



H&K Health Dose: October 4, 2022

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Congress This Week: Congress Passes CR Averting Government Shutdown

President Joe Biden on Sept. 30, 2022, signed into law the House and Senate approved [H.R. 6833](#), the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023. The continuing resolution (CR) extends federal government funding until Dec. 16, 2022, giving lawmakers time to pass a comprehensive fiscal year (FY) 2023 appropriations package when they return to Washington after the midterm elections.

The CR reauthorizes medical product user fees at the U.S. Food and Drug Administration (FDA) for five years, without larger policy riders. It includes \$12 billion in new assistance to Ukraine, \$2 billion for U.S. disaster relief, \$2.5 billion for New Mexico wildfires and \$1 billion in home heating assistance. It also includes language to allow the Federal Emergency Management Agency (FEMA) to access \$35 billion in disaster relief funds quickly to aid victims of Hurricane Ian.

The CR also includes short-term extensions of the low-volume payment adjustment to Medicare hospital payments, an extension of the Medicare Dependent Hospital Program, increased federal medical assistance percentage for the U.S. territories, and continuation of the maternal, infant and early childhood home visiting programs through Dec. 16, 2022. The CR did not include Biden Administration requests for \$22 billion in funding to combat the COVID-19 pandemic and \$4 billion to support the government's ongoing monkeypox response.

Meanwhile, Congress is scheduled to return to Washington in six weeks to complete its business after the election.

Several healthcare measures are up for consideration, including the PREVENT Pandemics Act, revisions to the FDA's accelerated approval process, measures to increase clinical trial diversity, an overhaul of diagnostics, listing requirements for dietary supplements, cosmetics regulations, a mental health package, The Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act, funding for long-COVID-19 research, Medicare Advantage (MA) prior authorization, extension of telehealth flexibilities and the Supporting Medicare Provider Act of 2022 – a Medicare fix to prevent the 4.4 percent Medicare conversion factor cut on Jan. 1, 2023.

Trauma Systems and Mobile Health Clinic Act Passes the House

The House of Representatives on Sept. 29, 2022, passed the Improving Trauma Systems and Emergency Care Act (H.R. 8163) and the Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act (S. 958). H.R. 8163 reauthorizes trauma care programs for five years and improves coordination during declared emergencies. The MOBILE Health Care Act would allow community health centers to use federal funding to establish mobile healthcare delivery sites in rural and underserved communities.



Biden Administration Hosts Conference on Hunger, Nutrition and Health

The White House on Sept. 27, 2022, [released](#) a [National Strategy on Hunger, Nutrition and Health](#) to build on the federal government's existing work to address hunger and diet-related diseases through action items across five main pillars: improving food access and affordability, integrating nutrition and health, empowering consumers to make and have access to healthy choices, supporting physical activity for all, and enhancing nutrition and food security research.

The next day, the White House hosted the Conference on Hunger, Nutrition, and Health for the first time in more than 50 years, which focused on the five main pillars. At the conference, the Biden Administration [announced](#) more than \$8 billion in private- and public-sector commitments related to the national strategy.

GAO Releases Telehealth Report

The U.S. Government Accountability Office (GAO) on Sept. 26, 2022, [released a new report](#) to Congress regarding telehealth in Medicare, recommending additional actions related to increasing oversight and provider/patient education. The report describes, among other issues, the utilization of telehealth services, Centers for Medicare & Medicaid Services' (CMS) efforts to identify and monitor risks posed by Medicare telehealth waivers, and a change in the U.S. Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) made to its enforcement of regulations governing patients' protected health information (PHI) during the COVID-19 public health emergency (PHE). GAO found that the use of telehealth services increased from about 5 million services pre-waiver (April to December 2019) to more than 53 million services post-waiver (April to December 2020).

The GAO report concludes with four recommendations:

1. CMS establishes/clarify guidance regarding billing and modifier for audio-only visits
2. CMS requires the site of service codes capturing services delivered to patients at home
3. CMS studies the quality of Medicare services delivered via telehealth, including audio-only, during the PHE
4. OCR should provide further resources to providers regarding educating patients on privacy issues related to using telehealth platforms

This GAO report follows a [recent report](#) from the HHS Office of Inspector General that found little evidence of waste and fraud related to Medicare telehealth services during the first year of the pandemic. These reports are part of a broader push to examine current telehealth flexibilities and determine how to extend them beyond the COVID-19 PHE.

REGULATORY UPDATES

CMS Announces 2023 Medicare A and B Premiums and Deductibles

Centers for Medicare & Medicaid Services (CMS) on Sept. 27, 2022, [released](#) 2023 premiums, deductibles and coinsurance amounts for Medicare Parts A and B and the Medicare Part D income-related monthly adjustment amounts. In 2023, the standard monthly premium for Medicare Part B enrollees will be \$164.90, a decrease of \$5.20 (from \$170.10) in 2022, and the deductible for all Medicare Part B beneficiaries will be \$226, a decrease of \$7 (from \$233) in 2022. The decreases stem from a decline in the price of Aduhelm and limitations on its usage, as the Alzheimer's drug was the main factor for the spike in monthly Part B premiums in 2022, according to CMS. For Part A, the inpatient hospital deductible will be \$1,600 in 2023, an increase of \$44 from \$1,556 in 2022.



For Part D, where higher income beneficiaries' monthly premiums are adjusted based on income, CMS set forth the 2023 monthly adjustment amounts, beginning with beneficiaries with less than \$97,000 in modified adjusted gross income (no monthly Part D adjustment) and incrementally increasing to a \$76.40 monthly premium adjustment for those whose modified adjusted gross income is greater than \$500,000.

CBO Report: Ways to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services

The Congressional Budget Office (CBO) on Sept. 29, 2022, published a report entitled, [Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services](#). In this report, CBO outlines multiple policy approaches available to Congress that would reduce the prices commercial insurers pay providers and thereby reduce premiums for that coverage. CBO's policy options include promoting competition among providers, promoting price transparency and capping the level or growth rate of prices. CBO determined that price-cap policies would have the largest effect on prices but that each of the three policy approaches would reduce the federal deficit.

CMS Reopens Comment Period on Medicaid Interim Final Rule

The Centers for Medicare & Medicaid Services (CMS) on Sept. 26, 2022, [reopened the comment period](#) for a 2020 interim final rule (IFR) that established requirements for states to claim a temporary increase in federal matching funds for Medicaid. Because of the possibility of changing circumstances since the IFR's publication and other policy considerations, CMS is considering modifying those requirements, which include enrollment deadlines and related policies. Comments are due by Oct. 24.

FDA Greenlights Amylyx's ALS Drug

Last week, the U.S. Food and Drug Administration (FDA) [announced the approval](#) of Relyvrio, an experimental drug combination from Amylyx Pharmaceuticals. It's the first amyotrophic lateral sclerosis (ALS, commonly known as Lou Gehrig's disease) drug to win approval in five years. Earlier this month, the FDA staff expressed concerns that the additional analysis came from the same small, mid-stage trial as initial data and could not be considered as a confirmation of the drug's benefits. Then, last month the drug received an unusual second chance review. The FDA panel reversed its March decision and voted in favor of approval. Now pricing and access debates will ensue as Amylyx Pharmaceuticals has priced its newly approved medicine at \$158,000 for a year's supply.