongoing, though President Biden and Democratic leaders acknowledged on the evening of December 16 that the Senate would not act on BBB before the end of the year, following a ruling from the Parliamentarian that an immigration proposal in the package would violate the Byrd Rule. The Senate is scheduled to return to session on January 3, 2022, with the House not returning until January 10.

Administration

Updates on Challenges to Biden Administration's Vaccine Mandates. On December 15, two federal courts issued orders that, together, significantly impact the Biden Administration's authority to implement and enforce the COVID-19 vaccine mandate issued by the Centers for Medicare and Medicaid (CMS).

The first order, issued by the U.S. Court of Appeals for the Fifth Circuit, has the effect of allowing the federal government to proceed with its efforts to implement the COVID-19 vaccine mandate issued by CMS in over two dozen states. The second order, issued by a federal court in Texas, bars the federal government from implementing the CMS vaccine mandate in the state of Texas. The combined effect of yesterday's orders, as well as recent actions by other federal courts, is that the Biden Administration is currently authorized to implement the CMS vaccine mandate in 25 states, but precluded from doing so in 25 states, creating a patchwork approach to the mandate.

It remains unclear how CMS will move forward with the mandate, especially given the original first compliance date of December 6. For more information, please see this Insight piece.

HHS Releases $9 Billion in Provider Relief Fund Payments. On December 14, HHS announced the distribution of approximately $9 billion in Provider Relief Fund (PRF) Phase 4 payments to health care providers who have experienced revenue losses and expenses related to the COVID-19 pandemic.

According to the agency's press release, the average payment for small providers is $58,000, for medium providers is $289,000, and for large providers is $1.7 million. The Phase 4 payments—which are distributed through HHS' Health Resources and Services Administration (HRSA)—were scheduled to begin on December 16 for more than 69,000 providers across all 50 states, Washington, DC, and eight territories (a state-by-state breakdown can be found here).

The remaining Phase 4 applications are being reviewed by HRSA and those payments will be made in 2022.

President Biden Issues Executive Order on Reducing Administrative Burden and Improving Customer Experience. On December 13, the President issued an Executive Order (EO) instructing federal agencies to take actions in six major categories to reduce administrative burden and improve the customer experience for organizations and the public.

December 24 & 31, 2021

Holiday Break – No Updates

January 7, 2022

Congress

Senate Turns Focus to Voting Rights. While Senator Joe Manchin (D-WV) effectively side-lined BBB in its current form prior to the holidays, Senate Majority Leader Chuck Schumer (D-NY) kept hope alive by expressing strong interest in continuing negotiations.

Without clarity on BBB, the Senate shifted focus to voting rights legislation this week, with Majority Leader Schumer declaring the Senate will vote before Martin Luther King Day. The Freedom to Vote Act has support from all 50 Democratic senators, but no Republicans. The John Lewis Voting Rights Advancement Act has 223 Democratic cosponsors in the House and 48 in the Senate, but both pieces of legislation will require 60 votes to overcome an anticipated filibuster. Therefore, this key Democratic priority may jump-start conversations over changing the filibuster.

Congress Faces Upcoming Budget Deadline. Congress is yet again facing an upcoming deadline to fund the federal government along with key programs. The current continuing resolution (CR) funding the government expires on February 18, 2022. Democrats would like to see a comprehensive funding bill pass rather than another short-term extension, as agencies are currently operating under Trump Administration funding levels. There is also some interest in an emergency supplemental funding bill to provide relief for tornado-ravaged parts of the South and Midwest, and the fires that destroyed parts of Colorado. The supplemental could also become an opportunity to include an extension of the monthly child tax credit that expired at the end of 2021, and COVID-19 relief items.

Looking ahead, the Biden Administration is scheduled to release its FY 2023 Presidential budget proposal next month, though there is some uncertainty around timing. While the President's Budget is non-binding and isn't implemented as written, it typically kicks off the congressional budget process and provides the Administration's recommendations and priorities for federal funding levels across the policy spectrum.

Administration

CMS Releases 2023 MA/Part D Technical Rule. The Center's for Medicare and Medicaid Services proposed technical policy changes to the 2023 Medicare Advantage (MA) and Part D programs for 2023. The proposed rule would require pharmacy price concessions be used to lower out-of-pocket prescription drug costs for Medicare beneficiaries and seeks to improve health equity in both Medicare Advantage (MA) and Part D.

