



Health Policy Briefing

September 13, 2021

House Committees Begin Markup of \$3.5T Reconciliation Bill

Committees of jurisdiction in the House of Representatives have made progress in recent days to advance major components of the \$3.5 trillion reconciliation package. The Education and Labor Committee reported out its portion of the Build Back Better plan last week, focusing on early child care and pro-worker measures, including for direct care workers. The package was advanced by a 28-22 vote along party lines.

Over a two-day markup last week, the Ways and Means Committee approved the largest expansion of the Medicare program in nearly two decades. The provision to add dental, vision, and hearing benefits to Medicare was approved in a 24-19 vote. Vision and hearing benefits would begin in 2022 and 2023 respectively, while coverage for dental benefits would begin in 2028. Rep. Stephanie Murphy (D-Fla.) was the only Democrat to vote with panel Republicans against the proposal, after [having noted](#) that the deadline was “too rushed” and “driven by politics rather than policy.” The Ways and Means portion of the tax and spending legislation would make permanent the recent two-year expansion of Affordable Care Act (ACA) premium subsidies and would provide \$425 million for the Health Profession Opportunity Grant program. The panel also voted to include elder justice legislation that would create ombudsman programs to target elder abuse and neglect, as well as a nursing home oversight measure. In addition, \$400 million in grants would be made available for three years to increase pay and staffing retention for employees of nursing homes and long-care facilities. The federal government would also be empowered to reduce payments to certain understaffed facilities. Ways and Means will reconvene on Tuesday to resume debate on the bill and to consider language related to drug pricing. Additional details on proposed tax increases and the revenue-raising portions of the bill are expected in the coming days.

The Energy and Commerce Committee is scheduled to begin marking up its portion of the social spending package today. The panel is proposing to include Democrats’ signature drug pricing

Inside

President Biden Announces New US Vaccine Mandates.....	2
GOP Doc Caucus Opposes WH Vaccine Mandate.....	3
House to Vote on CR Next Week.....	3
Senate to Consider Emergency Aid this Month.....	3
Yellen Updates Estimated Deadline for Action on Debt Limit.....	3
Klobuchar Treated for Breast Cancer Earlier This Year.	3
HHS to Make More Provider Relief Funding Available.	4
HHS Releases Report on Lowering Drug Prices.....	4
FDA Requests Input on Drug Pricing from Patent Office.....	4
2021 Key Deadlines and Expirations.....	5
Upcoming Congressional Hearings and Markups.....	6
Recently Introduced Health Legislation.....	6

legislation in the reconciliation bill. The measure would allow the Medicare program to negotiate the prices of certain medications – and extend those prices to employer-sponsored insurance – while penalizing manufacturers that raise the price of a drug above inflation. The bill would also cap out-of-pocket costs in Medicare Part D and permanently repeal the Trump-era rebate regulation. The drug pricing changes would help pay for an extension of the Affordable Care Act's (ACA) tax credits to individuals that make too much money to qualify for Medicaid in states that have opted to not expand their program until a federally-run Medicaid program is established in 2025. The proposal would also fund reinsurance programs to lower ACA marketplace premiums by 7%. The E&C package provides \$190 billion to home and community-based services (HCBS), meets the President's request for \$15 billion for pandemic preparedness programs, and provides \$3 billion to establish the Advanced Research Projects Agency for Health (ARPA-H).

The Budget Committee will combine the health care measures with various education, housing, climate, and transportation provisions ahead of the September 15 deadline set by the fiscal year (FY) 2022 budget resolution. House Speaker Nancy Pelosi (D-Calif.) aims to hold a vote on the reconciliation package this month, ahead of a vote on the \$550 billion bipartisan infrastructure framework, which is slated to have a vote by September 27. The Senate is not expected to meet the September 15 deadline, with certain Senate Democrats already stating that they wish to pare back the total size of the package, and Sen. Joe Manchin (D-W.Va.) calling on a pause in the development of the bill. Democrats will have to be unified in their support for the reconciliation bill in the evenly divided Senate, and Speaker Pelosi can only afford to lose three votes from her caucus when the bill comes to the House floor.

