Health Policy Update – November 16, 2021

Congress Passes Bipartisan Infrastructure Bill, Delays Reconciliation Bill Vote

After a marathon floor session that stretched in into the early morning hours, the House of Representatives finally passed the bipartisan Infrastructure Investment and Jobs Act on November 5th by a vote of 228 to 206. Thirteen House Republicans joined all but 6 Democrats to send the bill to President Biden's desk. It was signed into law yesterday. The bill included healthcare-related offsets including:

- Extending the 2% Medicare sequester by one year through 2031;
- Delaying implementation of the Trump Administration's rebate rule by 3 years; and
- Requiring drug manufacturers to pay rebates back to Medicare for single-use vial wastage in excess of 10% beginning in 2023.

Meanwhile, a vote on the reconciliation bill, known as the Build Back Better Act (BBBA), was delayed at the behest of centrist Democrats who insisted on first seeing a score from the Congressional Budget Office (CBO). While CBO has released cost estimates for some components of the bill, a comprehensive score is not expected until Friday, November 19.

Under a deal brokered by Speaker Nancy Pelosi (D-CA), the Democratic holdouts pledged to vote in favor of the BBBA in its current form so long as CBO confirms the package will not add to the federal budget deficit. That assurance was enough to convince most House Progressives to drop their opposition to the infrastructure bill which they had refused to support without first passing the reconciliation package.

Following passage of the infrastructure bill, the House held a procedural vote on the BBBA, passing it with a 221-213 vote. This suggests that House Democrats do have enough votes to pass the reconciliation measure, though its prospects remain uncertain in the Senate.

Lawmakers Reach Drug Pricing Deal in Proposed Reconciliation Package

While drug pricing reforms were initially missing from the revised reconciliation bill framework unveiled in late last month, Democratic lawmakers struck a last-minute agreement to include key provisions, including Medicare price negotiation. The Build Back Better Act (BBBA) would allow Medicare to negotiate the price of drugs in both Parts B & D, require manufacturers to pay back the federal government if prices increase faster than inflation, and impose a new $2,000 annual patient out-of-pocket maximum in Part D.

Here are the details of the Medicare negotiation provisions:

- Allows the HHS Secretary to negotiate prices for high cost drugs and insulin nearing or following the end of their market exclusivity in Medicare Part D beginning in 2025 and Medicare Part B beginning in 2027.
- Products must not have generic or biosimilar competition.
    - In 2025, HHS may negotiate up to 10 drugs in Part D
    - In 2026, HHS may negotiate up to 15 drugs in Part D
    - In 2027, HHS may negotiate up to 20 drugs in Parts B and D
    - In 2028 and beyond, HHS may negotiate up to 20 drugs in Parts B and D
- Negotiated prices, known as Maximum Fair Prices (MFP) would be available in both fee-for-service and Medicare Advantage, but not commercial plans.
- MFP ceiling prices are specified in the legislation based on a drug's years since FDA approval, creating price reductions of 25-60% off average manufacturer prices
- MFP agreements continue in perpetuity as the drug stays on the top 50 highest-spend drug lists for both Parts B and D.
- Renegotiations may be triggered for new indications, changes in exclusivity status, R&D and product costs, and market data.
- Manufacturers failing to negotiate with HHS would be subject to excise taxes of 65% on the drug's gross sales, rising to 95% for each quarter of noncompliance.

In addition to drug price negotiation, the House BBBA text includes the following:

- Requires pharmaceutical manufacturers to pay Medicare rebates for increasing list prices above the rate of inflation for both Parts B and D drugs. Beneficiary coinsurance would be limited to inflation-adjusted prices.
- Creates a temporary, 5-year payment add-on for biosimilars of ASP +8%.
- Redesigns the Medicare Part D prescription drug benefit to include a new maximum out-of-pocket cap of $2,000 per beneficiary. Patients would be allowed to spread their costs throughout the year, something known as "smoothing."
- Imposes new reporting and transparency measures on PBMs.
- Caps beneficiary insulin costs at $35 per month.
- Permanently repeals the Trump Administration's rebate rule.

