Holland & Knight

H&K Health Dose: February 6, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. Senate and U.S. House of Representatives are in session, with floor votes expected and significant health-related activity at the committee level. For the next two weeks, the Senate will be out for the Presidents Day recess.

FY 2025 Appropriations Process to Begin March 11, 2024

President Joe Biden is expected to submit the annual Fiscal Year (FY) 2025 President's Budget Request on March 11, 2024 – only three days after the last deadline to enact FY 2024 spending legislation without triggering a partial government shutdown.

Senators Release Discussion Draft of 340B Drug Pricing Legislation

On Feb. 2, 2024, a bipartisan group of senators circulated a discussion draft of legislation – the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act) – that would implement a number of reforms to the 340B drug pricing program.

In an accompanying summary of the discussion draft, legislators state that "the intent of the 340B program is to help safety net providers maintain, improve, and expand patient access to health care services by requiring drug manufacturers, as a condition of participation in Medicaid and Medicare Part B, to provide discounts and rebates to covered entities that serve a disproportionate share of low-income and underserved patients."

Among other provisions, the draft legislation would:

- "Provide statutory clarity" regarding certain aspects of contact pharmacy arrangements and define "patient" under the 340B statute
- "Ensure child sites are aligned with the intent of the 340B program"
- Impose additional transparency and reporting requirements on 340B participating covered entities
- Require the secretary of the U.S. Department of Health and Human Services (HHS) to issue guidance regarding auditing and compliance; establish a national third-party clearinghouse to prevent duplicate discounts
- "Ensure plans and PBMs cannot place differential terms on covered entities"'
- Direct the secretary of HHS to establish a user fee program for covered entities
- Require Medicaid and CHIP Payment and Access Commission (MACPAC) to submit a report to Congress on the efforts of state Medicaid agencies to prevent duplicate discounts under the 340B program

The senators also circulated a request for information (RFI) seeking stakeholder input on the draft proposal.

Nominee for ASPE Assistant Secretary Approved by Senate Committee on Finance

Dr. Rebecca Haffajee's nomination to serve as Assistant Secretary for Planning and Evaluation (ASPE) – the principal advisor to the secretary of the HHS "responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis" – was advanced on Jan. 31, 2024, by the Senate Committee on Finance. Dr. Haffajee has served as ASPE in an acting capacity since 2021 when she was first appointed by President Biden. The committee voted along partisan lines to approve

the nomination (14-13).Previously, the committee has considered Dr. Haffajee's nomination on two occasions. Ranking Member Mike Crapo (R-Idaho) has consistently expressed opposition to her nomination, citing "evasive answers to questions posed to her on religious liberty, abortion, and public health emergencies." During the nomination hearing on Jan. 31, 2024, Sen. Crapo stated he remains "troubled that Ms. Haffajee will support the HHS secretary's efforts to undermine state laws and individuals' constitutional rights."

House E&C Committee Hosts Healthcare Spending Hearing

The House Committee on Energy and Commerce (E&C) Subcommittee on Health held a hearing on Jan. 31, 2024, "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers," to after the Center for Medicare and Medicaid Services (CMS) released its 2022 estimates for healthcare spending in the U.S. The committee discussed the current healthcare coverage system, a lack of transparency and accountability, monopoly-like pricing and projected increases in medical expenditures both on the personal and federal level, coupled with projected decreases in federal tax revenues. Witnesses urged legislators to enact the Lower Costs, More Transparency Act (H.R. 5378) – a sweeping health transparency, health costs and drug pricing package passed by the House in fall 2023 – or similar legislation to reduce costs and increase transparency and accountability of healthcare institutions.

Congress Shows Continued Interest in AI with Finance Hearing and Caucus Launch

On Feb. 8, 2024, the Senate Committee on Finance will hold a hearing, "Artificial Intelligence (AI) and Health Care: Promise and Pitfalls," to examine the use of algorithms and artificial intelligence (AI) systems in healthcare. The hearing announcement comes after two members serving on the committee – Sens. Elizabeth Warren (D-Mass.) and Michael Bennet (D-Colo.) – co-led a Jan. 23, 2024, letter calling on Majority Leader Chuck Schumer (D-N.Y.) to pass legislation establishing an independent federal agency tasked with the comprehensive oversight of industries utilizing digital platforms and AI.

