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H&K Health Dose: February 22, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Both chambers are currently out for the President's Day recess – the U.S. Senate returns on Feb. 26, 2024, and the U.S. House of Representatives returns on Feb. 28, 2024 – two days before the first of two upcoming appropriations deadlines. Before adjourning, the Senate voted to advance a national security supplemental spending package crafted over a months-long negotiation process. The supplemental, which would provide $95 billion in aid to Ukraine, Israel and Taiwan if enacted, passed the Senate with bipartisan support in a 70-21 vote. The package also includes the FEND Off Fentanyl Act, which would provide $1.2 billion to curb fentanyl trafficking and allow for the sanctioning of fentanyl cartels. House Speaker Mike Johnson (R-La.) immediately rejected the package as "dead on arrival," citing concerns about border security. A scaled-back, bipartisan counterproposal led by Rep. Brian Fitzpatrick (R-Pa.) has gained some traction. However, both measures would face a rocky path forward as it stands now.

Current tensions could have far-ranging implications for the fiscal year (FY) 2024 appropriations process and for broader House dynamics overall. Rep. Johnson is facing pressure from members in both parties to hold a floor vote on one of the proposed national security/foreign aid/border security packages. At least one Freedom Caucus member, Rep. Marjorie Taylor Greene (R-Ga.), has recently threatened to push a Motion to Vacate in an effort to remove Rep. Johnson from leadership should the Senate-originating supplemental come to the House floor for a vote.

Timing adds an additional layer of complexity: When the House reconvenes, lawmakers will only have a few legislative days to negotiate details and advance FY 2024 spending legislation. Current short-term funding measures are set to expire on March 1, 2024, for some agencies, including the U.S. Food and Drug Administration (FDA), and on March 8, 2024, for the remainder, including the U.S. Department of Health and Human Services (HHS). These are also significant dates for several essential health programs such as the Community Health Center (CHC) program, Teaching Health Center Graduate Medical Education Program (THCGME) and National Health Services Corps (NHSC). Absent congressional action, these programs will either run out of funding or face dramatic cuts to existing funding once the March 1, 2024, and March 8, 2024, deadlines pass.

Additionally, President Joe Biden is scheduled to give his annual State of the Union address to Congress on March 7, 2024. Just days after this address and the aforementioned FY 2024 appropriations deadlines, the FY 2025 appropriations process will begin in earnest with the submission of the president's budget request on March 11, 2024.

FY 2024 Appropriations: Potential Health Cost Transparency Package; Other Measures

Some legislators are hopeful that the vehicle for the FY 2024 U.S. Department of Labor (DOL), HHS, U.S. Department of Education and Related Agencies (Labor-HHS) appropriations bill may provide an opportunity to advance a fairly wide-ranging health package. There is not yet any formal agreement in place or publicly available information regarding the scope of a proposed package. However, several members have indicated they are pushing for the inclusion of healthcare costs and transparency measures that mirror legislation finalized in late 2023.

- H.R. 5378, the Lower Costs, More Transparency Act (LCMTA), was passed by the House on Dec. 11, 2023, in a bipartisan 320-71 vote. This legislation is a top priority for retiring House Committee on Energy and Commerce (E&C) Chair Cathy McMorris Rodgers (R-Wash.). It would impose a number of

transparency requirements on hospitals, ambulatory surgical centers (ASCs), laboratories, imaging centers, Pharmacy Benefit Managers (PBMs) and health plans. The measure also includes several health extenders to provide funding for programs such as the CHC, NHSC, THCGME and the Special Diabetes Programs (SDPs).

- S. 3430, the Better Mental Health Care, Lower-Cost Drugs and Extenders Act (Better Act), was approved unanimously by the Senate Committee on Finance and reported to the full Senate on Dec. 7, 2023. It contains a number of PBM transparency measures and health extenders similar to those included in the LCMTA.
- S. 3548, the Health Care PRICE Transparency Act 2.0 (PRICE Transparency 2.0), was introduced by Sen. Mike Braun (R-Ind.) and Senate Committee on Health, Education, Labor and Pensions (HELP) Chair Bernie Sanders (I-Vt.) in December 2023.

Both the LCMTA and PRICE Transparency 2.0 would 1) codify the Hospital Price Transparency Rule and the Transparency in Coverage (TiC) final rule, 2) expand certain transparency requirements to ASCs, laboratories and imaging centers, and 3) increase maximum annual civil monetary penalties (CMPs) for hospital non-compliance to $10 million, depending on hospital size. Currently, the Centers for Medicare & Medicaid Services (CMS) has the authority to determine CMP amounts, which are currently capped at an annual maximum of $2 million. PRICE Transparency 2.0 differs from the LCMTA in that it would require public reporting of actual cash prices – not median discounted cash prices – for all services by 2025.