President Biden Announces New US Vaccine Mandates

During a [speech](#) on Thursday, President Joe Biden unveiled his ***Path Out of the Pandemic*** action plan to fight the COVID-19 pandemic and require more Americans to be vaccinated. The President's [COVID-19 Action Plan](#) has six main components:

1. Vaccinating the Unvaccinated
2. Furthering Protection for the Vaccinated
3. Keeping Schools Safely Open
4. Increasing Testing and Requiring Masking
5. Protecting Our Economic Recovery
6. Improving Care for Those with COVID-19

The Department of Labor through the Occupational Safety and Health Administration (OSHA) is tasked with issuing an Emergency Temporary Standard (ETS) to implement a requirement that all employers with 100 or more employees ensure that their workplace is fully vaccinated or that unvaccinated workers produce a negative test result at least on a weekly basis. The OSHA ETS is expected to be released in the coming weeks. Absent more details, already, key questions about the proposal include who would pay for the COVID-19 testing, how employers would verify workers' vaccination status, and its intersection with religious exemptions.

In a related [announcement](#) last week, the Centers for Medicare and Medicaid Services (CMS) will begin requiring COVID-19 vaccination of staff within all Medicare and Medicaid-certified [facilities](#), an expansion of previously-announced [emergency regulations](#) requiring vaccinations for nursing home workers. The Administration also stated that this requirement would apply to "clinical staff, individuals providing services under arrangements, volunteers, and staff who are not involved in direct patient, resident, or client care." CMS is currently developing an interim final rule with comment period that will be issued in October, but is encouraging facilities to begin complying with the new vaccination requirements immediately. Health professionals and clinical practices are likely affected under this provision if they work or provide services under arrangements at one of the above-listed facilities, including as part of a provider-based department; operate a CLIA-certified lab; serve as a DME supplier; or operate an ambulatory surgical center. Additional health professional offices may be further affected due to fee-for-service payments through Medicare, but the specifics of that would need to better defined in the upcoming CMS rule.

GOP Doc Caucus Opposes WH Vaccine Mandate

The GOP Doctors Caucus has issued a statement in opposition to President Joe Biden's executive orders mandating the COVID-19 vaccine for all federal employees and private businesses with more than 100 employees. "It is un-American for the federal government to mandate what personal health choices private businesses must require of their employees... Here is the simple truth when seeking health information, Americans should not listen to politicians, cable news, or social media — talk to your doctor," the lawmakers state.

House to Vote on CR Next Week

Majority Leader Steny Hoyer (D-Md.) expects the House of Representatives to vote on a stopgap spending bill the week of September 20, when the chamber returns to session from August recess. The potential length of the continuing resolution (CR) is still under debate. Hoyer also warned lawmakers that it may be necessary to add extra voting days in October to accommodate the chamber's busy schedule. Federal funding is currently authorized through September 30.

Senate to Consider Emergency Aid this Month

Senate Majority Leader Chuck Schumer (D-N.Y.) announced last week that he aims to enact disaster relief funding in response to Hurricane Ida and other natural disasters by the end of September. The White House has requested \$14 billion in emergency response spending for disasters that occurred prior to Hurricane Ida, which is estimated to require at least \$10 billion in additional aid, be included the forthcoming government funding package. An additional \$6.4 billion is requested to support various agencies working on Afghan resettlement.

Yellen Updates Estimated Deadline for Action on Debt Limit

Treasury Secretary Janet Yellen has updated her estimated debt-limit timeline, [notifying](#) Congress that extraordinary measures financing the government on a temporary basis will likely be exhausted during the month of October. After the debt limit was reinstated on August 1, the Treasury Department was forced to take "extraordinary measures" to prevent the U.S. from defaulting on its obligations. Yellen had previously estimated that those so-called extraordinary measures could be exhausted as early as September. If the Treasury exhausts all available extraordinary measures, the U.S. would be unable to meet its obligations for the first time in history. Action on the nation's borrowing authority is currently expected to move with a continuing resolution (CR) to fund the federal government beyond the end of the fiscal year on September 30, a vote that would require bipartisan support from 60 members in the equally-divided Senate. Many Republicans, however, have expressed opposition to a clean debt increase or suspension, with some suggesting that any change be tied to spending cuts and entitlement reform. Forty-six of the 50 Senate Republicans have said that they will not support a debt limit increase.

