H&K Health Dose November 16, 2021
A weekly dose of healthcare policy news

Legislative Updates

The CBO Waiting Game

The House returns this week hoping to pass the Build Back Better (BBB) reconciliation package. The House delayed a vote on the package in response to several requests from moderate Democrats to wait for the official Congressional Budget Office (CBO) cost estimate of the bill. The expectation is that CBO will release scores on the cost of the legislation, when ready, section-by-section. Notably, Ranking Members of the Senate and House Budget Committees Sen. Lindsey Graham (R-SC) and Rep. Jason Smith (R-MO) requested CBO cost estimates for the BBB Act if its temporary programs are made permanent. There is some expectation that CBO will show a shortfall, in part because of tax enforcement.

Democratic leaders expressed their hope of passing the reconciliation bill, subject to minor revisions, before Thanksgiving and to send it to the Senate for consideration. Notably, House Speaker Nancy Pelosi (D-CA) has told fellow Democrats that the House will not recess for Thanksgiving without passing the BBB.

The Senate is expected to begin consideration of the BBB Act no earlier than the first week of December. From there, the package is expected to be modified when it reaches the Senate, both to comply with the Senate's Byrd rule that requires reconciliation provisions to be tied to the budget and to gain the necessary support of every Senate Democrat. A "vote-a-rama" with several amendments is also likely. The process may take several weeks. Sen. Joe Manchin (D-W.Va.) has already expressed reservations about some of the bill's key provisions and has called for slowing the pace of negotiations. Congress also faces several deadlines the week following Thanksgiving recess, including the expiration of the current continuing resolution (CR) funding the federal government until December 3 and the date by which Congress must formally raise the nation's debt limit or risk a default. Accordingly, another continuing resolution will likely be needed before December 3.

If the BBB Act passes the Senate, then it is back to the House for possible final passage if the House accepts the changes made by the Senate. Otherwise, the back-and-forth continues.

Long-Anticipated Bipartisan Cures 2.0 Bill Introduced

Reps. DeGette (D-CO) and Fred Upton (R-MI) released the highly anticipated Cures 2.0, a bipartisan bill that would authorize the creation of Advanced Research Projects Agency for Health, or ARPA-H; make permanent certain temporary flexibilities for telehealth under Medicare, in addition to other public health advancements. The legislation builds on the 2015 Cures law and is the culmination of an over two-year long process involving a request for information followed by the release of a discussion draft in June.

The bill makes several meaningful changes, including codifying Medicare coverage of breakthrough device technologies, a proposal that was recently withdrawn by the Biden Administration. CMS said that it was concerned the clinical data necessary for the FDA breakthrough therapy approval may not meet Medicare's guidelines for a coverage determination as further discussed below. The bill also seeks to increase diversity in clinical trials, requiring the FDA to collect more real-world evidence for treatments, and advances several mechanisms to promote the development of cell and gene therapies at the FDA. In addition, the legislation makes a few additions to the original discussion draft, including support for decentralized clinical trials (Sec. 310), which will aid rare disease drug development, creating alternative mechanisms for access claims data for the purposes of research (Sec. 411), and designating a standards maintenance organization to establish standards for electronic prescribing, among others.

Regarding telehealth, the bill would permanently remove Medicare's geographic and originating site restrictions. The bill also would let HHS permanently expand the scope of providers that can offer telehealth services, as well as the types of services that can be reimbursed under Medicare. The bill also incorporates a measure that would provide guidance and strategies to states on integrating telehealth into Medicaid and CHIP. The legislation also would require a study on telehealth's impact on patient health.

The future of the overall bill is uncertain. Although the House has released an official bill, the Senate has not released a corollary measure. In addition, House Energy & Commerce Committee Chair Frank Pallone has not expressed significant interest in moving the measure to date. These factors, coupled with the upcoming reauthorization of FDA's user fee programs, which must be reauthorized by Sept. 30, 2022, provide several roadblocks to ultimate passage of the Cures 2.0 measure.