The LCMTA and the Better Act would both delay the implementation of annual $8 billion cuts to Medicaid Disproportionate Share Hospitals (DSHs) through 2025. Notably, as a pay-for to cover the costs of the Medicaid DSH cut provision, the LCMTA would implement a controversial site-neutral payment policy for Medicare Part B physician-administered drugs in off-campus hospital outpatient departments (HOPDs). Site-neutral payment has been the subject of much debate throughout the FY 2024 appropriations process. The Congressional Budget Office (CBO) estimated in January 2024 that, if enacted, the LCMTA site-neutral payment provision would save Medicare approximately $3.8 billion over a 10-year period. For legislators attempting to find offsets for the costs of other health priorities, these estimates are appealing. In the Senate, however, several members serving on key committees have expressed concerns about potential impacts on rural hospitals.

Several members are eager to address telehealth flexibilities currently slated to expire at the end of the calendar year (CY). Sen. Mark Warner (D-Va.) recently called for the passage of legislation to make the flexibilities permanent, though policies will likely not be considered until the end of the year.

Additionally, some of the 20-odd measures included in last week's House E&C Committee hearing, "Legislative Proposals to Support Patients and Caregivers," have also garnered attention. Specifically, provisions of legislation to reauthorize Dr. Lorna Breen Health Care Provider Protection Act, which supports programs addressing mental health education and awareness campaigns for healthcare workers, is a likely candidate for inclusion.

Temporary Medicare Physician Payment Fix Under Consideration; New Bipartisan Senate Working Group on Long-Term Reform

There is significant pressure to pass legislation addressing the 3.37 percent cut to the Medicare Conversion Factor (CF) that took effect on January 1, 2024. CMS has indicated that it would reprocess claims with the new rates should Congress retroactively address the cut. The Senate Committee on Finance's Better Act contains a measure to implement an extra 1.25 percent bump to payments under the Medicare Physician Fee Schedule (MPFS) for services furnished in CY 2024. This would partially offset the 3.4 percent cut down to 2.15 percent. The House E&C Committee also approved a measure to address the cuts in a December 2023 markup. The legislation, the Physician Fee Schedule Update and Improvements Act (H.R. 6545), would include an offset to

the CF reductions totaling 2.5 percent, among other longer-term reforms to physician pay.

Considering the pressure on legislators to pass a fix, it is likely that some payment relief for Medicare physicians will be included in a spending package – even if it is just a temporary stopgap measure. Currently, discussions are centered on a proposal to implement a 1.45 percent fix to address the prospective-only nature of it.

Broader Medicare PFS reform is also on the horizon for 2025. A bipartisan group of senators recently formed a bipartisan working group focused on long-term MPFS payment reform, as well as reforms to Medicare Access and CHIP Reauthorization Act (MACRA) value-based payment systems. According to a press release, the new working group will be "reaching out to stakeholders in the coming weeks to seek feedback and to begin developing policies" that would implement potential reforms. Members of the working group include Minority Whip John Thune (R-S.D.) and Sens. Catherine Cortez Masto (D-Nev.), Marsha Blackburn (R-Tenn.), John Barrasso (R-Wyo.), Debbie Stabenow (D-Mich.) and Mark Warner (D-Va.).

House Launches Bipartisan Task Force on AI

House Speaker Mike Johnson (R-La.) and Minority Leader Hakeem Jeffries (D-N.Y.) announced on Feb. 20, 2024, the formation of a new bipartisan task force on artificial intelligence (AI). The task force will consider policies intended to "ensure America continues to lead the world in AI innovation while considering guardrails…to safeguard the nation against current and emerging threats," according to a press release. Reps. Jay Obernolte (R-Calif.) and Ted Lieu (D-Calif.) will co-lead the task force.

Senate Committee on HELP to Examine "Food as Medicine"

Senate HELP Committee Chair Bernie Sanders (I-Vt.) recently sent a letter to FDA Commissioner Dr. Robert Califf "urging the FDA to require corporations in the food and beverage industry to put strong, evidence-based warning labels on their products to protect the health of the American people." Commissioner Califf was invited to testify.

In a press release announcing this action, Sen. Sanders announced that the committee would soon convene for a hearing centered on "Food as Medicine" initiatives. Sen. Sanders expressed interest in examining policies related to the role of food and beverage in diabetes management and weight management, as well as tobacco labeling. Other legislation at the nexus of health and nutrition such as the Medical Nutrition Equity Act may also come up.

