



Health Policy Briefing

July 5, 2022

House Appropriators Complete Work on FY23 Spending Bills

The House Appropriations Committee has completed action on all 12 fiscal year (FY) 2023 spending bills, teeing up floor votes on the appropriations measures in the House of Representatives later this month. The panel approved its Labor-Health and Human Services-Education bill on a party-line vote last week. The legislation totals \$242 billion, with \$124 billion for the U.S. Department of Health and Human Services (HHS), a more than 14% increase over current spending. Debate on the package centered on the overall funding level and the issue of abortion. For the first time since 1976, the bill does not contain the Hyde amendment banning the use of federal funds for abortions. During the markup, the panel also adopted an amendment to the bill’s report language urging HHS to ensure affordable access to abortion medication. While floor action on the bill is expected later this month, the evenly divided Senate means a continuing resolution (CR) will likely be needed to fund the federal government beyond the end of the fiscal year on September 30.

Progressives Urge WH to Act on Abortion

Following the Supreme Court’s recent decision to strike down *Roe v. Wade*, progressive members of Congress continue to push the administration to take drastic steps to ensure access to abortion across the nation. The lawmakers are pitching ideas including legislation to protect personal data in reproductive health apps, reinforcing the right of individuals to travel without interference, the provision of travel vouchers, and allowing abortions on federal property. Some are also pushing for changes to the structure of the Supreme Court by expanding the number of justices or instituting term limits. While White House officials have repeatedly stated that there is little that they can do to safeguard access to abortion without the support of Congress, President Joe Biden has said that he would support a change to the Senate’s filibuster rule to codify privacy rights and access to abortion. Senate Democrats, however, do not currently have the votes to change the chamber’s procedures. Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.) remain opposed to the elimination of or exceptions to the Senate’s filibuster rule.

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USICA Talks Threatened by Build Back Better

Senate Minority Leader Mitch McConnell (R-Ky.) has said that he will block bipartisan legislation to strengthen U.S. competition with China if Democrats decide to revive work on a partisan reconciliation package. Senate Majority Leader Chuck Schumer (D-N.Y.) has been in talks with Sen. Joe Manchin (D-W.Va.) on a scaled-back version of the Build Back Better proposal after the package stalled late last year over Manchin's concerns about the total size of the bill. The roughly \$1 trillion plan currently under consideration would include provisions to cap out-of-pocket drug costs for seniors, allow Medicare to negotiate drug prices, increase taxes for the wealthy and corporations, and address climate change. Lawmakers had hoped to finish conference negotiations on the *U.S. Innovation and Competition Act* (USICA) by the end of this month.

Sen. Leahy Undergoes Hip Surgery

Sen. Patrick Leahy (D-Vt.) underwent hip replacement surgery after suffering a fall at his home on Wednesday. According to his office, Leahy is comfortably recovering. It is unclear for how long he will be on medical leave. The Senate is scheduled to return to session for votes on July 11. As Appropriations Committee Chair, Leahy's absence could complicate plans to markup fiscal year 2023 spending bills in July. His absence could also impact Democrats' ability to push a scaled-back version of the Build Back Better economic agenda through reconciliation, which would require every Democratic vote for passage. Democrats had hoped to complete work on the budget package before the August recess begins on August 5, given that after Labor Day their focus will shift to funding the federal government before the end of the fiscal year.

Warren, Grassley Urge FDA to Finalize OTC Hearing Aid Rule

Sens. Elizabeth Warren (D-Mass.) and Chuck Grassley (R-Iowa) have sent a [letter](#) to the Food and Drug Administration related to an effort by hearing aid manufacturers, which the Senators believe would diminish the effectiveness of over-the-counter (OTC) hearing aids. "Although couched in concerns about patient safety, the changes sought by these dominant manufacturers and their representatives would have the effect of making OTC hearing products less effective, protecting manufacturers' existing market share and locking in their competitive advantage," the lawmakers argue. They express support for the agency's proposed rule to enact OTC hearing aid regulations and urge the agency to finalize a rule that is consistent with congressional intent and ensures OTC hearing aids are safe, effective, accessible and affordable for all Americans.

Hickenlooper, Smith Inquire About Contrast Media Shortages

Sens. John Hickenlooper (D-Colo.) and Tina Smith (D-Minn.) sent a [letter](#) to Commissioner of Food and Drugs Robert Califf asking what steps his agency is taking to address shortages of contrast media commonly used in medical imaging. These shortages have reportedly impacted as many as half the nation's hospitals and limited the ability of hospitals to provide the 50 million scans performed with contrast media each year. The lawmakers assert that this is "yet another example where our supply chain has shown to be incredibly vulnerable to isolated issues that can quickly become widespread crises impacting both domestic and global supply of critical products and putting people's lives at risk." They ask the agency to detail what it is doing to ease the shortage, how new contrast media products are being directed to facilities that need them the most, and how the Food and Drug Administration plans to respond to future supply chain issues in a timelier manner.

UFA Timeline Slips in Debate Over New Regulations

The timeline for passage of legislation to reauthorize medical product user fees at the Food and Drug Administration has begun to slip ahead of the September 30 expiration of the current user fee agreements. Lawmakers had aimed to deliver a package to the President for his signature before the congressional August recess. Still, this goal has become increasingly unlikely amidst ongoing negotiations to iron out the differences between the House-passed bill and the legislation advanced by the Senate Health, Education, Labor, and Pensions Committee. The Senate package contains provisions to overhaul the regulation of diagnostic tests, dietary supplements, and cosmetics that are not contained in the House package. The agency would be required to send out 60-day reduction-in-force notices, also known as pink slips if Congress does not act by the end of this month.

