



## H&K Health Dose: November 29, 2022

A weekly dose of healthcare policy news

### LEGISLATIVE UPDATES

#### Congress Returns for Lame-Duck Push

Democrats will control the U.S. Senate in 2023 by a margin of one or two votes, which the Georgia run-off election will determine on Dec. 6, 2022. Republicans have control of the U.S. House of Representatives, but with a narrow majority. Until the new Congress is sworn in on Jan. 3, 2023, Democrats will continue to control both chambers.

Congress has less than three weeks before the current continuing resolution (CR) expires on Dec. 16, 2022. However, it is considered increasingly likely that Congress will pass a short-term CR to provide more time to find a compromise and solidify end-of-the-year priorities. Congress may remain in session up until Dec. 23, 2022. In the healthcare space, several items that are considered must-pass during the lame duck include extending Medicaid funding for the U.S. territories; addressing the impending 4 percent Medicare PAYGO cut; expiring Medicare low-volume and Medicare-Dependent Hospital Program payment adjustments; and reauthorizing the Maternal, Infant, and Early Childhood Home Visiting Program. The looming question is whether Congress will tack on additional healthcare items such as the U.S. Food and Drug Administration (FDA) policies left out of the user fee reauthorization package passed earlier this year, Medicare physician payment issues, longer-term telehealth flexibilities, expanding access to mental health services and pandemic-related investments. Much of what could make it into a potentially large legislative year-end deal is still in flux in large part due to the fact that top-line spending figures are still being negotiated. In short, Congress is running out of time to accomplish a lengthy to-do list.

#### House Democrats to Vote on Leadership, Caucus Rules This Week

House Democrats are considering a proposal to institute term limits for committee leadership. The caucus' rules will be voted on during the party's leadership elections for the 118th Congress on Nov. 30, 2022. An amendment from Rep. Bill Foster (D-Ill.) would allow members to serve six years at the top of a committee. Following that period, they would need caucus approval to remain in the leadership post. Democrats are also considering an amendment to the rules from Reps. Suzan DelBene (D-Wash.) and Mark Pocan (D-Wis.) that would make caucus leadership responsible for appointing the chair of the Democratic Congressional Campaign Committee (DCCC).

#### Medicare Prior Authorization Transparency Bill Introduced in Senate

Sens. Roger Marshall (R-Kan.) and Maggie Hassan (D-N.H.) introduced legislation (S. 5117) to require the inclusion of information on prior authorization requirements and other utilization management techniques in the "Medicare & You" handbook and annual notice educational materials sent to seniors during the annual Medicare Open Enrollment period. The Medicare & You Handbook Improvement Act would require the Centers for Medicare & Medicaid Services (CMS) to include information on the description of utilization management techniques, including prior authorization and step therapy, and how a beneficiary can find which techniques apply under a specific Medicare Advantage (MA) plan or prescription drug plan. It would also include a description explaining that seniors who switch to an MA plan and later switch back to their original Medicare plan may be prohibited from purchasing supplemental coverage or must pay significantly higher premiums. Reps. Mike Kelly (R-Pa.) and Tom O'Halleran (D-Ariz.) have introduced companion legislation. The bill's sponsors are pushing for its inclusion in the year-end package.



## ARPA-H Launches Website and Twitter Account

The Advanced Research Projects Agency for Health (ARPA-H) officially launched its [website](#) last week. Authorized by Congress in March 2022, the new agency will bring together industry, academia and government through public-private partnerships for high-risk, high-reward endeavors intended to drive breakthroughs in biomedicine and health. The webpage highlights the new agency's focus areas of accelerating better health outcomes and supporting the development of high-impact solutions to health problems. ARPA-H's [Twitter account](#) will provide regular updates on its current initiatives. The program is currently funded at \$1 billion, but this is considered a "down payment." Additional funding is being pursued in the fiscal year 2023 budget package that is currently being negotiated by Congress.

## HHS Plan to Fund New COVID-19 Vaccine Initiative; GOP Leaders Oppose

The U.S. Department of Health and Human Services (HHS) announced a \$350 million initiative for Health Resources and Services Administration (HRSA)-supported health centers to increase COVID-19 vaccines in their communities, specifically focusing on underserved populations. The administration's public education initiative includes an additional \$125 million for organizations serving the elderly and disabled. All HRSA-funded health centers, as well as health centers that received American Rescue Plan funding, will be eligible for the Expanding COVID-19 Vaccination initiative.

Ranking House Energy and Commerce Committee Republican Cathy McMorris Rodgers (R-Wash.) and Rep. Tom Cole (R-Okla.) publicly slammed the administration for taking \$475 million from the Provider Relief Fund to pay for the initiative without providing a clear picture of the relief fund's current status.

CMS also issued new guidance emphasizing that payers and providers are required to ensure patients have access to the most recent COVID-19 vaccines and treatments. The [guiding memo](#) implores payers to assess billing practices for monoclonal antibodies and antiviral drugs and asks nursing homes in particular to review all relevant guidance.

## Senators Move to Advance Legislation to Improve Dual-Eligible Care

A bipartisan group of U.S. senators who sit on the Senate Finance Committee are working to develop legislation to improve how individuals dually enrolled in Medicare and Medicaid are cared for and covered. The group of lawmakers, led by Sen. Bill Cassidy (R-La.), recently sent a letter to healthcare and patient communities seeking information that would help Congress craft a bill to fix the structural problems plaguing the "dual-eligible" population.

## REGULATORY UPDATES

### HHS Proposes Changes to Substance Use Disorder Patient Record Protections

HHS issued a [proposed rule](#) on Nov. 28, 2022, that would make changes concerning confidentiality of patient records for Substance Use Disorder (SUD) under 42 CFR part 2. The rule aims to remove barriers to care coordination and increase patient privacy protections by aligning Part 2 records disclosure requirements more closely with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. Proposed changes include permitted future use and disclosure of Part 2 records based on a one-time patient consent; permitted redisclosure of Part 2 records in any manner permitted by the HIPAA Privacy Rule (with certain exceptions); new patient rights to obtain an accounting of disclosures and request restrictions; expanded prohibitions on the



use and disclosure of Part 2 records in legal proceedings; new civil money penalties for Part 2 violations; updated breach notification requirements; and updated HIPAA Privacy Rule Notice of Privacy Practices requirements to specifically address Part 2 records. Public comments are due 60 days after the rule is published in the Federal Register. A [fact sheet](#) is available with more information on the rule.

## **HHS Overhauls 340B Administrative Dispute Resolution Process**

HHS issued another major [proposed rule](#) that aims to overhaul and simplify the 340B administrative dispute resolution process, which is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts or diversion. In this rule, HHS aims to make the process more accessible by making it "more expeditious and less formal." Among other changes, the Biden Administration proposes to remove the current minimum threshold of \$25,000. Any claims that are already in process would be automatically transferred to the new process. Public comments are due 60 days after the rule is published in the Federal Register.

## **Monkeypox Renamed "Mpox" in Effort to Reduce Stigma**

Monkeypox has been officially renamed "mpox" by the World Health Organization (WHO). The name change is intended to reduce stigma associated with the disease, particularly amongst minority groups, and was advocated for by the Biden Administration.