Regulatory Updates

Provider Relief Fund Reporting 60-Day Grace Period to End Nov. 30

The Health Resources and Services Administration (HRSA) deadline for Provider Relief Funding (PRF) requirements will occur on Nov. 30. The Nov. 30 date marks the end of a 60-day grace period that allows providers to comply with reporting requirements and only applies to the Reporting Period 1 report submission deadline. Healthcare providers who received more than $10,000 from the PRF between April 30 and June 30, 2020 must file their report.

2022 Spells Record Premium Increases

CMS announced that average monthly Medicare Part B premiums would increase by a record $21.60 next year to $170.10. About half of that increase accounts for Medicare's coverage of Biogen Inc.'s costly new Alzheimer's disease drug, while the other half is due to usual cost growth plus making up for Congress' move to decrease premiums in 2021.

The Kaiser Family Foundation separately reported that annual family premiums for employer-sponsored health insurance rose 4% to an average of $22,221 in 2021, of which workers contributed an average of $5,969.

FDA's Big Week: Califf is the Pick; 2 Trump-Era Rules Rescinded

After weeks of speculation, President Joe Biden formally announced his intent to nominate former Commissioner Robert Califf for a second tour to lead the FDA. Califf previously served in the same role toward the end of the Obama administration. His nomination is expected to go through, despite opposition from Democratic WV Senator Joe Manchin. Califf is expected to prioritize issues like bringing more generics and biosimilars to the market, addressing pharmaceutical supply chain issues, and increasing access to innovative treatments like cell and gene therapies.

In the last week, the FDA also rescinded two Trump-era rules. The first would have expedited the typical 9-12 month waiting period for Medicare reimbursement of breakthrough medical devices, which Biden's FDA says would put patient safety at risk. The rule had been slated to take effect Dec. 15. The second had allowed certain lab-developed tests, including COVID-19, to bypass the FDA premarket review, which the Biden administration says leads to unreliable products. Moving forward, all lab-developed tests must receive emergency use authorization or traditional authorization before being offered to consumers.

This Week In 340B News…

According to a footnote from a recent federal court ruling, drug companies' restrictions on 340B program discounts to contract pharmacies have the cost covered hospitals and clinics $3.2 billion annually.

A new study found that converting up-front 340B drug discounts to post-sale rebates could increase hospital cash flow by 0.7%, though Kalderos funded the study, a billing software company that lets drugmakers audit 340B discounts by turning them into rebates.

Democrats' recent drug pricing provisions included in the Build Back Better Act includes some transparency provisions that would require pharmacy benefit managers (PBMs) to report the amount of copay assistance funded by drug makers, a list of every covered and dispensed drug, the total gross and net spending amounts for drugs, and the total amount health plans receive in rebates, fees and alternative discounts. PBMs would also be barred from entering into contracts with drug makers that fail to disclose certain information to health plans.

CMS Releases List of Third Party Arbiters to Carry Out No Surprises Act Pricing Negotiations

CMS released a list of applicants being considered for certification as independent dispute resolution entities (IDREs) to settle payment disputes between plans/issuers and providers/facilities under the No Surprises Act. Additional entities will be added weekly. Applications and supporting documentation can be viewed on the website, and the public is invited to comment on individual entities.

HHS Report Details $144 Billon in Overpayments in FY 2021

According to a new report, HHS had an overall improper payment rate of 13% across its programs for the fiscal year 2021, which amounted to more than $150 billion of improper payments, including $144 billion in overpayments. CHIP had the highest overpayment rate at 31.8%, followed by Medicaid at 21.6%, which accounted for roughly $98 billion of overpayments. Traditional Medicare had a 6.15% overpayment rate, and Medicare Part C had a 10.28% overpayment rate. The vast majority (72%) of overpayments were due to insufficient documentation.

New CMS Guidance Allows Hospitals to Share a Location But Remain Separate

According to new CMS guidance, a hospital can be located on the same campus or even building as another hospital, provided each entity can independently comply with Medicare and Medicaid conditions of participation requirements.