A legislative package addressing AI is likely in the works. Several other House and Senate panels have recently convened hearings centered on AI, with some specifically focusing on the use of AI in healthcare. In fall 2023, Senate Committee on Health, Education, Labor and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) released a white paper on AI, seeking feedback from stakeholders on the role of the federal government in regulating the emerging technology.

A digital health briefing commenced on Feb. 2, 2024, with the launch of the bipartisan Congressional Digital Health Caucus. Gary Shapiro, President & CEO of the Consumer Technology Association, opened the briefing by emphasizing the exponential growth of generative AI and the importance of fostering collaboration across diverse industries. Reps. Troy Balderson (R-Ohio) and Robin Kelly (D-Ill.), the co-chairs of the caucus, discussed the importance of including rural, historically underserved communities and clinicians' voices in the development and implementation of digital technologies in healthcare. The expert panel explored how AI is transforming healthcare while acknowledging bias and emphasizing the need for both flexibility and guardrails.

Senate HELP Committee Hearing on Prescription Drug Pricing

The Senate HELP Committee will convene on Feb. 8, 2024, for a hearing, "Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?" Witnesses will include the CEOs of three drug manufacturing companies. Two of the witnesses agreed to testify voluntarily after a back-and-forth with HELP Committee Chair Bernie Sanders (I-Vt.), in which Sen. Sanders threatened to compel their appearance via subpoenas.

House Hearings on Drug Shortages

The House Committee on Ways and Means held a hearing on Feb. 6, 2024, "to examine the pervasive problem of chronic drug shortages and its harmful impact on patient access to care in the United States."

In addition, the House E&C Committee's Subcommittee on Oversight also convened on Feb. 6, 2024, for a hearing, "Protecting American Health Security: Oversight of Shortcomings in the FDA's Foreign Drug Inspection Program." The hearing will center on the U.S. Food and Drug Administration's (FDA) oversight and enforcement authorities over foreign drug manufacturing facilities, with a particular focus on the quality of drugs manufactured overseas and the impact of reduced operations on drug shortages. According to a press release, lawmakers plan to examine why, after scaling back operations during COVID-19, the FDA's Foreign Drug Inspection Program "hasn't been widely restarted in countries like India and China, and how that affects domestic production."

House Budget Committee to Mark Up Bill Changing How CBO Scores Prevention

On Feb. 6, 2024, the House Committee on the Budget was expected to mark up a bipartisan bill to overhaul the Congressional Budget Office's (CBO) scoring methodology for preventive healthcare legislation. The bill, the Preventive Health Savings Act (H.R.766), would allow key committee legislators to request that CBO extend its evaluation period beyond its current 10-year scope to include two additional 10-year periods. This could significantly impact CBO's budgetary projections for health legislation and arguably more accurately reflect long-term healthcare savings for measures that address preventative care and chronic condition management.

Rep. Michael Burgess (R-Texas) – who leads the House Budget Committee Health Care Task Force, a panel that "serves as an incubator for finding new ways to improve health outcomes while reducing federal spending" – has introduced or co-led the Preventive Health Savings Act each Congress since it was first introduced in 2012. He announced the markup plan at a full committee oversight hearing on Jan. 31, 2024, at which Rep. Burgess pressed CBO Director Phillip Swagel on the potential budgetary impacts of covering anti-obesity medications, noting the "introduction of the new anti-obesity medications has kind of changed the equation" in terms of preventative care coverage.