Senate E&C Committee's Subcommittee on Health Legislative Hearing

At a legislative hearing held on Feb. 14, 2024, the House E&C Committee's Subcommittee on Health considered a wide range of legislation, including several bills to reauthorize health and public health programs. Among other measures, the committee discussed legislation to reauthorize programs addressing Alzheimer's research, the Lifespan Respite Care Program, the Traumatic Brain Injury (TBI) program, the Poison Control Grant Program, legislation regarding stillbirths and Down Syndrome, and several programs related to cancer screening and prevention. Other bills would reauthorize funding and resources for programs to support emergency medical services providers – specifically, the SIREN Reauthorization Act and the Emergency Medical Services for Children Reauthorization Act. Summaries of each bill can be found in the subcommittee's hearing memo. The next step for these bills is likely a Health Subcommittee markup.

Retirements

Rep. Mark Green (R-Tenn.) announced on Feb. 14, 2024, his intent to retire at the end of the year. He currently serves as chair of the House Committee on Homeland Security. Additionally, former Rep. Tom Suozzi

(D-N.Y.) was elected on Feb. 14, 2024, to retake his former seat, which was left vacant by former Rep. George Santos (R-N.Y.).

Rep. James Clyburn (D-S.C.) has stepped down from his role as assistant Democratic leader, a position he has held for just over a year. He previously served as the House Majority Whip. His decision follows similar moves by former House Speaker Nancy Pelosi (D-Calif.) and former Majority Leader Steny Hoyer (D-Md.) to step down from their respective leadership roles after the 2022 election. Rep. Joe Neguse (D-Colo.), chair of the Democratic Policy and Communications Committee, plans to run for assistant leader, according to two Democratic leadership aides.

REGULATORY UPDATES

CMS Issues MA Prior Authorization FAQs

The Medicare Advantage (MA) prior authorization FAQs provide additional guidance on the CMS final rule that went into effect on January 1, 2024. The rule prohibits MA plans from denying coverage for services covered by traditional Medicare. CMS also requires that prior authorization approvals remain valid for a patient's entire episode of care as long as the care is medically necessary. All MA plans must establish a utilization management committee that will review prior authorization policies annually to ensure they are consistent with coverage requirements, including traditional Medicare's national and local coverage decisions and guidelines.

CMS Issues Additional Guidance on Medicare Prescription Payment Plan

CMS released the second part of draft guidance on Feb. 15, 2024, for the Medicare Prescription Payment Plan, along with an accompanying fact sheet. Beginning in 2025, implementation of the Inflation Reduction Act's Medicare Prescription Payment Plan will allow people to pay Medicare Part D out-of-pocket costs throughout the year. While the draft part one guidance focused on Part D plan sponsor operational requirements, the draft part two guidance centers on education and outreach for the program.

Comments on the second draft guidance are due by email on March 16, 2024. Draft part one guidance and the accompanying fact sheet were released on August 21, 2023. Final part one guidance has not yet been published but is forthcoming, according to CMS.

FTC, HHS Issue RFI on Generic Drug Shortages

The Federal Trade Commission (FTC) and HHS are investigating the business practices of group purchasing organizations (GPOs) to determine their contribution to drug shortages. The agencies are requesting input from stakeholders through a joint request for information (RFI), released on Feb. 14, 2024. Some stakeholders have expressed concerns over their control over drug purchasing for hospitals. FTC Chair Lina Khan commented on the release: "For years Americans have faced acute shortages of critical drugs, from chemotherapy to antibiotics, endangering patients. Our inquiry requests information on the factors driving these shortages and scrutinizes the practices of opaque drug middlemen." The RFI comes after a 2022 FTC 6(b) study of PBMs in an ongoing effort to pinpoint contributing industries or industry practices to the drug supply shortage.

The agencies are requesting public input on:

- whether and to what extent manufacturers, GPOs and drug wholesalers are complying with their legal obligations under Section 3 of the Clayton Act and the Robinson-Patman Act
- whether and to what extent the available protections for GPOs under the Federal Anti-Kickback Statute affect market concentration and contracting practices by GPOs, as well as drug shortages

- whether and to what extent market concentration among GPOs and drug wholesalers has impacted smaller healthcare providers and rural hospitals
- whether and to what extent concentration among GPOs and drug wholesalers has disincentivized suppliers from competing in generic drug markets
- the impact of the prevailing GPO compensation model, which may rely on rebates, chargebacks and administrative fees from manufacturers and suppliers in exchange for favorable treatment, on generic manufacturers and other suppliers

Comments are due on April 14, 2024. This latest announcement notes another forthcoming joint RFI from the FTC, HHS and U.S. Department of Justice (DOJ) seeking input on how private equity and other corporations' control of healthcare is impacting Americans.

