Holland & Knight

H&K Health Dose: January 24, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. House of Representatives is in recess this week, and the U.S. Senate is in session. House GOP leadership has announced a change to the chamber's schedule for next month, deciding to cut their February 2024 recess short and hold votes Feb. 28 through March 1, 2024.

Congress Passes Continuing Resolution Into Early March

On Jan. 18, 2024, U.S. Congress passed another Continuing Resolution (CR), averting a partial government shutdown in the absence of regular fiscal year (FY) 2024 appropriations bills.

In the Senate, the CR quickly passed in a 77-18 vote. In the House, the process was slightly rockier, but the measure was approved with a comfortable margin (314-108). Republicans were divided evenly, with 106 voting against the CR and the other 107 voting in favor. Still, the CR was sent to the president's desk and signed into law with time to spare.

This latest CR is "laddered," similar to the previous stopgap measure that was passed in December 2023. Funding for the first set of appropriations bills will expire March 1, 2024: U.S. Department of Agriculture (USDA), Energy-Water, Military Construction, Veterans Affairs (VA) and Related Agencies, and Transportation, Housing and Urban Development (HUD). Funding for the second set of appropriations bills expires a week later on March 8, 2024: Commerce, Justice, Science and Related Agencies, U.S. Department of Defense (DOD), Financial Services and General Government, U.S. Department of Homeland Security (DHS), Interior Environments, U.S. Department of Labor (DOL), U.S. Department of Health and Human Services (HHS), U.S. Department of Education, Legislative Branch and State, Foreign Operations and Related Programs bills. Previously, these bills were slated to expire on Jan. 19 and Feb. 2, 2024.

In addition to extending appropriations, the measure also includes several policy extenders through March 8, 2024, for specific healthcare programs, including but not limited to funding for community health centers, the Teaching Health Centers Graduate Medical Education (THCGME) program, National Health Service Corps (NHSC), Special Diabetes Programs and preventing cuts to the Medicaid Disproportionate Share Hospital (DSH) program. It would also extend the 1.0 physician work geographic practice cost index (GPCI) floor through March 8, 2024.

The CR does not include mitigating Medicare physician payment cuts, extending funding for children's hospitals that provide physician training, continuing the Medicare advanced alternative payment model bonus, pharmacy benefit manager (PBM) reforms, reauthorizing the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act and addressing transparency reforms. Negotiations on these provisions are ongoing for potential inclusion in the final FY 2024 spending package.

Members of Congress Urge HHS to Permanently Extend Telehealth Flexibilities

Sens. Brian Schatz (D-Hawaii) and Roger Wicker (R-Miss.), as well as Reps. Mike Thompson (D-Calif.) and David Schweikert (R-Ariz.) and several other members, recently authored a bipartisan, bicameral letter to HHS Secretary Xavier Becerra. The letter urges HHS to prioritize telehealth, emphasizes the need for increased collaboration on telehealth reform and requests that HHS provide "timely technical assistance and data sharing to support Congress' legislative work."

The letter also highlights the CONNECT for Health Act (S.2016). Sen. Schatz has introduced an iteration of this legislation each Congress since the 114th Congress. If enacted, it would remove certain geographic restrictions limiting Medicare coverage of telehealth services, among other provisions.

Pandemic-related telehealth flexibilities extended by the Consolidated Appropriations Act of 2023 are currently slated to expire on Dec. 31, 2024, which may provide an opportunity for movement in this policy space. However, although the bill gained traction last year – and has an impressive 61 cosponsors in the Senate – there is no indication that legislators plan to bring the legislation up for a vote in the foreseeable future. A number of thorny policy issues – such as potential U.S. Food and Drug Administration (FDA) regulation of controlled medications prescribed via telemedicine – may further complicate negotiations.

Bicameral Legislation to Expand Hospital-Based Addiction Medicine Residency Training Slots

Last week, Reps. Brad Schneider (D-Ill.), Annie Kuster (D-N.H.), David Valadao (R-Calif.), Mike Carey (R-Ohio) and Mike Kelly (R-Pa.) introduced the Substance Use Disorder Workforce Act of 2024. This bipartisan legislation would make 1,000 new Medicare-supported residency positions available to hospitals that have – or are in the process of establishing – approved residency programs in addiction medicine, addiction psychiatry or pain medicine and their prerequisite programs. Of the 1,000 positions provided in the legislation, 500 would be set aside for hospitals with established programs in addiction medicine, addiction psychiatry or pain medicine, and 500 slots would be set aside for hospitals that have established or are establishing such programs. Hospitals would not be able to receive more than 25 slots each.