New Study Finds Childbirth Costs U.S. Tens of Billions

According to a new Mathematica and Commonwealth Fund study, health complications stemming from childbirth drain at least $32.3 billion from the U.S. economy. Maternal mental health disorders accounted for the largest share. Maternal health issues disproportionately impact communities of color and are an area of focus for the Biden administration and Build Back Better Act.

In the Courts

10 States Sue Over HHS COVID Vaccine Mandate for Healthcare Facilities

Last week, ten states sued HHS over its COVID-19 vaccine mandate rule, arguing that the power to require vaccines should reside with states and that the mandate will exacerbate current workforce shortages. The states include Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire. The rule applies to clinical and non-clinical staff who work at healthcare facilities that receive Medicare or Medicaid funding.

Unlike the separate OSHA rule for federal workers and contractors, it does not include a weekly testing alternative, but it does include religious and medical exemptions. In all, the rule would require more than 17 million health care workers to be fully vaccinated by Jan. 4, 2022. This is the first lawsuit brought against the CMS rule, though the OSHA rule faces several and was suspended by a federal appeals judge pending further litigation.

In related news, Senator Mike Crapo (R-ID), Ranking Member of the Senate Finance Committee, and Senator Richard Burr (R-NC), Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, released a joint statement opposing the vaccine mandate issued by the Biden Administration for Medicare and Medicaid providers.

An Uptick in False Claim Charges Against Private Equity Owned Healthcare Companies

There has been a recent uptick in False Claims Act lawsuits brought against private equity owners, and experts predict more in the coming years. It's unclear if a particularly scrutinizing lens drives the increase on private equity or if it just reflects their growing market share. Private equity deals in the U.S. healthcare sector surpassed $100 billion in 2018, compared with less than $5 billion in 2000. DOJ officials say knowledge of fraud is a key ingredient they are looking for following a directive started under the Obama administration that allows holding individuals accountable for corporate wrongdoing.

Another Opioid Lawsuit Commences

Another major opioid lawsuit kicked off this week; this time Washington State Attorney General Robert Ferguson is seeking $38 billion in damages from McKesson, Cardinal Health Inc. and AmerisourceBergen Corp. on the basis that they violated the state's consumer-protection laws and turned a blind eye to red flags about opioids. Drug distributors, manufacturers, and retailers face more than 4,000 lawsuits from state and local governments over the opioid crisis.

COVID Updates

- After weeks of steady decline, the weekly average of new COVID-19 cases is ticking upward, with significant variation across states. The 7-day average of new cases now stands at 86,778, after several weeks below 80,000.
- CDC Director Rochelle Walensky says senior Biden administration officials continue to debate behind closed doors about whether or not to make COVID-19 vaccine boosters available to all adults.
- The Biden-Harris Administration announced another $785 million in American Rescue Plan funding to support a variety of health-equity focused COVID-19 interventions to support community-based efforts to increase vaccine rates in minority, rural, low-income, and other at-risk groups and boost the public health workforce. The administration also committed another round of Johnson & Johnson shots to global vaccine efforts.
- Johnson & Johnson will split into two publicly traded companies, focusing on consumer goods and the other on its prescription drugs and medical devices businesses. The split is expected to happen in the next two years. J&J will remain the world's largest health products company by sales.
- AstraZeneca announced this week that it plans to start selling its COVID-19 vaccines at a profit.
- The World Health Organization developed a COVID-19 data tracker to gather the latest information on COVID worldwide in one place.

- Pfizer reported its COVID-19 oral antiviral candidate reduces the risk of hospitalization or death by 89%. Pfizer also agreed license its antiviral COVID pill to a UN-backed nonprofit to make it widely available in poor nations, pending emergency FDA approval. Moderna has also offered to share partial ownership of some of its COVID vaccine patents with the U.S. government.

- The Congressional Research Service posted a report on vaccines, diagnostics, and therapeutics for various COVID-19 variants.