CMS Seeks Input on Administrative Burden of Potential Prior Authorization Project

CMS is seeking stakeholder input on a new demonstration project focused on administrative burden ramifications of the Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC) Services. According to CMS, interested persons should send comments regarding 1) CMS' burden estimates, 2) the necessity and utility of the proposed information collection, 3) the accuracy of the estimated burden, 4) ways to enhance the quality, utility and clarity of the information to be collected, and 5) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Agencies Announce End of IDR Extension

HHS, DOL and the U.S. Department of the Treasury announced on Feb. 16, 2024, that all currently applicable federal Independent Dispute Resolution (IDR) extensions will end on March 14, 2024. Information on applicable IDR deadlines is available online.

CMS Proposes Changes to Oversight of AOs, ESRD and Kidney Transplant Programs

CMS released a proposed rule and corresponding fact sheet identifying shortfalls and intending to improve oversight of the nine-accrediting organization (AOs) that survey more than 9,000 accredited healthcare providers and suppliers for compliance with health and safety requirements. The rule proposes to address conflicts of interest, establish consistent standards, processes and definitions, and update the validation and performance standards systems.

Additionally, if finalized, the rule would establish changes to the psychiatric hospital survey process and provide technical corrections for end-stage renal disease (ESRD) facilities and kidney transplant programs. The rule also solicits comments from stakeholders and accrediting organizations (AOs) to refine and revise the AO oversight standards and processes. In addition, this proposed rule includes a request for information on the timeframes and expectations for the submission of AO applications. Comments on the proposed rule are due on April 15, 2024.

HHS OIG Releases Report on Medicare Telehealth Billing

In order to evaluate potential fraud, waste and abuse of expanded telehealth flexibilities, the Office of Inspector General (OIG) completed an audit of the compliance of clinicians from a limited number of claims from March through November 2020.

According to the report, 105 of the 110 sampled evaluation and management (E/M) services provided via telehealth met compliance standards. For the remaining five sampled E/M services, investigators determined that unallowable payments identified resulted primarily from clerical errors or the inability to access records.

Telehealth Industry Calls for DEA Guidance on "Red Flag" Geographic Issue

Last week, telehealth industry leaders released a joint letter calling on the U.S. Drug Enforcement Administration (DEA) to provide explicit guidance to the pharmacy community that geography of a prescriber in relation to the patient or the pharmacy should not be a "red flag" when a prescription is a result of a telehealth visit. According to the letter, "The distance of a telehealth prescriber from the patient alone should not give a pharmacist a signal that the prescription may be illegitimate." While "red flags" are not defined in statute, regulations or other official guidance, in response to the opioid epidemic, pharmacists have been directed to do their "due diligence" to ensure that prescriptions are legitimate. The letter argues that "pharmacists need clearer green lights from the DEA to appropriately dispense critical medications to patients, not continued 'red flags.'"

FDA Approves First Cellular Treatment for Advanced Melanoma

The FDA approved the first cellular therapy indicated for the treatment of adult patients with two types of melanoma, either unresectable or metastatic, that has previously been treated with other therapies. It is the first cell therapy to be approved for the treatment of solid tumors. Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research (CBER), said of the approval, "Unresectable or metastatic melanoma is an aggressive form of cancer that can be fatal. [This approval] represents the culmination of scientific and clinical research efforts leading to a novel T cell immunotherapy for patients with limited treatment options."

DOC Research Agreement Aims to Protect Against AI Misuse in Nucleic Acid Synthesis

The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) has entered a two-year cooperative research agreement with the nonprofit Engineering Biology Research Consortium (EBRC) to develop screening and safety tools to defend against the potential misuse of AI related to nucleic acid synthesis. Nucleic acid synthesis, the artificial development of genetic material, is a growing field with implications for engineering biology, therapy, data storage and nanotechnology if nucleic acid can be developed at scale and with low-cost implications. The research agreement fulfills a charge from last year's Executive Order on the Safe, Secure and Trustworthy AI for NIST to engage with stakeholders to develop guardrails to defend against potential misuse of AI related to the synthesis of genetic material. NIST will work with EBRC to develop best practices and policies.

