H&K Health Dose July 19, 2022
A weekly dose of healthcare policy news

Legislative Updates

Drug Pricing and ACA Credits Resurrected in Pared Down Build Back Better Act

Sen. Joe Manchin (D-W.Va.) announced that he is only willing to accept a reconciliation deal that is exclusively focused on Medicare prescription drug pricing negotiation and a two-year extension of the enhanced Affordable Care Act (ACA) tax credits, which are currently set to expire in December. According to the Congressional Budget Office (CBO), the drug pricing reforms would save or raise about $288 billion over 10 years. Permanently expanding the American Rescue Plan Act (ARP) credits, as most ACA stakeholders prefer, would have cost $220 billion, according to CBO. Democratic leaders, including President Joe Biden, have signaled support for the pared-down reconciliation package. Senate Majority Leader Chuck Schumer (D-N.Y.) has already sent the reconciliation prescription drug pricing provisions to the Senate parliamentarian for review, who is set to meet with Senate staff on July 21, 2022. However, a final agreement may not make it to the Senate floor until the first week of August.

User Fee Negotiations Hit Significant Roadblock

Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Richard Burr (R-N.C.) has pulled out of negotiations on reauthorizing the U.S. Food and Drug Administration's user fees. Sen. Burr introduced a clean version (S. 4535) of the reauthorization legislation last week that does not contain extensive reforms currently included in the bill (S. 4348) passed by the HELP Committee in June. HELP Committee Chair Patty Murray (D-Wash.) issued a statement shortly after critiquing Sen. Burr for his about-face on the user fee package.

In the House, Energy and Commerce Committee leaders Frank Pallone (D-N.J.) and Cathy McMorris Rodgers (R-Wash.) issued a statement urging the Senate to take up the House-passed proposal (H.R. 7667) quickly. Congress must reauthorize the user fee programs for the next five fiscal years before the current agreements expire on Sept. 30, 2022.

For now, it seems unlikely that major reform provisions in the Senate bill will be passed. That includes the Verifying Accurate Leading-edge IVCT Development Act (VALID Act) provisions that would create a new regulatory paradigm for the review and approval of some diagnostics; mandatory product listing provisions for dietary supplements; and quality manufacturing requirements for cosmetics. It is also unlikely that the user fee package will be passed in August, so FDA staff members will likely receive warnings about potential layoffs.

Appropriations Update

Senate Appropriations subcommittee chairs are working on drafting their fiscal year (FY) 2023 spending bills for release at the end of this month. In the House, Democratic leadership aims to pass nine of the 12 annual appropriations bills by the August recess. A continuing resolution (CR) will likely be necessary to keep the government funded beyond the end of the fiscal year on Sept. 30, 2022.

House Republicans Outline Affordable Health Care Policies

Last week, the Healthy Future Task Force on Affordability Subcommittee released priorities (press release; op-ed) to make healthcare more accessible and affordable, which included:

- improving workers' ability to control and afford healthcare, and improve small business owners' ability to provide health insurance at a low cost and high value for employees
- promoting innovation and transparency to empower patients and provide more affordable options
- lowering costs and increasing choices by fostering competition and targeting incentives that drive consolidation and limit competition

Regulatory Updates

CMS Releases CY 2023 OPPS Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) on July 15, 2022, issued its proposed Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems rule, which proposes updates to the outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year (CY) 2023.

The proposed rule projects an overall increase of 2.7 percent for OPPS payment rates in CY 2023, which is based on a market basket update of 3.1 percent reduced by a productivity adjustment of 0.4 percent. The agency estimates that this will result in an overall total of approximately $86.2 billion in payments to OPPS providers ($1.79 billion more than CY 2022).

Regarding the 340B Program, CMS announced that it would restore the Medicare outpatient payment to average sales price (ASP) plus 6 percent for CY 2023, given the recent U.S. Supreme Court's recent decision. The agency noted that it is evaluating how to address prior year cuts and is seeking public comment on potential remedies affecting cost years 2018-2022. Also of note, CMS proposes to remove 10 services from the inpatient-only (IPO) list.

Comments are due Sept. 13, 2022, and the final rule with comment is expected in early November. Holland & Knight will provide a detailed analysis in the coming days.

HHS Extends COVID-19 Public Health Emergency into Mid-October

U.S. Department of Health and Human Services Secretary Xavier Becerra officially extended the COVID-19 Public Health Emergency (PHE) into mid-October. By law, the PHE must be renewed in 90-day increments.

Biden Weighs Next Steps as Dobbs Fallout Continues

President Joe Biden is facing increasing pressure to respond to the recent U.S. Supreme Court ruling reversing *Roe v. Wade*. One option that he is evaluating is declaring a national reproductive health emergency, which abortion advocates and a group of 80 House Democrats have requested. However, experts argue that doing so comes with little additional legal authority and a small pot of funding to tap into and that other strategies would be more impactful.

Meanwhile, the U.S. Department of Justice announced a new reproductive rights task force that will actively monitor and evaluate all state and local legislation and enforcement actions that threaten access to reproductive care. A French drugmaker submitted an application to the U.S. Food and Drug Administration (FDA) for approval to make its daily birth control pills available over the counter, which would be a first in the United States but is relatively common worldwide. The pill was previously approved by the FDA on a prescription-only basis in 1973 and has not been sold in the U.S. for more than a decade.