To read a section-by-section summary of the BBBA, CLICK HERE.

Biden Administration Expands COVID-19 Vaccine Mandates

Earlier this month, the Biden Administration further expanded its vaccine mandates to include millions of more workers around the country. On November 4, the administration released an emergency regulation requiring COVID-19 vaccination for nearly all healthcare workers. The interim final rule with comment period issued by CMS requires all Medicare and Medicaid providers and suppliers to be fully vaccinated against COVID-19 by January 4, 2022. The rule is expected to impact some 17 million clinical and nonclinical employees at approximately 76,000 healthcare facilities across the country.

The new regulation does not provide an option for weekly testing in lieu of vaccination but it does provide for exemptions based on recognized medical conditions or religious beliefs, observances, or practices. According to CMS, providers or suppliers who fail to meet the requirements will be cited by a surveyor as being non-compliant and will then have an opportunity to demonstrate compliance before incurring enforcement action.

On the same day, the Occupational Safety and Health Administration (OSHA) issued a rule mandating that companies with 100 or more employees either ensure that their workers are fully vaccinated against COVID-19 by January 4 or test negative for the coronavirus at least once a week. While the rule specified that companies are not required to pay the costs associated with testing unvaccinated employees, they must provide paid time off for employees to receive and recover from the vaccine. The OSHA regulation also requires unvaccinated workers to wear masks on the job, a requirement that is slated to go into effect on December 5. According to OSHA, the rule applies to 84.2 million workers at 1.9 million private-sector employers.

On November 6, the United States Court of Appeals for the Fifth Circuit issued a stay freezing the OSHA rule from implementation. The court order came in response to a joint petition from several businesses, advocacy groups, and the states of Texas, Louisiana, Mississippi, South Carolina and Utah. Additional legal challenges to the rule have also been brought before other federal courts.

To read the CMS interim final rule with comment period, CLICK HERE.

Final 2022 Medicare Physician Fee Schedule Allows Conversion Factor Bump to Expire

The 2022 Medicare Physician Fee Schedule (PFS) rule, which was finalized by CMS on November 2nd, fails to address physician payment cliff as attention shifts to Congress. The looming payment cuts are in large part due to the expiration of a temporary 3.75% conversion factor increase for 2021, initially passed last year to help providers get through the COVID-19 pandemic.

By declining to renew the increase, CMS acknowledged that “several specialties, including interventional radiology, vascular surgery, radiation oncology, and cardiology,” will see their Medicare reimbursements decrease next year. According to the final rule's estimated aggregate impact by specialty, oncology is expected to see reimbursement cuts of -1%, though this estimate does not include the expiration of the temporary conversion factor adjustment for 2021.

A bipartisan group of lawmakers led by Representatives Ami Bera (D-CA) and Larry Bucshon (R-IN) is urging Congressional leaders to avert the looming conversion factor cuts in addition other scheduled reimbursement cuts providers are facing this year. The Bera-Bucshon letter was signed by 247 House members from both parties and is supported by dozens of healthcare stakeholders, including The Network.

In addition to the conversion factor cuts, the PFS final rule will extend coverage of some Medicare services provided via telehealth through December 31, 2023, to allow CMS additional time to evaluate whether they should be permanently added to the Medicare telehealth services list. The

rule also phases in a clinical labor pricing update over 4 years, an approach favored by The Network. This is the first update to clinical labor practice expense inputs in nearly 20 years.

To view a fact sheet from CMS on the 2022 PFS Final rule, CLICK HERE.

To view the Bera-Bucshon letter, CLICK HERE.