The proposed rule would also set maximum out-of-pocket limits for dual-eligibles in MA plans and revise timeframes associated with care and provider access for beneficiaries under MA during disasters and emergencies. Finally, the rule contains provisions on past performance considerations for new contracts, network adequacy requirements for MA plans, greater marketing and communications oversight, and more.

If finalized, the proposed changes would be effective January 1, 2023, meaning that Part D plans would need to account for these changes in bids submitted for contract year 2023.

HHS Releases Notice of Benefit and Payment Rule. This week, the Department of Health and Human Services released the 2023 Notice of Benefit and Payment proposed rule, which would require every state issuer participating in the federal exchange to offer at least one standardized plan option at each metal level in which it offers plans. The agency also announced that it plans to conduct network adequacy reviews in every state using healthcare.gov and will refine the Affordable Care Act Essential Health Benefits process as a part of the Administration's move toward advancing healthcare equity. The agency is accepting comments on the proposed rule for the next 30 days.

CMS Rescinds MFN Rule. The Centers for Medicare and Medicaid Services (CMS), posted a final rule in late December, rescinding the November 2020 Most Favored Nations (MFN) Model interim final rule and removed the associated regulatory text.

The MFN rule would have created a mandatory, seven-year payment model for the 50 highest-cost drugs and biologics in Medicare Part B to replace the current reimbursement formula for these drugs. Instead of adding a 6 percent administration fee to the average sale price (ASP) of the drug, the new reimbursement system would have been based on international pricing information from 22 different countries.

Following significant pushback from industry stakeholders as well as several court challenges, the agency announced that it will no longer implement the rule, which was scheduled to take effect January 1, 2022.

CMS Ends the SIP Component of the PCF Model. The Seriously Ill Population (SIP) component of Primary Care First (PCF) was designed to have advanced primary care practices, including providers whose clinicians are enrolled in Medicare and who typically provide hospice or palliative care services, coordinate care for high need, seriously ill beneficiaries. CMS has determined that the proposed SIP outreach method, which was designed to comply with statutory beneficiary privacy protections, is unlikely to result in sufficient beneficiary uptake to allow for model evaluation.

January 14, 2022

Congress

Senate HELP Committee Holds Hearing on COVID-19. On January 11, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing to discuss the federal government's response to the ongoing pandemic and how to address new variants.

The Committee heard testimony from four key leaders in the Administration's pandemic response efforts: Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci, Food and Drug Administration (FDA) Acting Commissioner Janet Woodcock, and Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Dawn O'Connell.

The witnesses faced tough questions from both sides of the aisle on the Administration's recent efforts related to access to testing, confusion surrounding evolving CDC guidance, and increased hospitalization rates among children, among other issues. The hearing was also marked with tense and often acrimonious exchanges between some Republican Senators and the witnesses.

New COVID Relief Package Anticipated. Efforts to craft a supplemental COVID relief package began to take shape this week, as the U.S. continues to battle the latest surge due to the omicron variant.

On January 13, President Biden announced additional commitments to fighting the pandemic, including the distribution of free masks, the deployment of military medical teams to additional states, and doubling the number of rapid tests the Administration will procure and make publicly available (up from 500 million to 1 billion), which follows on the announcement earlier this week regarding private insurance coverage for at-home tests (see related story below).

Much of the focus in Congress has been on non-health-related establishments that have been impacted, such as restaurants, bars, and gyms. Additional details and formal funding requests are expected to come into focus in the near term, as Congress determines a legislative path forward for the relief package.

The current continuing resolution (CR) funding the government expires on February 18, and the next appropriations bill—be it a comprehensive Omnibus for the remainder of FY 2022, or another short-term CR—provides a natural opportunity for COVID relief measures to be addressed. However, given that waiting until mid-February would leave a relief package open for more than a month, congressional leaders could decide to move ahead more quickly.

Administration

CMS Releases Proposed NCD on Alzheimer's Treatment, as HHS Secretary Calls for CMS to Reevaluate Medicare Part B Premium Recommendation. On January 11, the Centers for Medicare and Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) on the coverage of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (also referred to as Aduhelm).

