

TRP Special Report: Congressional Health Policy Outlook



An Overview of Fall 2021
Congressional Priorities

August 30, 2021

Presentation Overview

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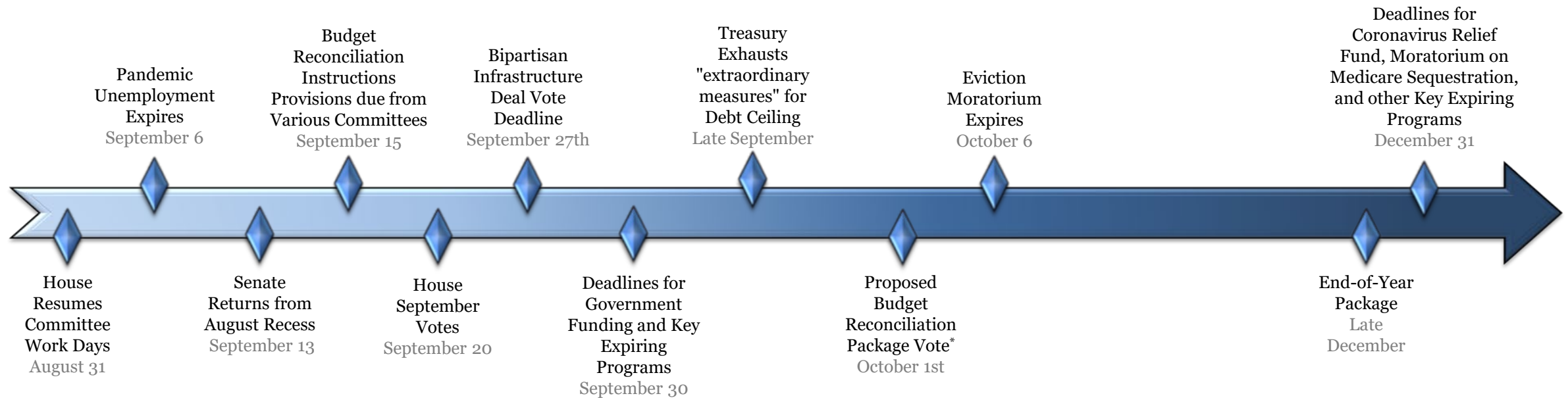
I. Fall 2021 at a Glance

- The House returned to Washington the week of August 23 with a packed agenda.
- The House is set to pass the bipartisan infrastructure deal (BID) no later than September 27.
- Key Committees of jurisdiction in both chambers will begin the process of crafting reconciliation language that conforms with the budget resolution's parameters, and lawmakers have a soft September 15 deadline to finalize their respective pieces.
- Unlike the House, the Senate has yet to pass the majority of its appropriations bills, which will likely lead to a continuing resolution (CR) in October.
- With a packed fall schedule, priorities for an end-of-year spending package are on the back burner. Among other things, the end-year package will likely address expiring COVID relief assistance and Medicare provider payments.



Fall Legislative Timeline

With the mid-term elections expected to eclipse much of next year's legislative calendar, Congress and the White House have an ambitious agenda for the rest of the year.



**timing may slip into mid October*

II. Bipartisan Infrastructure Bill

- The Senate passed the \$1 trillion bipartisan infrastructure deal (BID) on August 10.
- Now that House Speaker Nancy Pelosi (D-CA) clinched a path for the Democrats' reconciliation bill, the House is set to vote on the BID no later than September 27.
- While the BID includes "hard infrastructure" such as roads, bridges, and transportation, many of the bill's provisions are being funded by health care policies.

Three health measures will help pay for the infrastructure package.

Provision	Savings Generated*
Rebate Rule Delay	\$51 billion
REFUND Act	\$3 billion
Medicare Sequestration Extension	\$8 billion

*according to the Congressional Budget Office (CBO)



Infrastructure Funding: Rebate Rule Delay

- **What is it?** The so-called “rebate-rule” was issued at the end of the Trump Administration and would revise the anti-kickback statute so that rebates pharmaceutical manufacturers pay to Medicare Part D plans would no longer be protected. The rule would create a new safe harbor to protect discounts that are made at the point of sale.
 - ❖ The rule was projected to raise Part D premiums by 25 percent and increase federal spending by \$196 billion over 10 years.
 - ❖ The rule has never been implemented due to legal challenges and administration delays – earlier this year, the Biden administration delayed the rule until January 2023.
 - ❖ The BID would delay the rule again until January 2026, yielding \$51 billion in savings.
- **What’s Next?** After passage of the BID, Democrats are likely to consider eliminating the rule altogether to garner more savings for their reconciliation bill.