Klobuchar Treated for Breast Cancer Earlier This Year

Sen. Amy Klobuchar (D-Minn.) announced last week that she was diagnosed with breast cancer in February and has since completed a successful course of treatment, having undergone a lumpectomy and radiation treatment. Her doctor has told her that her chance of getting cancer again is no greater than the average person. "It's easy to put off health screenings, just like I did. But I hope my experience is a reminder for everyone of the value of routine health checkups, exams, and follow-through," she wrote in a [post](#) on Medium.

HHS to Make More Provider Relief Funding Available

The U.S. Department of Health and Human Services (HHS) has announced the availability of \$25.5 billion in new funding for health care providers affected by the COVID-19 pandemic. Providers who serve rural Medicaid, Children's Health Insurance Program (CHIP), or Medicare patients will receive \$8.5 billion in **American Rescue Plan** resources, and an additional \$17 billion will be allocated from the Provider Relief Fund (PRF). According to HHS' announcement, PRF Phase 4 allocations will be based on lost revenues and expenditures associated with the pandemic between July 1, 2020 and March 31, 2021 and will reimburse smaller providers operating on lower margins and working with underserved populations at a higher rate compared to other providers. Phase 4 will also include bonus payments for those serving Medicaid, CHIP, and/or Medicare patients. A single application will be used to apply for both programs; the application portal will open on September 29, 2021. HHS also made several other announcements regarding the PRF last week. Along with the release of the [methodology](#) used to calculate Phase 3 payments, HHS notes that providers who believe their payment was not calculated correctly will have the opportunity to request a reconsideration. Additional details about this process are forthcoming. Furthermore, because of recent natural disasters and the surge in the Delta variant, HHS will provide a final 60-day grace period for providers to complete the first period reporting requirements, which, before the grace period, was September 30, 2021. During the grace period, HHS will not initiate collection activities or similar enforcement actions for noncompliant providers.

HHS Releases Report on Lowering Drug Prices

The White House calls on Congress to pass a series of proposals aimed at cutting high drug prices in a new [report](#) issued last week. The plan, released by the U.S. Department of Health and Human Services (HHS) in response to a July executive order, expresses support for drug price negotiation, limits on price increases, promotion of competition in the pharmaceutical market, and more research into new treatments. It endorses a proposal backed by many Democrats that would allow the Medicare to directly negotiate the price of drugs, making the negotiated prices available to commercial insurance and employer-based plans as well. It also urges Congress to act to cap out-of-pocket spending for Part D beneficiaries, reduce price increases on existing drugs, increase generic and biosimilar competition, and to establish the President's proposed Advanced Research Projects Agency for Health (ARPA-H). These components track the drug pricing provisions included in the House budget reconciliation bill, described above. The HHS report also outlines the potential of several administrative changes that would not require congressional action, including a potential Part B drug payment reform model, the use of value-based payments for drugs, increased transparency around prices, rebates, and out-of-pocket spending, and permitting drug importation from other countries. The report discusses reducing regulatory barriers that may slow the approval of lower-cost alternatives as well.

FDA Requests Input on Drug Pricing from Patent Office

The Food and Drug Administration (FDA) has sent a [letter](#) to the U.S. Patent and Trademark Office (PTO) requesting input on efforts to combat rising drug prices. The letter stems from President Joe Biden's executive order to promote competition within the pharmaceutical industry. FDA asks whether PTO is considering means to limit patent thicketing and questions whether patent examiners should be given more time to review applications. In a separate [letter](#) sent to the PTO last week, Sens. Patrick Leahy (D-Vt.) and Thom Tillis (R-N.C.) urge the agency to reject patent applications that would undermine pharmaceutical competition.