Top Republican on Senate HELP Committee Continues Investigation Into 340B Revenues

Senate Committee on Health, Education, Labor and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) has expanded an ongoing investigation into the financial practices of healthcare entities that participate in the 340B Drug Pricing Program.

The investigation was opened in September 2023. Sen. Cassidy sought information related to 340B revenues of two hospitals "follow[ing] multiple reports of certain 340B recipients announcing record-setting profits with no transparency on if… that profit benefits patients." In November 2023, Sen. Cassidy announced he would also request similar revenue information from two Community Health Centers (CHCs). Last week, Sen. Cassidy again expanded the investigation and has submitted letters requesting information from two 340B contract pharmacies.

House Budget Committee Approves New Bipartisan Fiscal Commission

The House Committee on the Budget advanced legislation on Jan. 18, 2024, that would create a bipartisan fiscal commission comprising of 12 elected members and four outside experts who would provide recommendations and analysis to rein in the federal debt that include Medicare solvency concerns. Many Democrats oppose the plan, expressing concerns that the commission would slash funding for Medicare, Medicaid, Social Security and other safety net programs. However, three Democrats on the committee joined Republicans in voting to approve the bill, 22-12. The bill moves to the House floor.

Senate Committees Convene to Discuss Long COVID, Assisted Living Facilities, Patent Reform

The Senate HELP Committee held a hearing, "Addressing Long COVID: Advancing Research and Improving Patient Care," on Jan. 18, 2024. Administration witnesses were not asked to testify. Throughout the hearing, members on both sides of the aisle were critical of the National Institutes of Health's (NIH) long COVID research program, the Researching COVID to Enhance Recovery (RECOVER) Initiative. In his opening

statement, Ranking Member Bill Cassidy (R-La.) attributed some of the challenges and shortcomings in the RECOVER Initiative to a lack of congressional action on the Pandemic and All-Hazards Preparedness Act (PAHPA).

The Senate Committee on the Judiciary's Subcommittee on Intellectual Property convened to discuss the Patent Eligibility Restoration Act on Jan. 22, 2024, with panels featuring representatives from the Coalition for 21st Century Patent Reform, High Tech Inventors Alliance (HTIA), various law firms and a professor of law from George Mason University.

In addition, the Senate Special Committee on Aging addressed assisted living facilities and long-term care (LTC) options for older adults in a full committee hearing on Jan. 24, 2024.

Next Week: Senate HELP Committee to Vote on Subpoenas

In November 2023, Senate HELP Committee Chair Bernie Sanders (I-Vt.), along with a number of his colleagues, signed formal letters inviting the executives of several drug manufacturing companies to testify at an upcoming hearing. The hearing, "Why Does the United States Pay, By Far, the Highest Prices in the World for Prescription Drugs?" was tentatively scheduled for Jan. 25, 2024. However, two of the invitees declined to have their CEOs testify and instead offered senior officials. In response, Sanders announced on Jan. 18, 2024, that the committee would instead convene on Jan. 31, 2024, to vote to authorize subpoenas to compel the witnesses to testify. Should the committee vote to approve the measures, it would be the first time in more than 40 years – and the second time in history – that the panel has approved a subpoena.

Retirements

Retirements continue to roll in. Most recently, Reps. Jeff Duncan (R-S.C.) and Larry Bucshon (R-Ind.) announced their retirements. Rep. Bucshon is a member of Committee on Energy and Commerce, as well as the vice chair of the committee's Subcommittee on Health. Additionally, Rep. Bill Johnson (R-Ohio) moved his previously announced retirement up to Jan. 21, 2024, more than a month and a half earlier than expected. Energy and Commerce Committee Chair Cathy McMorris Rodgers (R-Wash.) announced the selection of Rep. Buddy Carter (R-Ga.) to replace Johnson as chair of the Energy and Commerce Committee's Subcommittee on Environment, Manufacturing and Critical Materials. Johnson resigned from Congress effective this week to start as president at Youngstown State University.

REGULATORY UPDATES

Centers for Medicare and Medicaid Services Releases Prior Authorization 2024 Final Rule

The Centers for Medicare and Medicaid Services (CMS) released the Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies final rule on Jan. 17, 2024, which requires payers to automate and provide transparency about prior authorization processes.