Request for Nominations: National Advisory Council for Healthcare Research and Quality

HHS' Agency for Health Care Research and Quality (AHRQ) is seeking nominations for candidates to serve on its National Advisory Council for Healthcare Research and Quality (Council). The Council provides advice and recommendations to the director of AHRQ and the secretary of HHS on national health research priorities to "make health care safer, higher quality, more accessible, equitable, and affordable." Seven current members' three-year terms will expire in November 2024. To fill these positions, AHRQ seeks nominations for individuals who are distinguished:

- in the conduct of research, demonstration projects and evaluations with respect to healthcare
- in the fields of healthcare quality research or healthcare improvement
- in the practice of medicine or other health professions
- as administrators of healthcare delivery systems
- as representatives of the private healthcare sector (including health plans, providers and purchasers)
- in the fields of healthcare economics, information systems, law, ethics, business or public policy
- as representatives of the interests of healthcare patients and consumers

AHRQ will accept nominations for candidates to serve on the Council in a representative capacity, as well as self-nominations. Nominations for candidates with expertise in healthcare delivery for priority populations are encouraged. The deadline to submit a nomination is April 22, 2024. Further details are available in the *Federal Register* notice.

HHS Fills Key Vaccine Advisory Panel Vacancies

After months of vacancies that left the Advisory Committee on Immunization Practices (ACIP) panel with less than half of its capacity, HHS announced last week that it will fill the eight vacant seats, including the chairmanship. ACIP, which provides recommendations to HHS and the Centers for Disease Control and Prevention (CDC) on federal vaccine policies, experienced lengthy shortages due to HHS' neglect to appoint replacements for seven members whose terms expired last year. HHS had also not filled a seat left vacant in January 2023 by Nirav Shah, who resigned from the committee when he was appointed to serve as principal deputy director of the CDC. ACIP is scheduled to convene for the first of its three annual meetings on Feb. 28-29, 2024. A draft agenda for the two-day meeting is available online.

CMS Adds MA Data to Health Equity Tool

The CMS Office of Minority Health (CMS OMH) updated the Mapping Medicare Disparities (MMD) Tool to include 2018 Medicare Advantage encounter data and new visual enhancements. This data set addition adds to the tool's prior Medicare Fee-For-Service data and will expand usability and applicability of the data for Medicare disparities insights for individuals with chronic diseases.

HHS, NGA Announce New Maternal Health Collaboratives

HHS launched a new "Postpartum Maternal Health Collaborative" on Feb. 14, 2024, with leaders of six states (Iowa, Massachusetts, Maryland, Michigan, Minnesota and New Mexico). The goal of the initiative is to bring together state experts, local providers, community partners and federal experts to improve understanding of the challenges being experienced among the postpartum population and support new solutions to improve postpartum mortality. In conjunction with this new HHS collaborative, the National Governors Association launched its Improving Maternal and Child Health in Rural America State and Territory Policy Learning Collaborative, which will focus on policy changes in rural areas.

CMS to Host Webinars on Innovation in Behavioral Health and Transforming Maternal Health Models

CMS will provide an overview of its Innovation in Behavioral Health (IBH) Model during a webinar on Feb. 29, 2024, at 2:00 p.m. ET. This value-based payment model will utilize community-based care to promote care coordination, care quality and improved outcomes for individuals with moderate to severe mental and behavioral health conditions and substance use disorders. The link to register and submit questions in advance of the webinar is available online.

Additionally, on Feb. 28, 2024, at 1:00 p.m. ET, CMS will host a webinar to provide an overview of the Transforming Maternal Health (TMaH) Model. Register online to attend.

CMS Finalizes DSH Medicaid Cuts

CMS finalized a rule on Feb. 20, 2024, implementing scheduled statutory cuts to Medicaid DSH, and the rule is scheduled to take effect on April 27, 2024. As noted above, several proposals to delay implementation of the cuts are currently under consideration for potential inclusion in an upcoming FY 2024 spending package.

The final rule does not contain any significant changes from the proposed rule issued earlier this year. Policies finalized by the rule include:

- a new methodology for the recalculation of DSH payments, reimbursements for hospitals serving a high proportion of low-income patients
- a newly finalized definition which says that hospitals can only receive reimbursements for services rendered to beneficiaries for whom Medicaid is their primary insurer(/payer)

The rule notes the 97th percentile hospital exception: an exception to the methodology for hospitals in and above the 97th percentile of all hospitals with respect to inpatient days made up of patients who, for such days, were entitled to Medicare Part A benefits and to supplemental security income (SSI) benefits (97th percentile hospitals). This would exempt certain "outlier hospitals" from being impacted by the cuts.

The final rule is intended to address potential overpayments to hospitals by limiting the ability to receive both government and private payer funds for the same service. The calculations will result in an $8 billion reduction in DSH payments annually from fiscal year 2024 to 2027.