



H&K Health Dose: April 18, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: The House and Senate are Back in Session and Discuss Healthcare Initiatives

After a long holiday recess, the U.S. House of Representatives and U.S. Senate are back in session. This work period in U.S. Congress will go through the Memorial Day recess. This will be an active work period pertaining to healthcare. Several committees are expected to start considering legislation on a number of issues, including pharmacy benefit managers (PBMs) and hospital transparency, and these conversations could expand to other issues. Notably, on April 19, 2023, the House Committee on Energy and Commerce is holding a hearing, "[Examining Existing Federal Programs to Build a Stronger Health Workforce and Improve Primary Care.](#)"

Additionally, House Majority Leader Steve Scalise (R-La.) announced on April 17, 2023 that House Republicans will unveil their debt ceiling plan on April 18, 2023. The default deadline is just weeks away, and GOP members have demanded that spending reductions for the upcoming 2024 fiscal year (FY24) balance the budget in 10 years. Debt ceiling discussions are likely to start taking shape following release of the plan.

President Biden Signs Resolution Terminating the COVID-19 National Emergency

On April 10, 2023, President Joe Biden signed into law H.J. Res. 7, the Pandemic is Over Act, a joint resolution terminating the national emergency related to the COVID-19 pandemic. The Biden Administration previously announced its intention to end both the COVID-19 pandemic national emergency and public health emergency (PHE) declarations on May 11, 2023. Congress acted to end the national emergency ahead of this timeline. The House of Representatives adopted H.J. Res. 7 at the end of January, with 11 Democrats joining House Republicans supporting the measure. The Senate adopted the joint resolution on March 29, 2023, by a vote of 68 to 23. President Biden's signature on H.J. Res. 7 puts an end to the COVID-19 national emergency originally declared on March 13, 2020 – which provided a framework for the secretary of the U.S. Department of Health and Human Services (HHS) to exercise certain emergency authorities with appropriate congressional oversight. According to the Centers for Medicare and Medicaid Services (CMS), the end of the national emergency "does not impact current operations at HHS, and does not impact the planned May 11 expiration of the federal PHE for COVID-19 or any associated unwinding plans...any existing waivers currently in effect and authorized under the 1135 waiver authorization for the pandemic, would remain in place until the end of the federal PHE for COVID-19." The [HHS Fact Sheet](#) explains some of what will and will not change as a result of the end of the PHE.

Senators Introduce Bipartisan Insulin Bill

Recently, Sens. Raphael Warnock (D-Ga.) and John Kennedy (R-La.) introduced [a bill](#) aimed at lowering insulin costs. The bill seeks to cap out-of-pocket costs for insulin at \$35 per month for those who are uninsured as well as those with private insurance. The Inflation Reduction Act (IRA) included a similar cap on insulin costs for Medicare beneficiaries, but Republicans blocked inclusion of the private insurance cap.

Meanwhile, Sens. Jeanne Shaheen (D-N.H.) and Susan Collins (R-Maine) are working to improve and reintroduce their own bill on lowering insulin costs. As co-chairs of the Congressional Diabetes Caucus, they introduced the



Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act during the last Congress. The bill would encourage manufacturers to reduce list prices while extending patient protections that foster broader access to insulin.

Senate HELP Committee Postpones Drug Pricing Markup

Chair Bernie Sanders (I-Vt.) had planned for the Senate Committee on Health, Education, Labor and Pensions (HELP) to hold a markup on a legislative package focused on pharmacy benefit managers (PBMs), biosimilars and generic drug pricing following the recess. Back in March, Sanders had announced to committee members that a markup focusing on bipartisan policies would be held on April 19, 2023. However, Sanders and Ranking Member Bill Cassidy (R-La.) are postponing the markup in order to receive information from experts in the relative fields. The committee held private roundtables on biosimilars, generic drugs and PBMs last week.

House Republicans Question FDA on the Safety of Generic Medications

Reps. Buddy Carter (R-Ga.), Randy Weber (R-Texas), Ronny Jackson (R-Texas), Mariannette Miller-Meeks (R-Iowa) and Diana Harshbarger (R-Tenn.) recently sent a letter to U.S. Food and Drug Administration (FDA) Commissioner Robert Califf. Pointing out that generic medicines account for roughly 90 percent of all prescriptions dispensed in the U.S., the members voiced concerns about the supply of potentially unsafe generic drug imports from foreign manufacturing facilities that have violated FDA regulations, particularly those from China and India. In the letter, the members requested information about what FDA procedures are in place to ensure that hospitals and pharmacies are alerted if they have purchased products from facilities that the FDA has placed under an import ban and if the FDA tests generic drug imports from facilities that have received a warning letter from the FDA.