The release of this final rule comes several years after CMS issued the May 2020 Interoperability and Patient Access Final Rule, which implemented the first phase of interoperability rulemaking by the agency. Then, in December 2020, CMS issued the Interoperability and Prior Authorization proposed rule, which proposed requirements for state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) programs, Medicaid managed care plans, CHIP managed care entities and qualified health plans (QHPs) relating to healthcare data exchange and prior authorization processes. In consideration of these comments, CMS issued the December 2022 Interoperability and Prior Authorization proposed rule. In the final rule, CMS formally withdraws the 2020 Proposed Rule.

In a change from the proposed rule, many of these requirements will take effect on Jan. 1, 2027, a one-year implementation delay from what was proposed.

Starting Jan. 1, 2027, impacted payers will be required to build and maintain application programming interfaces (APIs) that will help automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and decisions from their electronic health records or practice management system.

- Beginning in 2026, impacted payers must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request.
- Payers must send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests.
- Impacted payers must also add information about prior authorizations (excluding those for drugs) via a Patient Access API. This requirement becomes effective on Jan. 1, 2027.

Starting in 2027, to encourage providers to adopt electronic prior authorization processes, CMS will add a new measure titled Electronic Prior Authorization to the Health Information Exchange objective for the Merit-Based Incentive Payment System Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

Notably, CMS excluded all drugs – including Part B drugs paid through a medical benefit from this requirement. CMS notes in the final rule that it did not anticipate the overwhelming response it received in favor of including drugs, and so it will evaluate options for potentially including them in the future.

CMS Announces New Innovation in Behavioral Health Model

Last week, CMS announced a new model focused on improving quality of care and behavioral and physical health of Medicaid and Medicare populations. The state-based model aims to deliver person-centered, integrated care to Medicaid and Medicare populations with moderate to severe mental health conditions and/or substance use disorder (SUD). CMS announced plans to issue awards to Medicaid agencies in up to eight states to implement the model. Four key program elements include care integration, care management, health equity and health information technology (IT) expansion. CMS will release a Notice of Funding Opportunity (NOFO) in spring 2024. The model will launch in fall 2024 and run for eight years. This model is the first to address health-related social needs (HRSNs) such as housing, food and transportation as a practice participant's responsibility. Details surrounding how these measures will be implemented, incentivized and scored are to be determined.

Independent Dispute Resolution Operations Rule Comment Period Will Reopen for 14 Days

The Biden Administration is reopening the comment period on a proposed rule that aims to streamline and improve the No Surprises Act IDR process to give stakeholders more time to offer feedback. To provide feedback or for more information, please see details on the *Federal Register*.

Advanced Research Projects Agency for Health Launches PARADIGM Program

Advanced Research Projects Agency for Health (ARPA-H) announced the Platform Accelerating Rural Access to Distributed and Integrated Medical Care (PARADIGM) program. PARADIGM is "seeking a wide range of performers to help achieve the multidisciplinary goals of the program. Interested partners are invited to read the full solicitation and register for Proposers' Day. Successful applicants will join a diverse group of performers, all of whom are committed to bringing advanced medical services to underserved rural populations

throughout the country." The abstract due date is Feb. 27, 2024, at 4 p.m. ET, with the full proposal due April 26, 2024. Proposers' Day will occur on Feb 15, 2024. Registration closes on Feb. 5, 2024, at 5 p.m. ET.

FDA Extends NARCAN Shelf Life

The FDA announced on Jan. 17, 2024, that the shelf life of newly manufactured lots of naloxone hydrochloride 4 mg nasal spray (NARCAN) is extended from three years to four years. This extension applies only to NARCAN (4 mg) nasal spray products produced after Jan. 17, 2024. The shelf life of products that were produced and distributed prior to this announcement is not affected and remains unchanged. This action aligns with the FDA's ongoing effort to prevent overdoses and reduce overdose-related mortality through expanded access to naloxone and similar agents formulated to reverse opioid overdose.

FDA Approves CRISPR Therapy Casgevy for Second Indication

Casgevy has been authorized for an additional indication: The FDA has approved the cell-based therapy for patients 12 and older with transfusion-dependent beta-thalassemia, a blood disorder that reduces blood oxygen levels due to low hemoglobin production. In December 2023, the therapy's single indication for patients with sickle cell disease was approved. Casgevy is the first clustered regularly interspaced short palindromic repeats (CRISPR)-based genetic therapy to be approved by the FDA, making this the second approved usage of CRISPR-based genetic therapy available to date.