Under the proposal, CMS would cover the qualifying treatment through coverage with evidence development (CED)—limiting the population of patients eligible for coverage of the drug to Medicare patients enrolled in qualifying clinical trials. The NCD applies to Aduhelm, amyloid beta-directed antibody indicated for the treatment of Alzheimer's Disease, which was controversially approved by the FDA in June 2021 through the accelerated approval pathway.

If finalized in current form, CMS would review each clinical trial for coverage qualification, and trials that are determined to be outside of the CMS approved randomized controlled trials and trials supported by the National Institutes of Health (NIH) would be deemed nationally non-covered. CMS will announce a final decision by April 11, following a 30-day public comment period and evaluation.

On January 1, Biogen reduced Aduhelm's price by 50% from $56,000 to an annual $28,200 per patient price. In response, HHS Secretary Xavier Becerra instructed CMS to reevaluate its 2022 Medicare Part B premium recommendation, which the agency had previously substantially increased from 2021 in part because of the expected cost to the program to support use of the new Alzheimer's treatment.

Administration Releases Guidance Requiring Private Insurance Coverage of At-home COVID Tests. On January 10, the Biden Administration announced guidance implementing plans it announced in December 2021 to require private insurers to cover and reimburse plan participants for at-home COVID-19 diagnostic tests without cost-sharing. This guidance makes it a requirement that private and group insurance plans cover at-home COVID-19 diagnostic tests at no-costs to enrollees effective January 15.

Both CMS and the Department of Labor released FAQ documents on the new guidance (found here and here, respectively), which specify:

- Plans are not required to cover testing that is required for employment purposes.
- Insurers will not be able to impose a prior authorization of any kind or require an at-home test be ordered from a health provider to be eligible for coverage.
- Plans can limit coverage to up to eight tests per covered individual per month (e.g., a family of four can get up to 32 tests per month for free).
- Plans are incentivized to set up preferred pharmacy and retailer programs in which they cover the costs upfront, eliminating the need for consumers to submit a claim for reimbursement. The guidance also specifies that even if insurers make tests available for upfront coverage through preferred pharmacies or retailers, they are still required to reimburse tests purchased by enrollees outside of that network. For tests purchased outside of preferred networks, insurers will be required to reimburse enrollees up to $12 per test or less if the test is priced below that. The reimbursement appears to be per test, so an enrollee would be reimbursed at a rate of $24 if they purchased a two-pack of tests.

Regarding traditional Medicare coverage, the January 10 announcement does not change existing policy. In its FAQ document, CMS reiterated that: "Medicare pays for COVID-19 diagnostic tests performed by a laboratory, such as PCR and antigen tests, with no beneficiary cost sharing when the test is ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional…At this time original Medicare cannot pay for at-home tests through this program." Regarding Medicaid and CHIP coverage, CMS advises beneficiaries to contact their state Medicaid or CHIP agency for information, as coverage rules for at-home tests may vary by state.

Courts

On January 13, the Supreme Court released two emergency opinions that change the landscape of the three federal vaccine rules. In sum:

- A 5-4 Supreme Court majority let CMS enforce its vaccine mandate nationwide, impacting specified health care facilities.
- A 6-3 majority blocked the U.S. Occupational Safety and Health Administration (OSHA) from enforcing its vax-or-test Emergency Temporary Standard (ETS) applicable to large employers.
- The third federal vaccine rule – the federal contractor vaccine mandate – remains subject to multiple legal challenges and, at this time, the government is blocked from enforcing the mandate nationwide. The Supreme Court has not yet weighed in on this mandate.

With these rulings, the CMS Rule is now enforceable in every state, across the full spectrum of the facilities covered by the rule. The exact deadlines for enforcement may shift; however, as CMS has yet to issue updated specific guidance in response to the rulers and entities remain without clarity on state law interactions and the potential for future litigation. The OSHA "vax-or-test" ETS is stayed nationwide. Moreover, given that the OSHA ETS is a temporary standard lasting only six months, it is unlikely that the other litigation will come to a close with enough time for OSHA to win and begin any meaningful enforcement prior to the expiration date. These issues remain fluid and will likely lead to additional questions from providers and large employers.