Infrastructure Funding: REFUND Act

- **What is it?** Backed by Senate Judiciary Chair Dick Durbin (D-IL) and Sen. Rob Portman (R-OH), the Recovering Excessive Funds for Unused and Needless Drugs (REFUND) Act (S. 1287) would require drug companies to refund the Department of Health and Human Services (HHS) for unused portions of drugs packed in single-dose vials.
 - ❖ Under the bill HHS would issue rebate notices to manufacturers.
- The measure is included in the BID and would save around \$3 billion act.
- Supporters of the bill argue that the current system promotes waste, since vials usually contain more medication than may be needed to ensure that enough medication is available for high-dose patients.

Aggregate

- Synthesizes total Part B discarded medication
- Occurs quarterly
- This data is already reported on Part B claims



Calculate

- Calculates cost of discarded amounts
- Calculated based on Average Sales Price (ASP) or Wholesale Acquisition Cost (WAC) if ASP is unavailable



Notify

- Notify manufacturers of rebate owed
- Provide HHS with a rebate for 100 percent of discarded medication recorded above a 10 percent low-volume threshold, effectively creating a 90 percent rebate

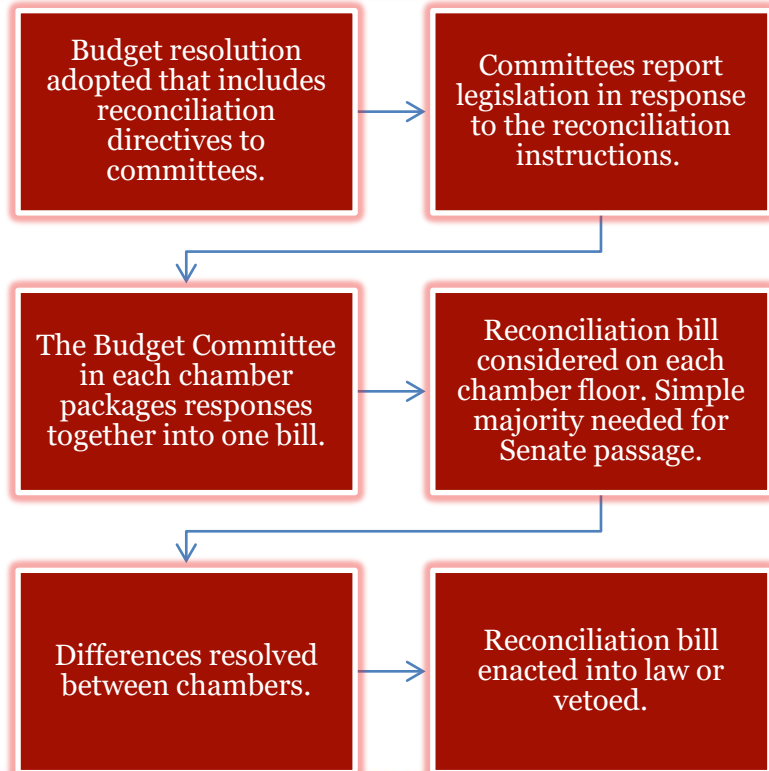
Infrastructure Funding: Sequestration Extension

- A provision in the BID would resume the 2 percent cuts to all Medicare payments beginning in 2022, through 2031.
 - ❖ This measure adds about \$8 billion to help pay for the BID.
 - ❖ The CARES Act had previously suspended the application of sequestration to Medicare from May 1, 2020, through December 31, 2021. Fee-for-service provider payments are not subject to the 2 percent reduction in payments during this time.
- Provider groups are pushing back against the cuts, citing the uptick in coronavirus Delta variant cases and associated increased costs.



