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A weekly dose of healthcare policy news

White House Releases Fiscal Year (FY) 2023 Budget Request

Yesterday, the Office of Management and Budget (OMB) released the FY 2023 <u>budget request</u>. The president's budget request starts the Congressional budget process. The budget presented by the Biden administration provides a roadmap to what the president would like to be implemented. However, it is not a requirement for Congressional authorizers and appropriators, and how much Congress integrates these ideas remains to be seen. Notably, policies that can be implemented without Congressional action should be given particular attention as the Biden administration believes they can be enacted through regulation or executive action.

Secretary Becerra will testify before the House Appropriations Subcommittee on Labor, Health and Human Services (HHS), Education, and Related Agencies this Thursday, March 31st. During that hearing, we will learn more about the Department's priorities. Investments in pandemic preparedness, behavioral health, maternal health, and workforce were among several of the priorities targeted in the Biden administration's <u>fiscal year (FY) 2023 proposed budget</u> for the Department of Health and Human Services (HHS). In total, the Biden administration proposed \$127.3 billion in discretionary budget authority and \$1.7 trillion in mandatory funding for FY 2023.

Highlights of the budget include:

- Advanced Research Projects Agency for Health (ARPA-H): The Budget includes \$5 billion for ARPA-H, compared to the \$6.5 billion requested in FY 2022. The goal of the agency is to "drive transformational innovation in health research and speed application and implementations of health breakthroughs" in areas such as cancer, diabetes, and dementia. Additionally, the budget contains an increase in funding (\$49 billion request) to the National Institutes of Health (NIH). Although the president's budget places ARPA-H at NIH, its ultimate location is still unclear. Many advocates have urged it to be independent of NIH, and last month's omnibus bill created it as a standalone agency within the Department of Health and Human Services (HHS). However, the bill gave HHS Secretary 30 days to decide whether to move it to NIH.
- Cancer Moonshot Initiative: The goal of the administration is to reduce the cancer death rate by at least 50% over the next 25 years while also improving the lives of cancer survivors. To this end, the administration proposes investing in ARPA-H, the National Cancer Institute, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).
- Prioritizing Mental and Behavorial Health: The budget request eliminates the 190-day lifetime limit on psychiatric services under Medicare, requires major health insurance coverage programs to cover three behavioral health visits per year without cost-sharing, and seeks to lower patients' costs for mental health services by requiring parity in reimbursement rates. The budget proposes to increase the number of mental health providers serving Medicaid beneficiaries, while also investing in workforce development and service expansion at primary care clinics and non-traditional sites. Finally, the budget makes investments in youth mental health, suicide prevention programs, and the National Suicide Prevention Lifeline. It also permanently funds Community Mental Health Centers.
- Workforce: The budget would add \$324 million in new workforce spending to a total of more than \$2 billion in FY 2023. This would include more than doubling the investment in behavioral health workforce development programs and increasing the National Health Service Corp by \$88 million to \$210 million. The budget also calls for investments in training for diversity, Teaching Health Centers Graduate Medical Education, public health and preventative medicine programs and nursing workforce development. At the same time, the budget proposes to decrease the investment in Children's Hospitals Graduate Medical Education (CHGME) by \$25 million to \$350 million.



Proposals (continued) by Category

1. Public health infrastructure and pandemic preparedness

The \$81.7 billion mandatory funding request for pandemic preparedness over five years stretches across the Office of the Assistant Secretary for Preparedness and Response, CDC, NIH, and FDA.

- \$18 million to evaluate the effects of telehealth on health quality, safety, equity, access, utilization, outcomes, and value.
- Over \$50 billion to research, develop and manufacture vaccines and therapeutics, and expand our clinical laboratory infrastructure to protect against future threats.
- \$975 million for the Strategic National Stockpile (an increase of \$130 million)
- \$9.3 billion to expand vaccine administration programs and new provisions to consolidate all vaccine coverage under Medicare Part B
- \$600 million to build a resilient public health infrastructure
- \$353 million to mount a global public health response and \$748 million for CDC efforts to protect Americans from global health threats.
- \$1.5 billion to support the CDC's efforts to respond to infectious disease outbreaks.
- \$45 million to study the effects of long-COVID
- New Secretarial authorities to grant certain flexibilities during future public health emergencies, including Emergency Use Authorization of drugs and devices without patient cost-sharing and laboratory testing flexibilities
- New funding to boost domestic manufacturing to shore up medical supply chains.
- \$97 million to advance nutrition research and reduce diet-related diseases
- \$402 million- a \$174 million increase- to support CDC environmental health activities.
- \$250 million to support data modernization and forecasting to identify future threats

2. Medical innovation and research

- \$92 million to support the revamped Cancer Moonshot Initiative.
- \$49 billion (a 9.6% increase) in NIH funding, including \$5 billion for the Advanced Research Projects Agency for Health (ARPA-H) to drive biomedical breakthroughs. The initial focus of this work would be geared toward cancer and other diseases like diabetes and dementia.
- \$268 million to support AHRQ research on health costs, quality, and outcomes.



- \$4.2 billion for the FDA to improve medical product safety and cybersecurity.
- \$34 million (a \$24 million increase) to optimize FDA inspections.
- Reauthorizations for PDUFA, the Generic Drug User Fee Act, the Biosimilars User Fee Act, and the Medical Device User Fee Act.
- \$20 million in new, one-time funding to support FDA's Oncology Center of Excellence programs (as part of the Cancer Moonshot)
- Amend the Hatch-Waxman 180-day patent challenge exclusivity provisions, so that the FDA can approve
 subsequent generic drug applications unless and until a first applicant begins commercial marketing of a drug
 and triggers the exclusivity period, at which point approval of subsequent applications would be blocked by 180
 days.