Republican Mike Flood to Replace Fortenberry in House of Representatives

Nebraska Republican Mike Flood will join the House of Representatives after winning a special election last week to complete the term of Jeff Fortenberry (R). Fortenberry resigned in March after he was convicted of federal charges related to an illegal campaign contribution. Flood, a radio broadcaster and a lawyer, served the eight consecutive years allowed under state law in Nebraska's legislature from 2004 to 2013, including serving as Speaker from 2007 to 2013. He returned to the Nebraska Legislature in 2021 after running unopposed in the 2020 election.

Another Breakthrough COVID Case

Rep. Betty McCollum (D-Minn.) has tested positive for COVID-19. The congresswoman is fully vaccinated and boosted. She was quarantined at home while participating remotely in last week's House committee work week.

Supreme Court Issues Ruling in Pill Mill, EPA Cases

In a unanimous decision last week, the U.S. Supreme Court rejected the Justice Department's attempt to make it easier to convict prescribers of pain medication. The two cases -- *Ruan v. United States* and *Kahn v. United States* -- concerned the conviction of two doctors prosecuted under the Controlled Substances Act for unlawfully prescribing opioids and other controlled substances. The opinion of the court, delivered by Justice Stephen Breyer, stated that the government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so after they produce evidence that he or she was authorized to dispense controlled substances. The justices vacated the appeals court decisions affirming the convictions and sent the cases back for further review.

The Supreme Court also ruled to block the Environmental Protection Agency (EPA) from curbing power-plant emissions in a decision that will impact the administration's ability to respond to future public health threats, according to many legal scholars. The court's ruling endorsed a legal approach known as the major questions doctrine, which states that federal agencies need precise congressional authorization to address issues of major financial or political importance in novel ways. The decision could call into question administration actions concerning COVID-19 health regulations, attempts to ban menthol in cigarettes, and steps to protect reproductive health care and LGBTQ rights.

Insurers Now Required to Post Pricing Information

As of Friday, July 1, health insurers are required to publicly list their negotiated rates with in-network providers, as well as out-of-network allowed amounts and billed charges for certain items and services. The Trump-era price transparency regulation includes penalties of \$100 per person per day per violation for insurers who do not release the information. The implementation of this rule comes 18 months after a similar requirement went into effect for hospitals.

FDA Advisors Recommend Omicron-specific Vaccine

The Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee has recommended that an omicron-specific element be added to Pfizer's and Moderna's COVID-19 vaccines. New coronavirus variants have been shown to be increasingly able to evade the immunity offered by current vaccines. Results from a National Institute of Allergy and Infectious Diseases clinical study testing combinations of second booster doses to determine an optimal shot are expected to be made public later this month.

Upcoming Congressional Hearings and Markups

Senate Finance Committee hearing to Consider the Nominations of Jay Curtis Shambaugh, of Maryland, to be an Under Secretary of the Treasury and Rebecca Lee Haffajee, of Massachusetts, to be an Assistant Secretary of Health and Human Services; 10:00 a.m.; July 12

Recently Introduced Health Legislation

H.R.8229 — To clarify the applicability of certain parity provisions to mental health and substance use disorder telehealth benefits; Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means

H.R.8225 — To amend title 38, United States Code, to improve the treatment of anesthesiologist assistants in the Veterans Health Administration of the Department of Veterans Affairs; Sponsor: Rep. Cawthorn, Madison [R-NC-11]; Committees: House - Veterans' Affairs

H.R.8238 — Making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2023, and for other purposes; Sponsor: Rep. Wasserman Schultz, Debbie [D-FL-23]; Committees: House - Appropriations

H.R.8239 — Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2023, and for other purposes; Sponsor: Rep. Bishop, Sanford D., Jr. [D-GA-2]; Committees: House - Appropriations

H.Res.1208 — Supporting the goals and ideals of Alzheimer's and Brain Awareness Month; Sponsor: Rep. Barragan, Nanette Diaz [D-CA-44]; Committees: House - Energy and Commerce

H.Res.1209 — Recognizing that it is the duty of the Federal Government to develop and implement a Transgender Bill of Rights to protect and codify the rights of transgender and nonbinary people under the law and ensure their access to medical care, shelter, safety, and economic security; Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Judiciary; Education and Labor; Energy and Commerce; Financial Services; Oversight and Reform

H.R.8245 — To require the Secretary of Health and Human Services to award grants to support community-based coverage entities to carry out a comprehensive coverage program that provides to qualifying individuals and small businesses health coverage and integrated social determinant of health support services to small business workers that promote improved health, long-term economic self-sufficiency, employment and retention, and for other purposes; Sponsor: Rep. Huizenga, Bill [R-MI-2]; Committees: House - Energy and Commerce; Education and Labor

H.R.8252 — To amend title XVIII of the Social Security Act to codify patients' rights to hospital visitation, and for other purposes; Sponsor: Rep. Van Drew, Jefferson [R-NJ-2]; Committees: House - Ways and Means; Energy and Commerce