III. Reconciliation

Budget Reconciliation Process



- On August 24, the House voted on party lines to pave a path for a \$3.5 trillion budget resolution for FY 2022. Democratic lawmakers in both chambers have until September 15 to finalize the bill's contents within their respective committees of jurisdiction.
- The budget resolution outlines an extensive wish list of Democrats' policies on health care, education, climate change and clean energy, tax reform, housing, labor, and more.
- Democratic leadership cautioned that the list of items contained in the resolution is "not final and not exclusive," as there is still disagreement regarding the size and scope of the bill.
- Hashing out a deal to win the support of both centrists and progressives will likely delay a House vote on the bill until October.
- It is likely that the House will write an expansive bill, and then the legislation will undergo reconstruction in the Senate to accommodate reconciliation guardrails and various interests of caucus members.

Health Policy Provisions on the Table for Reconciliation

The budget resolution calls for a series of broad policy proposals pertaining to health care, including:

Extending ACA's
income-based
subsidies

Medicare coverage of
dental, vision, and
hearing benefits

Lowering the
Medicare eligibility
age

Boosting Medicaid
home and
community-based
services

Addressing the
Medicaid coverage
gap

Expanding Graduate
Medical Education
slots

Funding to support
access to primary care

Investing in new
health equity
initiatives

Funding for future
pandemic
preparedness

Instituting a federal
paid family and
medical leave benefit

Reforming
prescription drug
pricing



Reconciliation: Medicare Expansion

Adding Hearing, Dental & Vision Coverage

- Democrats are pushing to expand Medicare benefits to include hearing, dental, and vision coverage.
 - ❖ Legislation to this end has been proposed by Rep. Lloyd Doggett (D-TX) in the House with strong Democrat support.
- While the Biden administration expressed support for these measures in the past, no specific policy proposals were outlined in the FY 2022 presidential budget priorities.
- In 2019, CBO estimated that these provisions would raise spending by approximately \$358 billion over the 2020-2029 period.