3. Behavioral health

- New provisions to modernize Medicare mental health benefits and apply the Mental Health Parity and Addition Equity Act to Medicare.
- \$7.5 billion for grants and demos to improve Medicaid mental health provider capacity plus an additional \$55 million demo to increase SUD treatment capacity in Medicaid.
- \$4.6 billion for SAMHSA mental health activities, a \$2.5 billion increase to expand access to crisis and early intervention services, and investment in children's mental health.
- \$1.7 billion for the Community Mental Health Block Grant to expand access to vulnerable populations and a permanent expansion of the Community Behavioral Health Clinic Demo.
- New authorities to regulate and enforce behavioral health network adequacy and payment parity for behavioral
 health services among public and private plans, including requiring at least three behavioral health visits per year
 with no cost-sharing and disallowing states from prohibiting same-day billing for mental and physical health visits for
 Medicaid.
- Over \$550 million for youth mental health programs and supports.
- \$447 million for Behavioral Health workforce development and burnout prevention programs
- \$11.4 billion across programs for opioid use disorder and overdose prevention programs
- \$50 million to co-locate navigators and mental health specialists in nontraditional settings.
- A \$10 million increase in mental health research.
- \$1 billion for community behavioral health clinics and community mental health centers.
- \$20 million to expand access to and collect data on mental health.



4. Access and inequities

- Additional funding to support research on health inequities and enhanced data collection on race, ethnicity and social determinants, including alternative payment models.
- \$5.7 billion in additional funding for community health centers and \$790 million for community-based services.
- Over \$1.5 billion in maternal mortality and morbidity programs.
- \$553 million for family planning, teen pregnancy prevention, and women's health initiatives.
- A \$2.5 billion funding increase plus mandatory funding (a notable shift from discretionary) increases to strengthen the Indian Health Service over the next decade.
- \$10.65 billion for HIV prevention and treatment programs over the next decade.
- \$1.9 billion for CDC violence and gun mortality prevention programs.
- \$374 million for Rural Health programs, a \$43 million increase.
- \$2.1 billion for HRSA workforce programs to expand access, particularly rural areas.
- \$45 million to HRSA to expand access to telehealth services among providers and others
- \$133 million to expand the diversity of health professionals.
- \$1.6 billion- a \$274 million increase- for chronic disease prevention and wellness programs.
- \$3.5 billion over ten years to phase in the enhanced Medicare conversion factor update for Qualifying APM Participants one year earlier to avoid a gap in incentives.
- An expansion of Medicare coverage requirements to cover services furnished by community health workers plus an exemption of such services from Medicare cost sharing requirements.

5. Investing in children

- \$405 million to support various CDC child health and safety initiatives.
- \$4.9 billion for the unaccompanied children program
- \$932 million for child welfare and abuse prevention programs and \$519 million for family violence prevention programs and support services.
- \$20.2 billion for early childcare and education programs.
- \$10 billion to support foster care initiatives over the next decade.



6. Core Departmental functions

- \$3 billion for information technology investments, including \$646 million for cybersecurity enhancements and modernizing Medicare payment systems.
- \$52 million for ONC to improve interoperability of Health IT systems and data sharing, plus new authority to issue opinions on what constitutes "information blocking."
- Enhanced funding to strengthen HHS oversight and fraud investigations, including the 340B Program, Medicare
 Advantage and Medicaid managed care plans, long-term care facilities, information blocking, and discriminatory
 practices.
- \$15 million for a new initiative to improve the accessibility of CMS data to the public and \$5 million for AHRQ to develop an all-payer claims database.
- \$10 million in additional funding to continue addressing the Medicare appeals backlog- which has been reduced by 93%.

Fight for COVID-19 Relief Funding Continues

The Senate is working to draft a new COVID-19 spending bill after the previous \$15.6 billion proposal stalled. The relief funding was initially included in the omnibus but removed due to concerns of partially offsetting those federal funds with previously allocated yet unspent state and local pandemic relief money. Senator Mitt Romney (R-UT) said last Thursday he's working with GOP leaders on a counterproposal to the offer from Democrats but didn't detail the possible offsets. The White House has urged that \$22.5 billion is necessary. However, the White House is also taking an additional approach to funding more COVID initiatives in the aforementioned 2023 budget proposal -- with nearly \$82 billion over five years for HHS to "prevent, detect and respond to emerging biological catastrophes."

Looming Deadlines

- The U.S. Department of Health and Human Services (HHS) <u>reporting portal</u> remains open only through March 31, 2022, at 11:59 p.m. (ET) for Provider Relief Fund Period 2 reporting. On April 5, 2022, at 11:59 p.m. (ET), HHS will close claim submission due to insufficient funds under two programs reimbursing providers for COVID-19 vaccinations one for the <u>uninsured</u> and the other for the <u>underinsured</u>.
- March 31 is the deadline to <u>apply</u> for new residency slots included in the Consolidated Appropriations Act. There will be up to 200 slots available starting in FY 2023, with priority going to qualifying hospitals serving geographic areas and underserved populations with the greatest need. FY 2023 slots will be announced on Jan. 31, 2023 and become effective July 1, 2023. Additional information can be found in these <u>CMS FAQs</u> and PDF of application questions.

New CMS Actuary Report

In a new CMS actuary report, annual growth in health spending is expected to average 5.1% over the next decade, which aligns with predicted GDP growth. The government's share of national health spending is expected to fall to 46% by 2024, down from a record high of 51% in 2020. Near-term trends are significantly impacted by the ongoing COVID-19 pandemic and recovery, though they are expected to normalize in 2024. Medicare spending is expected to average 7.2% over the next decade, the fastest rate among all major payers. For more information and to access the full report, read the CMS fact sheet.