Bipartisan Effort to Address the Physician Fee Schedule

Several doctors in the House have joined together in an effort to address payment uncertainty affecting Medicare-participating physicians. Reps. Raul Ruiz (D-Calif.), Larry Bucshon (R-Ind.), Ami Bera (D-Calif.) and Mariannette Miller-Meeks (R-Iowa) introduced the [Strengthening Medicare for Patients and Providers Act](#), a bill seeking to increase the physician payment rate by connecting annual updates to inflation as measured by the Medicare Economic Index (MEI). In recent years, the Medicare reimbursement rate has become a predictable battle in health policy, with those in the healthcare industry consistently voicing concerns about the failure of Medicare payments to keep pace with rising costs.

REGULATORY UPDATES

CMS Releases FY24 IPPS Proposed Rule

On April 10, 2023, the Centers for Medicare & Medicaid Services (CMS) posted the FY24 Inpatient Prospective Payment System (IPPS) proposed update, along with proposed policy and regulation changes. The proposed rule would update Medicare payment policies and quality reporting programs relevant for inpatient hospitals, and would build on key agency priorities, including advancing health equity and improving the safety and quality of care. The [proposed rule](#) and a [CMS factsheet](#) are available. The proposed rule is scheduled to be published in the *Federal Register* on May 1, 2023, and comments are due on June 9, 2023. (See Holland & Knight's previous alert, "[CMS Proposes FY 2024 Inpatient Payment Policies for Hospitals](#)," April 17, 2023).



CMS Finalizes CY24 Policy Changes for Medicare Advantage and Part D – Prior Authorization Reform Included

On April 5, 2023, the CMS [released](#) its Medicare Program; Contract Year 2024 (CY24) Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program and Programs of All-Inclusive Care for the Elderly (CMS-4201-F), along with a [fact sheet](#) and [press release](#). The final rule contains policies for Medicare Advantage (MA) and Medicare Part D plans in CY24. The final rule is informed by public feedback received after an August 2022 request for information (RFI) on MA. Notably, the rule includes reforms aspects of prior authorization in MA. CMS will require that MA plans provide a minimum 90-day transition period when an enrollee who is currently receiving an active course of treatment switches to a new MA plan, and CMS will require MA plans establish Utilization Management Committees (UMCs) to ensure they are consistent with coverage requirements.

CMS Releases the FY24 Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) Proposed Rule

On April 3, 2023, the CMS released the FY24 Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) [proposed rule](#), along with a [fact sheet](#). This rule proposes to 1) increase IRF payment rates by three percent, 2) revise and rebase the IRF market basket to a 2021 base year from a 2016 base year, and 3) permit hospitals to establish a new IRF and be paid under the IRF PPS after the start of a cost reporting period when certain conditions are met. This proposed rule is scheduled to be published in the *Federal Register* on April 7, 2023, and comments are due by 5 p.m. on June 2, 2023.

HIPAA Privacy Enforcement Flexibilities

The HHS Office for Civil Rights (OCR) announced that enforcement discretion regarding certain Health Insurance Portability and Accountability Act (HIPAA) privacy considerations will end on May 11, 2023. As a result, HIPAA flexibilities will end for a number of services, including COVID-19 testing and vaccination, as well as public health activities. However, OCR is permitting a 90-day transition period for providers to come into compliance with HIPAA for the delivery of telehealth. This means that providers have until Aug. 9, 2023, to come into compliance with HIPAA requirements for the delivery of telehealth, including the use of telehealth communications technologies. Additional details are available on the [HHS website](#).

HHS Announces National Cancer Plan to Advance Cancer Moonshot

On April 3, 2023, HHS announced the creation of a [National Cancer Plan](#) to advance the president and first lady's Cancer Moonshot vision of cutting cancer mortality by at least half within 25 years and improving quality of life for those impacted by cancer. Developed by the National Institutes of Health's (NIH) National Cancer Institute (NCI) in collaboration with the cancer community, the plan provides a framework for the federal government and all of society to collaborate to end cancer. The plan establishes eight goals and corresponding strategies to 1) prevent cancer, 2) detect cancers early, 3) develop effective treatments, 4) eliminate inequities, 5) deliver optimal care, 6) engage every person, 7) maximize data utility and 8) optimize the workforce. The president's FY24 proposed budget requests Congress provide a \$503 million increase from FY23 levels for NCI and additional funding for the Cancer Moonshot initiative.



HHS Proposes New Rule on Transparency for Artificial Intelligence

On April 11, 2023, the HHS Office of the National Coordinator for Health Information Technology (ONC Health IT) issued a notice of proposed rulemaking (HTI-1 proposed rule) to alter the ONC Health IT Certification Program. The HTI-1 proposed rule would implement provisions of the 21st Century Cures Act and, according to the agency, seeks to "advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information." As part of the rulemaking, those creating artificial intelligence (AI) used in healthcare will be required to publicly disclose information on data used to inform algorithms to receive HHS' certification. Currently, certification is voluntary except for certain technologies. The FDA has also taken steps to regulate AI. Earlier in April, the FDA issued draft guidance related to increasing patient access to AI/machine learning-enabled devices to advance public health. The HTI-1 proposed rule will be formally published on April 18, 2023, and public comments will be accepted through June 20, 2023.