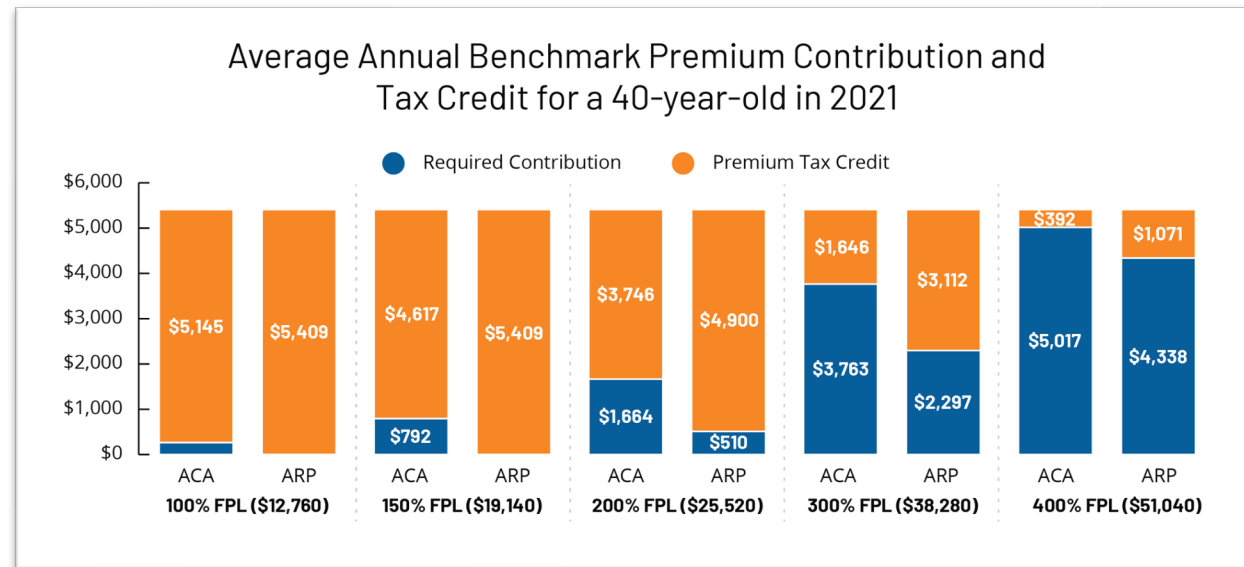
Lowering the Medicare Eligibility Age

- Democratic leaders are pushing to lower the Medicare eligibility age as part of the reconciliation bill.
 - ❖ Legislation proposed by Sen. Debbie Stabenow (D-MI) would allow for coverage starting at age 50.
- President Biden proposed lowering the eligibility age to 60 during his presidential campaign and reiterated this priority in his FY 2022 budget proposal.
 - ❖ However, the policy was omitted from a White House fact sheet that highlighted the Biden-Harris health agenda.
 - ❖ Senate Finance Chair Ron Wyden (D-OR) hinted at a lack of enthusiasm for the measure in a statement, highlighting each of the reconciliation health policies except for eligibility age.
- The Committee for a Responsible Federal Budget (CRFB) has estimated that lowering the eligibility age to 60 would cost \$200 billion over a decade.



Reconciliation: Extending ACA Subsidy Assistance

- Congressional Democrats and the White House are looking to make permanent an expansion of Affordable Care Act (ACA) income-based subsidies that was included in the American Rescue Plan (ARP).
- The ARP increased premium subsidies at all income levels for health plans sold in the ACA marketplaces.
 - ❖ The measure is set to expire after the 2022 coverage year.
- CBO estimated that the ARP's increased premium subsidies would increase federal deficits by \$34.2 billion over the 2021-2030 period.
- The CRFB estimates an increase of \$165 billion in costs over 10 years if these provisions are made permanent.



via the Kaiser Family Foundation

Reconciliation: Medicaid Expansion

Home and Community-Based Services

- Democrats are looking to provide state Medicaid programs with more funding for home and community-based services (HCBS) to offer individuals with disabilities and seniors quality home care.
- Congress is likely to tie that funding to requirements for better benefits and increased wages for caregivers, as is outlined in [S. 2210](#) and [H.R. 4131](#) introduced by Sen. Bob Casey (D-PA) and Rep. Debbie Dingell (D-MI).
 - ❖ This legislation is estimated to come with a price tag of \$250 billion as currently drafted.
- President Biden has proposed \$400 billion in funding for HCBS.
- Some Members wish to cap spending on HCBS in the budget reconciliation package at \$150 billion.

The Medicaid Coverage Gap

- Democrats are seeking alternative means to deliver health care to those who do not qualify for either Medicaid or premium subsidies in the ACA marketplace.
 - ❖ Sens. Tammy Baldwin (D-WI), Raphael Warnock (D-GA), and Jon Ossoff (D-GA) introduced [S. 2315](#) that would create a federal Medicaid-style program for those living in non-expansion states.
- Biden's FY 2022 budget priorities proposed a new federal, premium-free option that would extend affordable health coverage to those in the coverage gap.
 - ❖ The CRFB estimates that this measure would cost \$300 billion over 10 years.



Reconciliation: Drug Pricing

- Senate Democrats are looking to offset many of the health-related funding provisions in reconciliation through prescription drug pricing reforms.
- Although Sen. Wyden has not released specifics for the proposal, he did offer his drug pricing principles earlier this year.
 - ❖ This includes negotiating Medicare prices, curbing drug price increases that exceed inflation, and encouraging pharmaceutical innovation.
- CBO has estimated that Medicare drug price negotiation provisions in H.R. 3 — the House Democrats' policy wish list to promote lower drug prices — would save \$456 billion over 10 years.
 - ❖ Senate Budget Chairman Bernie Sanders (I-VT) has said more than \$600 billion in drug savings could be included in the reconciliation bill, which may also account for full repeal of the Trump-era "rebate rule."

Current Drug Pricing Legislation Proposals

Drug price negotiation

Medicare Part D benefit redesign

Medicare Part B and Part D inflation rebates

Promoting generic, biosimilar development and uptake

Manufacturer price reporting

Reconciliation: Drug Pricing, cont.