House Oversight Committee Marks Up PBM Reform Legislation

The House Committee on Oversight and Accountability was slated to convene for a business meeting on Feb. 6, 2024, where members marked up provisions of a sweeping Pharmacy Benefit Manager (PBM) reform bill, the Delinking Revenue from Unfair Gouging (DRUG) Act (H.R.6283). This legislation, introduced by Reps. Mariannette Miller-Meeks (R-Iowa) and Nanette Barragan (D-Calif.), would implement the following PBM reforms to Medicare Part D and private employer-sponsored health plans. However, the committee will consider only the provisions of the bill within its jurisdiction – those reforms that would apply to Federal Employee Health Benefit (FEHB) plans. PBM reforms included in the bill are as follows:

- Implement de-linking policies, requiring PBMs to only charge a flat fee (bona fide service fee) for a drug's placement
- Prohibit "spread pricing," when a PBM charges the health plan more than they paid for a medicine
- Prevent PBMs from paying affiliated pharmacies more than competing pharmacies for the same services
- Ban "patient steering" practices, whereby a PBM encourages or requires patients to use its affiliated pharmacies
- Impose potential civil monetary penalties of $10,000 for each day of a PBM's violation

Retirements

Rep. Brian Higgins' (D-N.Y.) last day in Congress was Feb. 2, 2024. He announced his intent to step down in November 2023 after nearly two decades in the House. Additionally, Rep. Victoria Spartz (R-Ind.) announced on Feb. 5, 2024, that she will file to run for her seat again in 2024 – a reversal from her previous decision to not seek re-election. A full list of House members retiring or seeking other office is available on the House website.

REGULATORY UPDATES

CMS Releases Proposed Payment Updates for 2025 Medicare Advantage and Part D Programs

CMS released its 2025 Medicare Advantage (MA) Advance Notice on Jan. 31, 2024. CMS projects a 3.7 percent increase in Medicare Advantage (MA) payments for 2025, translating to a substantial $16 billion boost. This is only slightly higher than the 2024 increase but significantly higher than the 1.03 percent increase projection from the 2024 advanced notice. CMS is proposing a phased approach to the Part C Risk Adjustment Model. The proposed strategy involves blending 67 percent of the risk score derived from the updated 2024 MA risk adjustment model with 33 percent from the 2020 MA risk adjustment model. This combination results in a 3.86 percent blended MA risk score trend for the calendar year 2025.

In compliance with the Inflation Reduction Act (IRA), updates have been proposed to the Part D risk adjustment model, including calibrating the model by using more recent data years and adjusting the normalization methodology to reflect differences in risk score trends between MA prescription drug plans (MA-PD) and stand-alone prescription drug plans (PDP). Star ratings proposals include measure specification updates, adjustments to the list of measures in the Part C and D Improvement measures, and the introduction of the Categorical Adjustment Index for the 2025 Star Ratings. Additionally, CMS is seeking input on significant measure specification updates and inviting comments on new measure concepts that align with their "Universal Foundation" of quality measures.

At a recent MedPAC meeting, staff highlighted data showing overpayments by the federal government are projected to cost $88 billion more than it would be if those individuals were in fee-for-service Medicare. MedPAC staff note that this is the greatest disparity to date. MA is receiving increased attention from policymakers and other interested parties. Last week, Sens. Catherine Cortez Masto (D-Nev.), Tim Scott (R-S.C.), Gary Peters (D-Mich.) and Shelley Moore Capito (R-W.Va.) led a group of more than 60 senators in a letter urging CMS to "consider the ongoing implementation of program reforms finalized last year and provide stability for the MA program in 2025."

A fact sheet on the 2025 MA and Part D Advance Notice is available on the CMS website. Comments on the rule are due by March 1, 2024, and the final notice will be published on or before April 1, 2024.

CMS Releases Draft CY 2025 Part D Redesign Program Instructions, Seeking Comment

CMS released the Draft Calendar Year (CY) 2025 Part D Redesign Program Instructions on Jan. 31, 2024. The draft guidance contains information related to the upcoming implementation of IRA reforms to the Medicare Part D benefit slated to take effect on Jan. 1, 2025. As described in the draft guidance, the CY 2025 updates include the following:

- A newly defined standard Part D benefit design consisting of three phases: annual deductible, initial coverage and catastrophic coverage
- The lower annual out-of-pocket (OOP) threshold of $2,000
- The sunset of the Coverage Gap Discount Program (CGDP) and establishment of the Manufacturer Discount Program (Discount Program)

- Changes to the liability of enrollees, sponsors, manufacturers and CMS in the new standard Part D benefit design

CMS is accepting comments on the draft guidance – which was notably not issued through the typical notice-and-comment rulemaking process – via email through March 1, 2024. The final guidance is expected to be published no later than April 1, 2024.

