Holland & Knight

H&K Health Dose: January 30, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. House of Representatives and U.S. Senate are in session this week, with notable healthcare activity at the committee level.

FY 2024 Appropriations Agreement Reached

Senate Committee on Appropriations Chair Patty Murray (D-Wash.) and House Committee on Appropriations Chair Kay Granger (R-Texas) reached an agreement on Jan. 25, 2024, on subcommittee allocations for each of the 12 fiscal year (FY) 2024 appropriations bills. As of Jan. 30, 2024, no specifics on the agreement have been released. This agreement follows a deal between House Speaker Mike Johnson (R-La.) and Senate Majority Leader Chuck Schumer (D-N.Y.) that was reached in early January 2024, setting topline numbers at $772.7 billion for nondefense spending.

The most recent Continuing Resolution (CR) extends funding for four of the annual appropriations bills through March 1, 2024. Funding for the remaining eight bills, including the Labor, Health and Human Services, Education bill, is set to expire on March 9, 2024. The House and Senate Committee on Appropriations subcommittees still need to finalize details for each of the 12 bills before any measures come to the floor for a vote. While there are a number of potential contentious policy issues that will need to be resolved, legislators appear to be on track to meet the early March 2024 deadlines. The FY 2025 appropriations process is expected to begin shortly thereafter. This is good news for a potential healthcare package, because it means there may be something to which it can be attached.

Senate Finance Committee White Paper Proposes Bonus Payments to Hospitals for Drug Shortage Prevention Measures

Democrats on the Senate Committee on Finance released a white paper on Jan. 25, 2024, "Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs," discussing several policy proposals to address ongoing and persistent generic drug shortages. This release follows a Dec. 5, 2023, hearing in which members indicated that a legislative solution may be on the horizon. In the white paper, members note that the policies included only reflect "the Committee's preliminary areas of interest and ideas" and that it is "not a final or exhaustive" list of policies under consideration. Members also requested input from stakeholders and other experts to inform potential reforms.

Specific policy options contained in the white paper include multiple bipartisan ideas for fixing the drug shortage crisis. Many proposals call for paying hospitals more when they maintain buffer supplies and buy from drugmakers that invest in shortage mitigation measures. Medicare could pay bonuses to hospitals that have procedures for fending off shortages and pay an additional bonus when hospitals demonstrate that those procedures work. Similarly, hospitals could be paid for how well they perform on drug shortage measures, which could include either bonuses or pay cuts. The paper also calls for reforms or new pilot programs in Medicare Part D to bolster incentives for pharmacies to purchase generic medicines from drug manufacturers that invest in shortage mitigation, quality and drug supply chain resilience, as well as potential reforms to the Medicaid Drug Rebate Program (MDRP) that targets generic medicines in shortage.

Prior Authorization Legislation Likely to be Reintroduced Following CMS Final Rule

Earlier this month, the Centers for Medicare and Medicaid Services (CMS) issued its highly anticipated Interoperability and Prior Authorization final rule (CMS-0057-F), which seeks to streamline prior authorization processes and improve the exchange of electronic health data. The final rule applies to Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans and CHIP managed care entities.

The final rule includes several policies that mirror provisions of the Improving Seniors' Timely Access to Care Act. This legislation, which would only impact MA plans' use of prior authorization, had significant momentum in the 117th Congress. In 2022, the bill passed the House unanimously, but it was stalled in the Senate due to a higher-than-expected cost estimate released by the Congressional Budget Office (CBO). The legislation has not yet been reintroduced as a standalone bill in the 118th Congress, although reintroduction in the near future is likely.

While the Improving Seniors' Timely Access to Care Act only applies to MA plans, it goes further than the CMS final rule in some respects. Throughout the rulemaking process, those supportive of the legislation urged CMS to include in the final rule 1) "real time" electronic prior authorization for certain routine items and services, 2) a requirement that plans respond to certain prior authorization requests for urgent services within 24 hours (in the final rule, the timeline is 72 hours for such services), and 3) granular-level metric reporting.