➤ Drug Price Negotiation

- ❖ Congress is considering allowing the federal government to negotiate drug prices with pharmaceutical companies on behalf of Medicare beneficiaries.
- ❖ H.R. 3 would require HHS to negotiate the price of at least 50 brand-name drugs without generic competitors, starting in 2025, based on the prices paid in six countries.
- ❖ The Senate Finance Committee is reportedly considering alternatives to the international reference pricing provisions in H.R. 3, and may instead rely on new U.S.-based pricing benchmarks to guide government negotiations.
- ❖ President Biden's Competition Executive Order endorsed Medicare drug price negotiation, as well as other proposals, such as inflation caps. It also required HHS to develop proposals to lower prices by August 23, 2021, though the report will not be made public until several weeks later.

➤ Medicare Part D Redesign

- ❖ Cap out-of-pocket spending on Medicare Part D drugs;
- ❖ Ensure that Part D plans are incentivized to promote drugs that offer the most value at the lowest cost; and
- ❖ Require drug manufacturers to provide cost discounts.



Reconciliation: Drug Pricing, cont.

➤ Medicare Parts B and D Inflation Rebates

- ❖ A smattering of legislation, including H.R.3, propose an inflation-based penalty that would require drug manufacturers to pay a rebate to the federal government if their prices for drugs covered under Medicare Parts B and D increased faster than the rate of inflation.

➤ Promoting Generics and Biosimilars

- ❖ Several pieces of legislation introduced in the 117th Congress look to promote generic and biosimilar adoption and uptake.
- ❖ Specific provisions include, but are not limited to, increasing access to biosimilars and generics through provider incentivization, limiting “pay-for-delay” deals, reducing “sham” petitions, addressing patent thickets, and more.

➤ Manufacturer Reporting

- ❖ Lawmakers are proposing a transparency component for prescription drugs, as seen in [H.R. 19](#), [S.909](#), [H.R. 2158](#), and [S.1898](#), which would require manufacturers to report certain price increases to HHS, which would then publish these increases publicly.
- ❖ Details of reporting requirements vary throughout the various legislative proposals, though the process would likely mirror the REFUND Act.



Reconciliation: Health Care Services & GME

Access to Primary Care

- Funding for access to primary care is a priority for Senate Democrats. Entities set for expansion include:
 - ❖ Community Health Centers (CHC)
 - ❖ The National Health Service Corps (NHSC)
 - ❖ Teaching Health Center Graduate Medical Education (GME)
- In 2019, bipartisan legislation from Senate HELP Chair Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) contained provisions related to the extension of CHCs, NHSC, and Teaching Health Centers that operate GME programs.
 - ❖ At that time, CBO estimated that these provisions would increase direct spending by \$22.2 billion over a 10- year period.

Graduate Medical Education

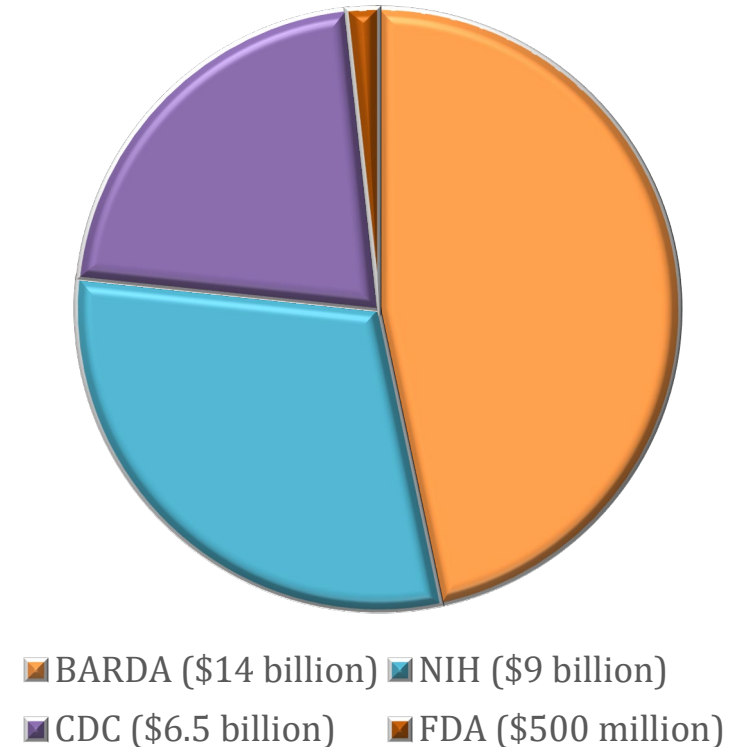
- Senate Democrats aim to tackle health care provider shortages through a GME funding boost.
- Legislative proposals in this realm look to:
 - ❖ Permanently authorize the Teaching Health Center GME program;
 - ❖ Give hospitals in rural and underserved areas additional flexibility to build out GME slots available in their residency programs; and
 - ❖ Increase residency positions eligible for GME payments under Medicare for qualifying hospitals.
- While President Biden's proposal includes a \$330 million appropriation to GME, the CRFB projects that the expansion of GME, as proposed in 2019, would cost \$20 billion over a 10-year period.