CMS Finalizes OPPS Final Rule as Stakeholders Call for RO Model Changes

Finalized the same day as the Physician Fee Schedule, CMS' 2022 Hospital Outpatient Prospective Payment System final rule also includes the administration's proposed Radiation Oncology (RO) Model. The final rule made few changes to the original proposal which has been strongly criticized by oncology stakeholders – including The Network – for its proposed reimbursement reductions to providers that could threaten access to high quality care for patients.

Starting January 1, 2022, the model will provide bundled payments for a 90-day episode of care to certain radiotherapy providers and suppliers furnishing radiotherapy for a variety of cancers. In September, The Network submitted detailed comments to CMS urging the agency to reduce the discount factor to 3% for both the professional and technical components, provide a 5% APM incentive bonus for technical payments to freestanding practices, and modify the trend factor to prevent additional downside risk and provide payment stability among other recommendations to reduce burdensome data collection and reporting requirements. While CMS finalized its proposal to reduce the discount factor from 3.75% to 3.5% for the professional component and 4.75% to 4.5% and to adopt an Extreme and Uncontrollable Circumstances policy that could delay reporting requirements related to the COVID-19 public health emergency, overall, CMS continued to largely ignore stakeholder feedback.

The impact of the RO Model reimbursement reductions combined with looming PFS cuts to providers, is estimated to significantly impact the financial stability of many practices. In response to these concerns, stakeholders are pursuing a legislative strategy to freeze certain radiation oncology payments, reduce the RO Model's discount factors to 3%, and allow Model participants to earn the full Advanced APM bonus.

To read The Network's comment letter on the RO Model, CLICK HERE.

Federal Courts Issue Conflicting Opinions on Controversial 340B Program

Two different federal courts reached conflicting decisions earlier this month in response to lawsuits filed by drug manufacturers challenging the Department of Health and Human Services' enforcement of 340B discounts for contract pharmacies.

One judge found that the federal government overstepped its bounds when it threatened to penalize Novartis and United Therapeutics for eliminating the discounts to certain contract pharmacies earlier this year. The second judge, however, took the opposite view in a case brought by Sanofi and Novo Nordisk and ruled that the arrangements hospitals and clinics make with contract pharmacies are consistent with federal law and that drug companies cannot impose restrictions on the 340B program.

The 340B discount program requires drug makers to offer discounts, typically between 25 to 50 percent, on all outpatient drugs to hospitals and clinics that serve low-income populations. Approximately 12,400 covered health care entities are covered under the program, including 2,500 hospitals.

In 2020, several manufacturers began refusing to offer the discounts to pharmacies contracting with 340B-entities rather than dispensing them in-house. The manufacturers claimed this practice was an abuse of the program resulting in duplicate discounts. HHS responded by issuing an advisory legal opinion (which was later withdrawn amid controversy) saying the drug makers are obligated to provide discounts even if hospitals and clinics use contract pharmacies to deliver drugs. In response, several manufacturers challenged the policy in court.

These most recent rulings leave unanswered key questions about whether HHS has the authority to regulate 340B contract pharmacy arrangements.

To read the Sanofi and Novo Nordisk ruling, CLICK HERE.

To read the Novartis and United Therapeutics ruling, CLICK HERE.

New Study Finds Hospitals Upcharge Private Insurers

A new study from *JAMA Internal Medicine* found that hospitals are charging private health insurers “considerable markups” on highly used outpatient drugs. While the actual amounts vary widely, the study found that private insurers are often paying several times more than what Medicare pays for the same drugs.

The drugs featured in the study include many commonly used drugs such as Remicade, Neulasta, and Keytruda. Of the drugs mentioned, the largest variation came from Remicade, an IV drug used to treat a wide array of autoimmune conditions, which saw commercial insurers paying 800 percent more than what Medicare would have paid at a Mayo Clinic hospital in Phoenix.

The study relied on previously confidential pricing information that is now required to be disclosed under a federal price transparency rule that took effect in January.

To read the full study, CLICK HERE.