

Wynne Health Group Weekly



FRAMING THE WEEK

With Congress back from summer recess, we provide a status update on various health-related legislative priorities, including government funding and COVID-19 aid, mental health, Food and Drug Administration (FDA) user fees, and interoperability. All of these items require bipartisan support in the Senate, but lawmakers' appetite for bipartisanship is waning as midterm elections are only nine weeks away. Democrats are [slightly favored](#) to win the Senate, and Republicans are [favored](#) to win the House.

FY 2023 Appropriations

We anticipate Congress will pass a continuing resolution (CR) for fiscal year (FY) 2023, level funding the government through early December. Democratic leaders are considering December 9 or 16. The deadline for congressional action is September 30. Democratic leaders are also contemplating attaching a provision to codify protections for same sex marriage. Before the recess, Senate Majority Leader Chuck Schumer (D-NY) signaled that he wanted to hold a vote on the Respect for Marriage Act ([H.R. 8404](#)), which passed the house by 267-157 (including 47 Republicans).

The Biden Administration is requesting the CR include emergency funding for top priorities – \$22.4 billion for the COVID-19 response, \$4.5 billion for the monkeypox response, and \$13.7 billion for Ukraine. Whether Democrats can reach a deal with Republicans remains to be seen. Sen. Mitt Romney (R-UT), who brokered the \$10 billion bipartisan package, rescinded his support for additional funding after learning that the White House diverted \$10 billion from funding that Congress allocated for testing and medical supplies to purchase treatments and vaccines ([WHG summary](#)).

Table 1. COVID-19 Response

	Biden Proposal (Sept. 2022)	Senate Dem Proposal (July 2022)	Bipartisan Senate Deal (Apr. 2022)
Total	\$22.4 billion	\$21 billion	\$10 billion
Domestic Response	\$18.4 billion	\$16 billion	\$10 billion
Global Response	\$4 billion	\$5 billion	None

The Administration specifically requests \$18.4 billion for the Department of Health and Human Services (HHS), including:

- \$7.1 billion for vaccines, treatments, personal protective equipment for the Strategic National Stockpile, funding to cover the cost of administration of vaccines for the uninsured and underinsured, and improved access to treatment for people with long COVID;
- \$8 billion for research and development of next-generation COVID vaccines and therapeutics; and
- \$1.3 billion for ongoing phase 3 clinical trials for vaccines and for surveillance and lab capacity to detect emerging variants.

As for FY 2023 funding, lead appropriators in both chambers have not yet announced an agreement on topline numbers. House and Senate appropriation bills introduced by Democrats serve as a starting point

for negotiations with Republicans later this year. So far, the House [passed](#) a six-bill minibus of FY 2023 bills, including the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill, along party lines (220-207). The House Appropriations Committee has marked up all of their FY 2023 bills. Sen. Patrick Leahy released all of 12 of the FY 2023 Senate appropriations bills at the end of July. These bills have not gone through the Committee markup process, nor will they, so they do not have the full weight of the Senate. But they do serve as the Senate mark for purposes of Conference negotiations with the House.

Mental Health

The inclusion of some provisions from the Senate Finance Committee's youth mental health and telemental proposals (full summaries [here](#) and [here](#)) in the gun safety bill signed into law earlier this year has raised some questions on the timing of Senate floor action on a more comprehensive mental health package. Discussion drafts from the Committee's three remaining workgroups – workforce, parity, and care integration – are expected in the coming weeks. If the Committee does not release these remaining drafts before the end of the summer, it is unclear whether a more comprehensive mental health package would be able to pass before the end of the current Congress.

Separately, the House passed the **Restoring Hope for Mental Health and Well-Being Act of 2022 (H.R. 7666)** by a vote of 402-20 earlier this June. The bipartisan bill would reauthorize over 30 programs related to mental health and substance use disorder within the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) for FY 2023 through 2027 ([WHG Summary](#)). A similar reauthorization bill in the Senate, the **Mental Health Reform Reauthorization Act of 2022 (S. 4170)**, has not yet been marked up by the Senate Committee on Health, Education, Labor and Pensions (HELP) ([WHG summary](#)). If more comprehensive reform as urged by Senate Finance is not possible, it is likely Congress will consider legislation more so along these lines in a year-end package.

FDA User Fees

Congress has until September 30 to reauthorize the Food and Drug Administration (FDA) user fee programs for the next five years. The Senate has three potential pathways for advancing the reauthorization:

- The House passed, bipartisan **Food and Drug Amendments of 2022 (H.R. 7667)** ([WHG summary](#));
- The Senate Health, Education, Labor, and Pensions (HELP) Committee-Advanced **Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act (S. 4348)** ([WHG summary](#)); and
- Senate HELP Committee Ranking Member Richard Burr's (R-NC) **FDA Simple Reauthorization Act (S.4335)** ([WHG Summary](#)).

Negotiations this summer focused on reconciling the differences between the House and Senate versions, including the House proposal to modernize the Accelerated Approval Pathway and the Senate proposal to create regulatory oversight for in vitro clinical tests (IVCTs). However, following the passage of drug pricing reform in the Inflation Reduction Act and the tight time constraints, Congress may choose to pursue Sen. Burr's clean reauthorization package.

If Congress fails to pass reauthorization before September 30, FDA Commissioner Robert Califf has [indicated](#) that carryover funding for the prescription drug user fee program (the program that would run out of funding first) would last approximately 5 weeks into the new fiscal year. At that point, the agency would

have to prepare to issue furlough notice to employees funded by the user fees. Notably, the reauthorization of the FDA user fee programs has only been delayed once in the past 25 years.