Pandemic Preparedness

- The Senate's budget resolution instructs the Senate HELP Committee to draft provisions on pandemic preparedness.
- President Biden called for a \$30 billion investment to address future pandemics, which would address vaccine response time for infectious diseases, bolstering the strategic national stockpile, improving supply chain resilience, and training pandemic responders.
- However, Democrats are considering slashing the \$30 billion to as little as \$5 billion in order to stay under the \$3.5 trillion cap. The number may be subject to more cuts as negotiations on the bill's price tag continue.

Proposed Funding Allocations



Reconciliation: Other Notable Issues

Health Equity

- Funding for maternal, behavioral, and racial justice health equity initiatives were included in the reconciliation package.
- Lawmakers signed on to a letter calling for the inclusion of provisions aimed at improving maternal health and access to coverage for new moms in the budget.
- Senators have also proposed legislation to this end to make postpartum Medicaid coverage permanent.
- President Biden's budget proposal also looks to reduce maternal mortality rate and end race-based disparities in maternal mortality through more than \$200 million in funding.

Paid Family and Medical Leave

- Democrats are pushing for a first-of-its-kind federal paid family and medical leave (PFML) program.
- Legislation has been proposed in the Senate to this end.
- President Biden's budget proposal calls for the creation of a federal PFML program to allow workers to take the time they need to bond with a new child, care for their own serious illness, or care for a seriously ill loved one.
- In 2019, CBO cost estimates for similar provisions reflect an increase in direct spending by \$547 billion over the 2020-2030 period.



IV. Appropriations Status Update

- The House and Senate are working through the 12 spending bills for FY 2022, though Congress will most likely need to pass a continuing resolution (CR) to avoid a government shutdown before the September 30th deadline.
 - ❖ **House.** Disagreements over police funding, immigration, and the Pentagon's budget have stalled the process on appropriations bill from Commerce-Justice-Science, Homeland Security, and Defense, respectively.
 - ❖ **Senate.** Only three bills have passed the full committee, and a timeline for consideration on the Senate floor is unclear as of now.

Context

Last year, Congress did not pass an omnibus spending bill until December, and lawmakers appear to be following a similar timeline as negotiations continue. This year's package is being slowed over defense, criminal justice, and the Hyde Amendment.



Appropriations Overview

Status of FY2022 Appropriations Bills

Subcommittee Bill	House Status	Senate Status
Agriculture-Food and Drug Administration	Passed House	Passed Full Committee
Commerce-Justice-Science	Passed Full Committee	Not Yet Introduced
Defense	Passed Full Committee	Not Yet Introduced
Energy-Water Development	Passed House	Passed Full Committee
Financial Services and General Government	Passed House	Not Yet Introduced
Homeland Security	Passed Full Committee	Not Yet Introduced
Interior-Environment	Passed House	Not Yet Introduced
Labor-HHS-Education	Passed House	Not Yet Introduced
Legislative Branch	Passed House	Not Yet Introduced
Military Construction-Veterans Affairs	Passed House	Passed Full Committee
State-Foreign Operations	Passed House	Not Yet Introduced
Transportation-Housing-Urban Development	Passed House	Not Yet Introduced



Agriculture-FDA Appropriations Bill

The Ag-FDA bill passed the full House, and the Senate version has been approved by the committee.