A fact sheet on the Draft CY 2025 Part D Redesign Program Instructions is available on the CMS website.

CMS Makes Initial Offers in Medicare Drug Price Negotiation Program; Announces Availability of New Information and Resources

CMS sent initial offers to the participating drug companies for the 10 prescription drugs selected for negotiation in the first cycle of the Medicare Drug Price Negotiation Program on Feb. 1, 2024. Negotiations will continue over the next several months and will conclude by Aug. 1, 2024. If the participating drug company and Medicare agree upon a maximum fair price, the new drug price will take effect in Medicare beginning in 2026.

In a press release announcing this action, HHS also announced the launch of a new website that will serve as a "resource hub" for Medicare beneficiaries seeking information about IRA prescription drug pricing programs and their implementation. According to the press release, the website will "house informational materials in plain language, including key messaging, fact sheets, toolkits, social media graphics, videos, and more."

The press release also highlighted HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) published several reports related to drug pricing. Three of the reports compare domestic drug prices and availability with those in other Organisation for Economic Co-operation and Development (OECD) countries. A fourth report analyzes the impact of IRA provisions expanding access to the Low Income Subsidy (LIS) program.

CMS Releases ICRs Related to Implementation of IRA Medicare Prescription Drug Provisions

Last week, CMS proposed two Information Collection Requests (ICRs) related to IRA provisions impacting Medicare Part D prescription drug beneficiary cost-sharing requirements, as well as Medicare Part B and Part D drug manufacturer rebates.

Under the Medicare Prescription Payment Plan Program (MPPP), MA plans will be required to allow enrollees to elect to pay their out-of-pocket Part D prescription drug cost sharing amounts in monthly installments spread out over the plan year, rather than upfront at the pharmacy counter. This option will be available to MA plan enrollees beginning Jan. 1, 2025. Last year, CMS released draft guidance indicating it would establish new reporting requirements for Part D plans as part of its implementation of MPPP. In the ICR released last week, CMS outlines its proposed requirement for Part D plans to report certain beneficiary-level data elements on an annual basis. The full text of the ICR is available on the CMS website, and comments may be submitted through Regulations.gov. The 60-day comment period closes on March 26, 2024.

The Medicare Prescription Drug Inflation Rebate Program requires drug manufacturers to pay a rebate to Medicare if the manufacturer raises the price of certain Part B and Part D covered drugs or biologics faster than the rate of inflation. Manufacturers may request a "rebate reduction" in instances of severe supply chain disruptions, or when certain rebatable generic drugs are likely to be in shortage. In revised guidance released in December 2023, CMS stated it would propose an ICR "addressing information that must be submitted by a drug company in order to receive consideration for a rebate reduction under these policies, including the process steps for that submission." The ICR issued last week contains this "Rebate Reduction Request" information. The full text of the ICR is available on the CMS website, and comments may be submitted through Regulations.gov. The 60-day comment period closes on March 29, 2024.

Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions Transcripts Available

CMS held a series of public, virtual Listening Sessions as part of the Medicare Drug Price Negotiation Program in fall 2023. Patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties were invited to share perspectives regarding the first round of drugs selected for participation in the Medicare Drug Price Negotiation Program. Redacted transcripts of these sessions, one for each selected drug, are now available on the CMS website.

SAMHSA Issues Final Rule on Telehealth; Other Flexibilities for OUD Treatments

The Substance Abuse and Mental Health Services Administration (SAMHSA) published its Final Rule, "Medications for the Treatment of Opioid Use Disorder," on Feb. 2, 2024. The rule makes permanent certain temporary pandemic-era flexibilities allowing telehealth visits for certain opioid use disorder (OUD) treatments.