Interoperability and Prior Authorization

Earlier this summer, the House Ways & Means Committee marked up the Improving Seniors' Timely Access to Care Act of 2022 ([H.R. 8487](#)) that would require Medicare Advantage (MA) plans to establish an electronic prior authorization program, increase transparency for MA prior authorization policies, and establish beneficiary protection standards regarding prior authorization in MA. The bill was favorably forwarded by voice vote to the House. The House is expected to vote on the legislation later this fall. The Senate version of the bill ([S. 3018](#)) has 39 cosponsors (19 D and 20 R) and has not yet been marked up. It is possible the bill could be included in a year-end package given its bipartisan and bicameral support.

On the regulatory front, the Office of Management and Budget (OMB) recently began reviewing a [proposed rule](#) that would implement certain provisions of the 21st Century Cures Act regarding the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rule would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program. The timing for promulgation of the rule communicated by OMB is October 2022, though that is subject to delay.

THIS WEEK IN HEALTH POLICY

Mon. (9/5)

- Labor Day

Tue. (9/6)

- **10:30am – ONC Meeting: Adopted Standards** – The Office of the National Coordinator of Health Information Technology (ONC) holds a meeting of the Health Information Technology Advisory Committee (HITAC) Adopted Standards Taskforce to make recommendations on ONC-adopted standards and implementation specifications. [Details.](#)
- **1:00pm – SAMHSA Meeting: Women's Services** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Advisory Committee for Women's Services to discuss program strategies. [Details.](#)

Thurs. (9/8)

- **10:00pm – NIH Meeting: Aging** – The National Institutes of Health (NIH) National Institute on Aging holds a meeting of the National Advisory Council on Aging to hear the director's report. [Details.](#)
- **1:00pm – NIH Meeting: Deafness and Communication Disorders** – NIH holds a meeting of the National Deafness and Other Communication Disorders Advisory Council to hear the director's report. [Details.](#)

Fri. (9/9)

- **10:30am – ONC Meeting: Public Health Data Systems** – ONC holds a meeting of the Public Health Data Systems Task Force 2022 to identify and prioritize policy and technical gaps associated with information systems relevant to public health and identify improvements that can be made. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Roundup of CMS information releases on long-term services and supports and children's health** – In the Policy Hub Insight Bank [here](#).
- **Blog on President Biden's Executive Order Protecting Access to Reproductive Health Services** – On the Commonwealth Fund's To the Point [here](#).
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here](#).
- **WHG Regulatory Outlook – Summer 2022 Update** – In the Policy Hub Insight Bank [here](#).
- **WHG Issue Brief on the Nutrition Policy Landscape** – In the Policy Hub Insight Bank [here](#).
- **WHG A Suite Of Potential Executive Actions For A Post-Roe World** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri. (9/2)

- **MedPAC convened** virtually for Day Two of its September 2022 public meeting and held sessions on reforming Medicare's wage index system and high-cost Part B drugs. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (9/1)

- **MedPAC convened** virtually for Day One of its September 2022 public meeting and held sessions on context for Medicare payment policy, standardizing MA benefits, and MA encounter data. All WHG session summaries are available on Policy Hub [here](#).

REGULATORY LOOKBACK

Fri. (9/2)

- **The USDA announced** that it will continue to cover the added cost of non-contract formula so that participants in the WIC program can purchase alternate sizes, forms, and brands of infant formula. [Details](#).
- **The VA announced** an IFR to remove the exclusion on abortion counseling and establish exceptions to the exclusion of abortion services for VA beneficiaries and beneficiaries enrolled in CHAMPVA. [Details](#).

Thurs. (9/1)

- **CMS released** a proposed rule entitled, "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes." Comments are due November 6. [Details](#).
- **SAMHSA announced** \$47.6 million in new grant opportunities funded by the Bipartisan Safer Communities Act. [Details](#).

Weds. (8/31)

- **HHS OIG released** an audit recommending that the HRSA improve its oversight of cybersecurity in the Organ Procurement and Transplant Network. [Details](#).
- **The USDA announced** that it has partnered with 42 states and territories to provide approximately \$12.5 billion in summer food buying benefits for families with children. [Details](#).
- **SAMHSA announced** the award of \$79.1 million in overdose prevention grants as part of President Biden's National Drug Control Strategy. [Details](#).

Mon. (8/29)

- **HHS issued** a letter to state governors inviting them to work with CMS and apply for section 1115 waivers to increase access to reproductive care. [Details](#).
- **HHS announced** it is investing \$98.9 million in grant funding to 59 returning Navigator organizations for the 2023 Open Enrollment Period. [Details](#).

COMMENT & APPLICATION DEADLINES

- **September 6:** CMS is seeking [nominations](#) for two Technical Expert Panels (TEPs). [Details](#).
- **September 6:** The CDC [released](#) a notice of grant funding to establish and fund regional Tuberculosis (TB) Centers of Excellence (COE). [Details](#).
- **September 13:** CMS [released](#) the CY 2023 Hospital OPPS and ASC Payment System Proposed Rule. Comments are due September 13. [Details](#).
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details](#).
- **September 19:** The FDA [issued](#) draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. [Details](#).
- **September 19:** HHS [announced](#) it is seeking nominations for individuals to participate as either a voting or non-voting member on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. [Details](#).
- **September 29:** The FDA [issued](#) draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for the Clinical Laboratory Improvement Advisory Committee (CLIAC). [Details](#).
- **September 30:** CMMI [announced](#) a new demonstration model aimed at improving oncology care. [Details](#).
- **October 1:** The CDC [seeks](#) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details](#).
- **October 26:** The FDA [issued](#) a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](#).
- **November 6:** CMS [released](#) a proposed rule entitled, "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes". [Details](#).

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