



H&K Health Dose: March 14, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Biden Submits FY 24 Budget Request Congress

Last week, President Joe Biden submitted his [fiscal year 2024 \(FY 24\) budget request](#) to U.S. Congress, officially kicking off the appropriations process and revealing the Biden Administration's key healthcare priorities. Additionally, the Biden Administration has released [supplemental documents](#) such as its analytical perspectives and historical tables.

A main component of the budget focuses on Medicare solvency. The president proposes to increase the Medicare tax rate from 3.8 percent to 5 percent on earned and unearned income above \$400,000, as well as to eliminate a tax loophole that allowed certain business owners to avoid paying Medicare taxes on some of their income. Notably, the budget request represents the administration's funding goals for the coming year, and it also sheds light on the administration's policy goals. With tight margins in both chambers, it is unlikely that many legislative policies will move forward. However, stakeholders can look to the budget's policy goals as potential regulatory or executive actions that the Biden Administration could implement without the need for congressional action.

The U.S. Department of Health and Human Services (HHS) [budget in brief](#) contains details for each of HHS' various subagencies and divisions, including the Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), Substance Use and Mental Health Services Administration (SAMHSA) and the Administration for Strategic Preparedness and Response (ASPR), among many others. The HHS would see an 11.5 percent increase to its overall budget. This includes \$144.3 billion in discretionary and \$1.7 trillion in mandatory proposed budget authority.

Some highlights include the following:

- Providing \$150 billion over 10 years to improve and expand Medicaid home and community-based services, such as personal care services
- Authorizing HHS to negotiate supplemental drug rebates in Medicaid on behalf of interested states in order to pool purchasing power and capping Medicare Part D cost-sharing on certain generic drugs – such as those used to treat chronic conditions – to \$2 per prescription per month
- Continued investments in the behavioral health workforce, youth mental health treatment, certified community behavioral health clinics, community mental health centers and mental health research
- Requiring states to provide 12 months of postpartum Medicaid coverage
- Providing \$30 million for rural hospitals at risk of closure and to support expansion of hospital service lines to meet rural communities' needs
- Making permanent the enhanced premium tax credits that were extended through 2025 in the Inflation Reduction Act (IRA)
- Doubling funding for community health centers
- Expanding the National Health Service Corps (NHSC) and Teaching Health Center Graduate Medical Education program (THCGME)
- Providing Medicaid-like coverage to individuals in states that have not adopted Medicaid expansion



- Providing a \$1 billion increase for the new Advanced Research Projects Agency for Health (ARPA-H) for a total of \$2.5 billion
- Providing \$7.8 billion for FY 24 for the National Cancer Institute (NCI) to drive progress on ways to prevent, detect and treat cancer and reauthorize the 21st Century Cures Act Cancer Moonshot through 2026
- Requiring 340B covered entities to annually report to HRSA how the savings achieved through the 340B Program benefits the communities they serve, and provide HRSA regulatory authority to implement this requirement
- Establish a new capped mandatory program to provide uninsured adults with access to routine and outbreak vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost

Biden officials will testify before select congressional committees over the coming weeks to present and discuss the proposed budget as Congress works through its own appropriations process.

Senate Republicans Call for CMS to Scrap Newly Proposed Payment Model

On March 9, 2023, Republicans from the U.S. Senate Committee on Finance sent a [letter](#) to HHS Secretary Xavier Becerra and Administrator Chiquita Brooks-LaSure asking for reconsideration of the Accelerating Clinical Evidence Model recently announced by the Biden Administration. The new mandatory model is one of three CMS is testing in an effort to lower high drug cost. Under the model, CMS would develop payment methods for drugs approved under the FDA's Accelerated Approval program. The Senate Republicans argue that "While the Secretary's report cites the model as an incentive for timely completion of confirmatory trials, Congress enacted a suite of policies last year to provide the FDA with extensive authorities and tools aimed at achieving that goal." These senators believe that the model usurps responsibilities delegated by Congress to the FDA, and that if finalized, the proposal would delay access to life-saving treatments. CMS and the FDA are currently examining the feasibility of the model.

Legislation on Improving Access to Generic Medications

This week, two members of the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) are dropping legislation to expand access to generic medications and cut down on unnecessary red tape to get medications to the market quicker. Sen. Maggie Hassan (D-N.H.) and Sen. Rand Paul (R-Ky.) reintroduced the [Increasing Transparency in Generic Drug Applications Act](#), a bipartisan bill that would require the FDA to streamline the approval process for generic medications. This bill passed through the U.S. House Committee on Energy and Commerce and the Senate HELP Committee last Congress, enjoying bipartisan support.

COVID Origins Bill Awaits Biden's Signature or Veto

On March 10, 2023, the House unanimously passed the [COVID-19 Origin Act](#), sending the legislation to the president's desk. The bill would require the Biden Administration to declassify all information relating to the origin of COVID-19. Sen. Josh Hawley (R-Mo.) was the lead sponsor of the bill, and it passed under unanimous consent on the Senate side. The Biden Administration has not yet indicated whether the president plans to sign the bill into law or whether it will become President Biden's first veto.



REGULATORY UPDATES

ASPR Cybersecurity Implementation Guide for Healthcare Organizations

The Administration for Strategic Preparedness and Response (ASPR) released the Cybersecurity Framework Implementation Guide last week to support the healthcare sector in preventing cybersecurity incidents. The document, which was jointly developed with the Health Sector Coordinating Council (HSCC) Cybersecurity Working Group, outlines steps organizations can immediately take to manage cyber risks to their information technology (IT) systems. It aims to assist healthcare organizations in implementing the National Institute for Standards and Technology's (NIST) Cybersecurity Framework, including by guiding risk management principles and best practices, providing common language to address and manage cybersecurity risk, outlining a structure for organizations to understand and apply cybersecurity risk management, and identifying effective standards, guidelines and practices to manage cybersecurity risk cost-effectiveness based on business needs.

MQSA Final Rule Published; Mandates Reports on Breast Density

On March 10, 2023, the FDA issued a final Mammography Quality Standards Act (MQSA) rule. FDA is issuing this final rule to update the mammography regulations that were issued under the MQSA of 1992 and the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is issuing updates to modernize the regulations by incorporating current science and mammography best practices. These new regulations will impact services at approximately 8,700 mammography facilities across the U.S.

By the rule's effective date of Sept. 10, 2024, mammography facilities will need to comply with the amended MQSA regulations. Accordingly, the lay report for every mammography patient must include a paragraph on the significance of breast density. For patients with low breast density, the lay report received by the patient will read: "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, breast cancer risks, and your situation." For patients with dense breasts, the lay report states: "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests, in addition to a mammogram, may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." The rule also establishes four categories for reporting breast tissue density in the mammography report that is provided to the patient's healthcare provider.