Under the Final Rule, telehealth visits – including audio-only telehealth visits – are permitted for the initiation of buprenorphine treatment. Audio-visual telehealth visits are permitted for the initiation of methadone treatment. Although the rule still requires patients to obtain doses of methadone in person at an Opioid Treatment Program (OTP) clinic, it expands eligibility for patients to receive take-home doses of methadone. The rule also ends an admission criterion requiring patients to have a one-year history of OUD before being eligible for treatment through the OTP. Previously, these flexibilities were set to expire on Dec. 31, 2024.

A final rule by the U.S. Drug Enforcement Agency (DEA) to regulate non-OTP provider prescription of buprenorphine via telehealth to patients with OUD is still pending.

Sickle Cell Disease Announced as Initial Focus of CMMI's CGT Access Model

Last week, the Center for Medicare and Medicaid Innovation (CMMI) announced that sickle cell disease will be the first focus of its Cell and Gene Therapy (CGT) Access Model, which "seeks to test whether a CMS-led approach to negotiating and administering outcomes-based agreements (OBAs) for cell and gene therapies… will improve access and health outcomes for people with Medicaid and reduce health care costs."

The CGT Access Model is a voluntary model for states and manufacturers that will operate through Medicaid to expand access to gene therapies for the treatment of sickle cell disease and may be expanded to other types of CGTs in the future. To be eligible, a manufacturer must have an FDA-approved sickle cell disease gene or cell therapy by May 2024. State Medicaid agencies then may voluntarily choose to accept the negotiated OBA contract, provided the state agrees to provide basic coverage for Medicaid beneficiaries. Participating states may also receive, through CMS, additional funding for engaging in "activities that increase equitable access to cell and gene therapies and promote multi-disciplinary, comprehensive care for people with Medicaid with sickle cell disease receiving gene therapy." CMS says states may begin to participate in the model between January 2025-2026.

More information, including a fact sheet, is available on the CMS CGT Access Model website.

CMS Requests Vendor Engagement Ahead of 2025 eCQM Reporting/Performance Periods

CMS is requesting that vendors and other interested parties with the technical capabilities review and provide feedback on draft electronic clinical quality measure (eCQM) specifications that include logic and header changes for eCQMs under consideration for CMS quality reporting and payment programs. Electronic health record (EHR) vendors and interested parties can review the draft measures in the Clinical Quality Language (CQL) standard for logic expression and test the Health Quality Measures Format (HQMF) code by directly consuming machine readable XML files for eCQMs. This provides a unique opportunity for vendors to engage in the specification process and expose technical errors to CMS. According to CMS, testing will assist CMS in

identifying instances in which the XML code produces errors so that issues can be resolved prior to posting the fully specified measures in spring 2024. The draft measures in HTML, XML and JSON formats are available now through Feb. 9, 2024.

CMS Announces Increased Participation in ACO Initiatives

CMS published a press release on Jan. 29, 2024, noting increased participation in CMS' accountable care organization (ACO) initiatives in 2024. The announcement highlights the advance investment payment, a financial methodology change that came out of the major Medicare Shared Savings Program (MSSP) reform of the 2023 Physician Fee Schedule (PFS) Final Rule, as well as other programs that seek to promote and support ACOs that care for underserved and medically complex populations. The announcement is supplemented by new participation lists, fact sheets, data sets and quarterly reports.

BPC Urges FDA, CMS Collaboration to Streamline Coverage, Improve RWE

The Bipartisan Policy Center (BPC) released a set of recommendations on Jan. 29, 2024, for enhanced coordination between the FDA and CMS by improving information sharing. According to BPC, most of the recommendations do not require congressional modifications to existing statutes governing the agencies. Instead, BPC says they focus on solutions to establishing a more balanced flow of information to facilitate collaboration between the FDA and CMS. Just two days following the release, BPC held an event, "Addressing Information Asymmetry: Improving CMS and FDA Collaboration," to unveil the report that featured two former CMS and FDA directors.

Final FDA Quality Management Rule Offers Two-Year Phase-In Period

The FDA issued the Quality Management System Regulation (QMSR) Final Rule on Jan. 31, 2024, to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation. This rule establishes the international device quality standard for medical device quality management systems set by the International Organization for Standardization (ISO). QS regulation will apply until the rule becomes effective in February 2026. CMS states that in addition to cost savings, the rule should ensure quicker access to newly developed medical devices for patients leading to improved quality of life of the consumers.