House Bill

*Provides FDA with **\$3.471 billion** in discretionary funding.*

- Includes **\$50 million** to accelerate medical product development as mandated in the 21st Century Cures Act.
- Includes a targeted increase of **\$72 million** to address the opioid crisis, medical supply chain surveillance, rare cancers, and increasing and strengthening in person inspections of foreign drug manufacturers.

Senate Bill

*Provides FDA with **\$3.414 billion** in discretionary funding.*

- **\$48.8 million** increase to address the medical and device supply chain, drug safety surveillance, the opioid crisis, and rare cancers and diseases.
- Includes an increase of **\$24 million** for International Mail Facilities for a total of \$62 million to address the opioid crisis.

Labor-HHS-Education Appropriations Bill

- The Labor-HHS-Education bill passed the House but has not yet been introduced in the Senate.
- The bill provides a total of \$119.8 billion for HHS, an increase of \$22.9 billion above the FY 2021 enacted level and \$129 million below the President's budget request.

\$240M for
Hospital
Preparedness
Program

\$3.5B for
PHSSEF

\$10.6B for
CDC

\$4.3B for CMS
Administrative
Expenses

\$9.16B for
SAMHSA

\$49B for NIH

\$905M for the
SNS

\$380M for
AHQR

\$9.1B for
HRSA

\$823M for
BARDA

V. End-of-Year Package Prospects

- Congress will likely pass an end-of-year legislative package which will include funding for the remainder of Fiscal Year 2022, updates to Medicare provider payments, COVID relief provisions, and a variety of other health provisions.
- Lawmakers will likely leverage the appropriations process to tackle several expiring policies and programs throughout the fall.

Key Expiring Health Policy Deadlines

Coronavirus Relief Fund for states and localities	December 31, 2021
CARES Act Charitable Deductions, Health & Dependent Care spending account changes	December 31, 2021
CARES Act suspension of Medicare sequestration	December 31, 2021
Delayed implementation of Medicare oncology rules	December 31, 2021
Statutory PAYGO sequestration stemming from the ARP	December 31, 2021



Medicare Provider Payments

- Without action from Congress, physician practices face a combined 9.75 percent cut under Medicare in FY 2022 compared to FY 2021. While it is unclear what relief Congress will provide, reducing the brunt of these cuts in some capacity is expected to be a priority for Congress in their end-of-year package.
- ❖ **Medicare Sequestration.** The ARP Act extended until January 1, 2022 the current reprieve from the 2 percent sequester stemming from the Budget Control Act of 2011. Those cuts are currently slated to kick back in this January.
- ❖ **Statutory PAYGO Sequester.** An additional 4 percent in 'PAYGO' sequestration cuts triggered by the ARP Act – which exceeded budgetary thresholds – would also begin in January. Should lawmakers fail to act, it will mark the first time that Congress has failed to waive Statutory PAYGO.
- ❖ **Medicare Physician Fee Schedule.** Congress enacted a 3.75 percent temporary increase in the Medicare physician fee schedule (PFS) in FY 2021 to avoid payment cuts associated with budget neutrality adjustments (related to E/M cuts). Those payment increases are scheduled to expire at the end of the year.



End-of-Year Package: Other Health Priorities

- Coronavirus Relief Fund for States and Localities
 - ❖ The CARES Act created a \$150 billion Coronavirus Relief Fund for states, local governments, tribes, and territories. State and local governments must spend or lose remaining funds given to them by the end of 2021, under an extension provided in the December COVID relief and omnibus package.
- CARES Act Charitable Deduction, Health & Dependent Care Spending Account Changes
 - ❖ The CARES Act temporarily increased the amount of charitable contributions that can be deducted to 100 percent of income (up from 60 percent) for individuals. It also created a temporary above-the-line charitable deduction of up to \$300 for donations made in 2020. The [December COVID relief and omnibus package](#) extended these provisions for an additional year, and it also allows workers with health and dependent care flexible spending accounts to roll over remaining funds from 2020 into 2021 or from 2021 into 2022.
- Delayed implementation of Medicare Oncology Rules
 - ❖ This package may also include new Medicare Radiation Oncology Rules that will delay the implementation of the radiation oncology model under the Medicare program, which will give providers more time to adapt to changes in the payment system.