MA Continues to Garner Attention from Congress and CMS

Senate Committee on Finance Chair Ron Wyden (D-Ore.) sent letters to several third-party marketing organizations that participate in the MA enrollment period to seek information on how the companies use insurance agents, lead generators and other data to target, market to and direct seniors towards certain MA plans. This inquiry follows the committee's previous work investigating MA practices, including a hearing last year that examined the upcoming MA enrollment period and marketing rules. Meanwhile, further highlighting interest in doing more in the MA arena, CMS is requesting public input on all aspects of data related to the MA program. CMS is also seeking detailed information from beneficiary advocates, healthcare providers and other stakeholders on common challenges and experiences in the MA program for which limited data is currently available. Comments on the request for information (RFI) are due on May 29, 2024. CMS calls for input on a wide array of topics. Stakeholders with data-related recommendations related to beneficiary access to care – including provider directories and networks – should submit comments, as well as those with insights into prior authorization and utilization management denials, beneficiary experiences with appeals and prior authorization algorithms.

Legislation to Permanently Extend Telehealth Flexibilities Reintroduced in Senate

Sens. Bill Cassidy (R-La.), Tina Smith (D-Minn.), John Thune (R-S.D.) and Ben Cardin (D-Md.) reintroduced the Telemental Health Care Access Act of 2023 on Jan. 24, 2024. The legislation would permanently eliminate the "in-person visit requirement" for Medicare patients who receive mental or behavioral health services furnished via telehealth. Under this requirement, such patients must have seen a provider in-person within six months of their first telehealth visit and annually thereafter.

Congress established the in-person requirement when it made permanent a key pandemic-era flexibility allowing Medicare coverage of telehealth for mental health services. However, subsequent legislation has delayed implementation of the requirement, most recently through Dec. 31, 2024. Several other telehealth flexibilities are also set to expire at the end of the year. These include flexibilities allowing Medicare reimbursement for certain audio-only telehealth services such as Evaluation and Management (E/M) visits. Legislators and witnesses at a Senate subcommittee hearing in November 2023 warned Congress should act

quickly to address the temporary accommodations, as regulatory uncertainty could push providers away from virtual care.

Senators Push for New Federal AI Agency to Centralize Regulation of Digital Platforms

In a Jan. 23, 2024, letter to Senate Majority Leader Chuck Schumer (D-N.Y.), Sens. Elizabeth Warren (D-Mass.), Michael Bennet (D-Colo.), Lindsey Graham (R-S.C.) and Peter Welch (D-Vt.) called for the establishment of an independent federal agency tasked with the comprehensive oversight of industries utilizing digital platforms and artificial intelligence (AI). In the letter, legislators argue that a decentralized approach to regulating such industries would "result in a fragmented regulatory landscape ripe for exploitation." They note that historically, it has been necessary to create new regulatory entities to effectively address new technologies and assess associated policy challenges, drawing parallels to industry changes that led to the establishment of the U.S. Food and Drug Administration (FDA), Federal Communications Commission (FCC) and Federal Aviation Administration (FAA).

Agencies' statutory authority to regulate AI and digital technology was also examined in a Jan. 25, 2024, U.S. Government Accountability Office (GAO) report, "Selected Emerging Technologies Highlight the Need for Legislative Analysis and Enhanced Coordination." As discussed in the report, the FDA indicated it lacks the statutory authorities needed to effectively regulate AI, particularly with regard to the authorities needed to regulate AI-enabled medical devices. However, GAO concluded that the FDA has not "clearly identified, documented, and communicated to Congress the specific legislative changes that would help it address these challenges." The report noted that, as a result, "FDA may miss opportunities to fully realize the public health benefits of this technology," and recommended that it identify and communicate potential legislative changes to Congress. The report also referenced Senate Committee on Health, Education, Labor and Pensions (HELP) Committee Ranking Member Bill Cassidy's (R-La.) continued interest in drafting legislation to expand the FDA and CMS authorities to conduct oversight over the use of AI in healthcare.