AMA Panel Again Scraps Plan to Revamp Remote Monitoring CPT Codes

The American Medical Association (AMA) Current Procedural Terminology (CPT) code editorial panel will no longer evaluate a proposal to revamp remote physiologic and remote therapeutic monitoring CPT codes. The proposal would have collapsed remote patient monitoring (RPM) and remote therapeutic monitoring (RTM) codes that now operate as distinct code sets, which BPC recently recommended remain separate while more data is collected on the individual services. The proposal may be reworked and considered in a future meeting, though nothing has been suggested to this effect as of yet.

FDA Finalizes Guidance on Human Gene Therapy Products

The FDA released a final guidance document on Feb. 1, 2024, "Human Gene Therapy Products Incorporating Human Genome Editing: Guidance for Industry," to provide recommendations on the development of human gene therapy products that involve human genome editing, including information on best practices for product safety, quality, manufacturing, testing and clinical trial design. The FDA Center for Biologics Evaluation and Research's (CBER) Office of Therapeutic Products will host a public webinar on Feb. 29, 2024, to discuss the recently finalized guidance. Additional information on the CBER webinar, including a registration link, is available on the FDA website.

CMS OMH Calls for Health Equity Proposals Closing Feb. 9, 2024

The deadline to submit proposals for lightning talks, panels, single presentations and posters for the CMS' Office of Minority Health (OMH) 2024 Health Equity Conference is quickly approaching on Feb. 9, 2024, at 5:00 p.m. ET via email. Visit the conference's website for more information on proposal requirements.

CDRH Extends Public Comment Deadline on Use of DHTs for Undiagnosed Diabetes Detection

Last week, the FDA's Center for Devices and Radiological Health (CDRH) extended a deadline requesting information regarding "how digital health technologies (DHTs) including artificial intelligence and machine learning (AI/ML) may help with early detection of risk factors for type 2 diabetes, prediabetes, and type 2 undiagnosed diabetes." CDRH seeks input on questions related to community engagement and consortia efforts, science and innovation, patient outcomes, and clinical integration and implementation. More information is available on the FDA website, and public comments can be submitted online.

AHRQ Announces National Webinar on Integrating Patient-Reported Outcomes into Practice

The Agency for Health Research Quality's (AHRQ) Digital Healthcare Research Program will host a webinar on Feb. 27, 2024, "Integrating Patient-Reported Outcomes into Practice: Benefits, Challenges, and Recommendations for Action." A panel of expert speakers will discuss research findings related to uses of digital health technology to incorporate patient-reported outcomes in clinical settings, among other topics. The event announcement and registration link are available online.

HHS Hosts First-Ever "Food is Medicine" Summit

Last week, HHS hosted an in-person "Food is Medicine" summit in Washington, D.C., for stakeholders at the intersection between food and health. At the summit, HHS Secretary Xavier Becerra announced three new public-private partnerships aimed at reducing the prevalence of chronic disease through nutrition. HHS' Office of the Assistant Secretary for Health (OASH) is currently developing a federal toolkit and implementation guidance to support a new, larger Food is Medicine initiative within HHS. The initiative will aim to "develop and implement a federal strategy to reduce nutrition-related chronic diseases and food insecurity to improve health, wellbeing, and racial equity in the United States." The all-day summit featured speakers, including U.S. Department of Agriculture (USDA) Secretary Tom Vilsack, Sens. Cory Booker (D-N.J.) and Roger Marshall (R-Kan.), and Reps. Barbara Lee (D-Calif.), Jim McGovern (D-Mass.) and Chellie Pingree (D-Maine).

Registration Open for FDA's Rare Disease Day 2024 Virtual Public Meeting

The FDA's Office of Orphan Products Development (OOPD) will host its annual Rare Disease Day public meeting on March 1, 2024. The virtual meeting will include opening remarks from FDA Commissioner Dr. Robert Califf and OOPD Commissioner Dr. Sandra Retzky, as well as several panels featuring officials from across FDA and expert speakers from the private sector. More information, including the agenda and registration link, is available online.