2021 Key Deadlines and Expirations

As Congress returns from August recess, lawmakers will face a series of important deadlines and expirations in the coming weeks. Hart Health Strategies Inc. has compiled the following timeline for the forthcoming legislative period:

- Sept. 13: Senate returns to session; E&C reconciliation markup
- Sept. 14: W&M reconciliation markup
- Sept. 15: Deadline for committees to report their portions of the reconciliation package
- Sept. 20: House returns to session
- Sept. 27: Deadline for House consideration of the Infrastructure Investment and Jobs Act (H.R. 3684)
- Sept. 28: Comment deadline for Amendments to the FAR Buy American Act Requirements proposed rule to implement E.O. addressing domestic preferences in government procurement
- Sept. 30: FY 2021 funding and other major programs (surface transportation and National Flood Insurance) expire; End date of emergency sick leave and family leave employer tax credits, SNAP benefit increase, COBRA premium subsidies, and VA cost-sharing waiver; FDA UFA reauthorization deadline for administration review and clearance; Majority Leader Schumer says Senate to enact emergency relief funding by end of the month
- Fall 2021: Expected release of HELP Committee package to improve public health and medical preparedness and response programs
- Fall 2021: Deadline for raising or suspending debt limit; Secretary Yellen estimates exhaustion of extraordinary measures during the month of October, CBO estimates October or November
- Mid-Nov.: Limit on Dr. Woodcock's ability to remain as Acting FDA Commissioner, unless an individual has been nominated for the position
- Dec. 31: Expiration of certain tax extenders, including energy and mortgage insurance premiums; End date of expanded EITC, child tax credit, child and dependent care tax credit, employee retention credit, and Medicare sequestration suspension
- Jan. 2022: Negotiated UFA agreement due to Congress
- Jan. 31, 2022: End date of student loan repayment and interest accrual suspension

Upcoming Congressional Hearings and Markups

House Energy and Commerce Committee markup of the Build Back Better Act; 11:00 a.m.; September 13

House Ways and Means Committee markup of the Build Back Better Act; 9:00 a.m.; September 14

Recently Introduced Health Legislation

H.R.5169 — *To improve care furnished and to support the workforce in skilled nursing facilities under the Medicare program and in nursing facilities under the Medicaid program, and for other purposes. Sponsor: Rep. Neal, Richard E. [D-MA-1]; Committees: House - Ways and Means; Energy and Commerce*

H.R.5165 — *To amend titles II and XVIII of the Social Security Act to lower the Medicare eligibility age to 60, and for other purposes. Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Energy and Commerce; Ways and Means*

H.R.5163 — *To facilitate support and services to women who find themselves with an unexpected pregnancy, to meet the emotional, physical, social, financial, and other needs women encounter during pregnancy, childbirth, and child-rearing, and for other purposes. Sponsor: Rep. Fortenberry, Jeff [R-NE-1]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor; Agriculture; Judiciary; Financial Services*

H.R.5161 — *To expand small employer pooling options to provide paid family and medical leave. Sponsor: Rep. Ferguson, A. Drew, IV [R-GA-3]; Committees: House - Education and Labor; Ways and Means*

H.R.5157 — *To facilitate direct primary care arrangements. Sponsor: Rep. Crenshaw, Dan [R-TX-2]; Committees: House - Ways and Means; Energy and Commerce; Education and Labor*

H.R.5154 — *To prohibit commercial DNA testing services from disclosing the genetic information of United States nationals to foreign entities, and for other purposes. Sponsor: Rep. Burchett, Tim [R-TN-2]; Committees: House - Energy and Commerce*

H.R.5149 — *To amend the Public Health Service Act with respect to the designation of general surgery shortage areas, and for other purposes. Sponsor: Rep. Bera, Ami [D-CA-7]; Committees: House - Energy and Commerce*