Drug Manufacturing CEOs Agree to Testify at Senate HELP Committee Hearing on Drug Costs

Senate HELP Committee Chair Bernie Sanders (I-Vt.) announced that the CEOs of two drug manufacturing companies will appear as witnesses at a Feb. 8, 2024, hearing to examine prescription drug costs. Previously, the two companies declined invitations for their CEOs to appear before the committee, instead offering senior officials. The HELP Committee was expected to convene this week for votes to authorize subpoenas compelling the invitees to testify. Both companies reversed course ahead of the scheduled subpoena votes, and the two CEOs will appear at the Feb. 8, 2024, hearing voluntarily. The CEO of a third drug manufacturing company accepted the committee's initial invitation to testify; that CEO will also join the Feb. 8, 2024, hearing.

Key House Panel to Hold Hearing on Federal Healthcare Spending

The House Committee on Energy and Commerce (E&C) Subcommittee on Health will convene for a hearing on Jan. 31, 2024, "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers." In a press release published by the E&C Committee Chair Cathy McMorris Rodgers (R-Wash.) and E&C Committee Subcommittee on Health Chair Brett Guthrie (R-Ky.), the hearing is described as an opportunity to discuss the "factors…causing cost increases for individuals, for the health care sector, and for federal health programs such as Medicare and Medicaid."

Bipartisan Congressional Digital Health Caucus Launch

Reps. Troy Balderson (R-Ohio) and Robin Kelly (D-Ill.) are the co-chairs of a new, bipartisan Congressional Digital Health Caucus established to "inform policymakers of rapid advancements in digital health innovation, highlighting the potential impacts on patients and the health care system, and ensuring that all Americans benefit from the transformative power of digital health tools." A congressional briefing to announce the caucus

launch will be held on Feb. 1, 2024. A panel will discuss current developments, potential challenges and other policy considerations related to AI in healthcare. Congress has shown significant interest in digital health technologies and understanding the role of AI in healthcare, with several key committees convening hearings last year to examine the issue.

In related news, a bipartisan group of senators have sent a letter to Majority Leader Chuck Schumer (D-N.Y.) calling for the creation of a federal agency responsible for regulating the technology industry. Schumer has recently convened a series of AI Insight Forums underscoring the need for a comprehensive approach to AI. The letter, which was signed by Sens. Michael Bennet (D-Colo.), Lindsey Graham (R-S.C.), Elizabeth Warren (D-Mass.) and Peter Welch (D-Vt.), also endorses the Digital Platform Commission Act (S. 1671) and the Digital Consumer Protection Commission Act (S. 2597) to establish a new enforcement authority to oversee the tech sector.

Retirements

Rep. C.A. "Dutch" Ruppersberger (D-Md.) recently announced he would retire from Congress at the end of the year after more than two decades serving in the House. Currently, Ruppersberger is a member of the House Committee on Appropriations and sits on the Commerce, Justice, Science and Related Agencies Subcommittee. He previously served for 12 years on the House Committee on Intelligence, including for four years as its ranking member.

Additionally, Rep. Kelly Armstrong (R-N.D.) – who is currently in his third term representing North Dakota's sole congressional district – announced his intent to run for governor rather than seek reelection to Congress. Armstrong is the vice chair of the House E&C Committee, a position he has held since January 2023. Notably, the announcement of Armstrong's retirement brings the total to eight members of Congress leaving the House E&C Committee. A full list of House members retiring or seeking other office is available online.

REGULATORY UPDATES

MACPAC Holds January Public Meeting; Approves Seven Recommendations to Congress

The Medicaid and CHIP Payment and Access Commission (MACPAC) held its January 2024 Public Meeting last week. The advisory panel discussed potential recommendations to increase congressional and regulatory oversight of Medicaid managed care organization (MCO) denials and to improve the appeals process for beneficiaries.
MACPAC voted in favor of including seven recommendations in its upcoming report to Congress, which will be released in March 2024. Those recommendations are as follows:

- Require states to establish an independent, external medical review process for beneficiaries who have exhausted internal appeals channels
- Issue federal guidance on the content and clarity of denial notices
- Require MCOs to allow beneficiaries to opt in to receive electronic denial notices
- Extend the timeline for enrollees to request a continuation of benefits
- Issue guidance to states to ensure beneficiaries are aware of their rights and potential recoupment
- Require states to collect and report data on denials, beneficiary use of continuation of benefits and appeal outcomes
- Require states to conduct routine clinical audits of denials
- Publish the Managed Care Program Annual Reports on the CMS website in a standardized format

MedPAC and MACPAC Release Data Book on Dually Eligible Beneficiaries

The Medicare Payment Advisory Commission (MedPAC) and the MACPAC jointly released the 2024 Data Book on Beneficiaries Dually Eligible for Medicare and Medicaid. The new "Duals Data Book" describes the disproportionate share of spending that Medicare and Medicaid dual-eligibles or "duals" comprise in both programs. According to the report – which reports on the duals population's composition, service use and spending in calendar year 2021 – duals accounted for 35 percent of Medicare spending while only representing 19 percent of the total Medicare population. Similarly, Medicaid duals accounted for 27 percent of spending while only representing 13 percent. The report was expanded this year beyond traditional FFS and reported on managed care enrollment. Reflective of the continuing shift from FFS to "value-based" arrangements, around 40 percent of duals were exclusively enrolled in FFS in 2021.

HRSA Launches New National Maternal Health Initiative

Health Resources and Services Administration (HRSA) Administrator Carole Johnson, joined by Rep. Lauren Underwood (D-Ill.), co-chair of the Black Maternal Health Caucus, launched a year-long Enhancing Maternal Health Initiative. According to the official press release, the initiative aims to achieve measurable progress in maximizing the impact of HRSA grants and programs to address maternal mortality and improve maternal health; foster new partnerships and collaborations among HRSA grantees in high-need, high-opportunity jurisdictions to address maternal mortality and improve maternal health; and strengthen HRSA's internal capacity to maximize the impact of HRSA's maternal health grants, programs and resources. This initiative builds upon the Biden Administration's Mental Health Blueprint released in 2022, among other ongoing efforts.

New NIH Women's Health Office of Autoimmune Disease Research to Host Roundtables

The Office of Autoimmune Disease Research (OADR) is a newly established office in the Office of Research on Women's Health (ORWH). The office is guided by directives in the Consolidated Appropriations Act (CAA) 2023, as well as National Academies of Sciences, Engineering and Medicine's (NASEM) Enhancing NIH Research on Autoimmune Disease report. OADR-ORWH will hold two sessions, hosted by Dr. Vicki Shanmugam, Director of ORWH and OADR, who will provide OADR-ORWH updates and solicit public feedback.

Session 1 is a community roundtable designed to engage community partners, including advocacy groups, patients and other interested members of the public, on how to improve opportunities for and participation in autoimmune disease research and share recent findings. Register online to attend the "Updates on OADR-ORWH" Session 1: Community Roundtable on Feb. 2, 2024, at 12:00 p.m. EST.

Session 2 is an academic roundtable designed to engage OADR-ORWH's academic partners, including researchers, scientists and physicians. Register online to attend the "Updates on OADR-ORWH" Session 2: Academic Roundtable on Feb. 23, 2024, at 12:00 p.m. EST.

FDA Reorganizes to Establish "Super Office" on Medical Device Cybersecurity and Digital Health

The FDA has elevated and expanded the Office of Strategic Partnerships and Technology Innovation (OST), which handles activities, including medical device cybersecurity and digital health. Effective immediately, OST has become a "super office" that includes five offices: 1) Office of Readiness and Response, 2) Office of Equity and Innovative Development, 3) Digital Center of Excellence, 4) Office of Technology and Data Services, and 5) Office of Supply Chain Resilience.

CMS to Issue Initial Offers for First Round of Medicare Drug Cost Negotiation Program Selected Drugs

The statutory deadline for the Centers for Medicare and Medicaid Services (CMS) to submit its first round of initial offers under the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program is Feb. 1, 2024. The first 10 drugs selected to participate in the program were announced in August 2023. By Feb. 1, 2024, CMS must provide drug manufacturers with a proposed "maximum fair price and a concise justification" of the agency's reasoning for the initial offer. Drug manufacturers will have 30 days to respond. The negotiation period will end on Aug. 1, 2024, with negotiated prices effective in 2026.