HHS, Departments of Labor and Treasury Issue New Contraception Guidance

The 51st anniversary of *Roe v. Wade* was on Jan. 23, 2024, and the Biden Administration unveiled a series of actions to provide abortion care in emergencies. In a letter to Medicare Plans, private insurance plans and state Medicaid and CHIP programs, Secretary Xavier Becerra announced that HHS, alongside the U.S. Department of Labor and U.S. Department of the Treasury, issued new guidance to help group health plans and issuers comply with the requirements to cover contraception without cost-sharing. The announcement reiterates reproductive health as a priority for the Biden Administration. New FAQs outline how plans and issuers can make sure they meet their contraception coverage obligations. Additionally, HHS announced updates to the Medicare Part D formulary clinical review process. Plan year 2024 will include additional birth control types such as intramuscular long-acting contraceptives, and subsequent plan years will include intrauterine devices (IUDs).

GAO Reports on Workforce and Veteran Maternal Health

The Government Accountability Office (GAO) released the report, "Veterans Health: VA Should Improve Its Monitoring of Severe Maternal Complications and Mental Health Screenings," on Jan. 17, 2024. The report recommends that the VA start reviewing screening results or what demographic data it will use when monitoring severe maternal complications to address disparities. The report found that severe maternal morbidity increased from 2011 to 2020 in VA-paid delivery hospitalizations, with the rate highest among Black veterans.

In addition, the GAO released the report, "Federal Workforce: Actions Needed to Improve the Transfer of Personnel Security Clearances and Other Vetting Determinations," on Jan. 22, 2024. The report recommends addressing agency transfer security clearance continuity and agency access to a classified IT system, among other challenges. The GAO found that reciprocity data the Office of the Director of National Intelligence (ODNI) collected from agencies were inconsistent and incomplete.

JUDICIARY UPDATES

Chevron Cases Pose Potential Implications for HHS Agencies

The U.S. Supreme Court heard arguments on Jan. 17, 2024, regarding *Relentless Inc. v. Department of Commerce* and *Loper Bright Enterprises Inc. v. Raimondo* over the long-standing *Chevron* Deference Principle. Associate Justice Neil Gorsuch argued that *Chevron* is "exploited against the individual in favor of the government." Justices Ketanji Brown Jackson, Elena Kagan and Sonia Sotomayor argued for upholding the *Chevron* case, suggesting that the overturning would require that courts make policy decisions that are more aptly handled by experts at federal agencies. Major healthcare stakeholders – including the American Chemical Society (ACS), American Heart Association (AHA) and American Academy of Pediatrics (AAP) – filed an amicus brief urging the Supreme Court not to overturn the *Chevron* Deference. These stakeholders concluded their brief by stating that "authority over federal programs and policies should lie with a centralized agency of relevant subject matter experts that are accountable to Congress, the White House, and the courts to guarantee a stable, regulatory foundation for complex health policies that govern our multi-trillion-dollar American health care system. Overturning the *Chevron* decision would threaten to disrupt access to care in every geographic region, at every income level, and with every kind of medical care and public health need served by Medicare and Medicaid."

Biden Administration Concedes to D.C. District Court on Copay Accumulator Suit

The Biden Administration is no longer pursuing the overturning of a Trump Administration rule that permitted health insurers to avoid counting drug manufacturer copay assistance towards beneficiaries' annual limits on deductible and out-of-pocket costs. The U.S. Department of Justice (DOJ) moved to withdraw its appeal on Jan. 16, 2024, of a recent decision by the U.S. District Court for the District of Columbia. The decision was praised by many lawmakers on Capitol Hill, including Sens. Tim Kaine (D-Va.) and Roger Marshall (R-Kan.), as well as Reps. Buddy Carter (R-Ga.), Nanette Barragan (D-Calif.) and Mariannette Miller-Meeks (R-Iowa). The lawmakers had urged the administration to drop its appeal and introduced the Help Ensure Lower Patient (HELP) Copays Act (S. 1375/H.R. 830), which would prohibit the use of copay accumulator programs. Nineteen states have already acted to ban copay accumulator adjustment programs.

GLOBAL UPDATES

World Health Organization Releases Health Artificial Intelligence Guidance

The World Health Organization (WHO) released new guidance on ethics and governance of artificial intelligence (AI) for health on Jan. 18, 2024. The 98-page guidance addresses one type of generative AI, large multi-modal models (LMMs), which can accept one or more types of data input and generate outputs that are not limited to the type of data input. This guidance is timely, as LMMs have been predicted to have wide use and application in healthcare, scientific research, public health and drug development.