FDA Seeks Nominees for Gene Therapy Committee

The FDA is requesting written requests for nominations for a nonvoting industry representative to serve on the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) and its Center for Biologics Evaluation and Research (CBER). Nominations may either be self-nominated or nominated by an organization. All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Application Portal. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website.

NSF to Launch National AI Research Pilot

The National Science Foundation (NSF) launched the National Artificial Intelligence Research Resource (NAIRR) pilot. Led by the NSF in partnership with 10 other federal agencies and 25 nongovernmental partners, the pilot makes available government-funded, industry and other contributed resources in support of the nation's research and education community. This action builds upon NAIRRR's June 2021 report to culminate computational, data, software, model, training and user support resources, and will focus on supporting research and education across the nationwide research community.

HHS Releases New Cybersecurity Performance Goals

The Administration for Strategic Preparedness and Response (ASPR) released a new set of voluntary healthcare and public health sector specific cybersecurity performance goals (CPGs). The CPGs, which aim to better protect the healthcare sector from cyberattacks, improve response when events occur and minimize residual risk, were previously outlined in an HHS cybersecurity concept paper released in December 2023.

JUDICIARY UPDATES

No Surprises Act Suit Given Partial Revival

A group of surgeons have had their federal surprise billing case partially revived. As ordered by a three-judge panel on the U.S. Court of Appeals for the Second Circuit, the plaintiff can amend their case in lower court to reflect new arguments in their No Surprises Act challenge. The federal law seeks to protect patients from surprise medical bills for emergency care from out-of-network providers, and it set up a process for insurers and clinicians to settle disputes over payment amounts. The plaintiffs argue that regulations to impose guardrails on the No Surprises Act's arbitration process – a process used to resolve payment disputes for surprise out-of-network bills between payers and out-of-network clinicians – are invalid under the Administrative Procedure Act. In addition, the plaintiffs argue that major provisions of the No Surprises Act establishing the arbitration process and banning providers from sending balance bills to patients violate the Seventh Amendment, due process under the Fifth and Fourteenth Amendments, and the Takings Clause. The outcome of this suit carries substantial implications for the occurrence of unforeseen medical billing, including impacting access and affordability for patients.

Fourth Circuit Tests Meaning of New Drug for Rebate Program, *Chevron* Deference Dispute

A U.S. Court of Appeals for the Fourth Circuit panel deliberated the definition of "line extension" of a drug in a case involving the Medicaid Drug Rebate Program. A district court decision is on appeal to uphold the CMS' recent definition of "line extension" as a "new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary)." A maker of products that would now be considered a line extension, contended before the Fourth Circuit that the definition is too broad under the Administrative Procedure Act and may impede drug innovation. The Fourth Circuit Court of Appeal panel debated the plain meaning of the underlying statute, and the matter of the *Chevron* deference was examined within the context of the case. One panelist expressed apprehension that a narrow interpretation of the definition could lead to reduced rebates and impede CMS authority.

DOJ Investigates AI Tools, References Pharmaceutical Company Case

The U.S. Department of Justice (DOJ) is conducting an inquiry into AI embedded in electronic medical records (EMRs), which prompt doctors to recommend treatments. Prosecutors have initiated subpoenas directed at pharmaceuticals and digital health companies to determine ramifications and correlation between these AI algorithms and anti-kickback and false claims violations. AI is becoming increasingly utilized in EMRs to match patients with particular drugs and devices.

DOJ is monitoring potential legal ramifications for companies that derive benefits from treatment recommendations associated with this technology. Several pharmaceutical companies have disclosed to shareholders in recent years that federal prosecutors have issued subpoenas to investigate the companies related to EMRs. DOJ attorneys pointed to the $145 million penalty of an EMR technology developer after its' admission of soliciting and receiving kickbacks from a pharmaceutical company in exchange for using clinical decision software to influence doctors' opioid prescription decisions.