

# **H&K Health Dose: January 31, 2023**

A weekly dose of healthcare policy news

### **LEGISLATIVE UPDATES**

#### This Week

The House and Senate are in session and moving forward with legislative activity. Hearings of interest to healthcare stakeholders are also underway, and committee announcements are expected in the Senate. On Feb. 1, 2023, the House Committee on Energy and Commerce's Subcommittee on Health will hold a legislative hearing focused on the illicit fentanyl poisoning crisis, a cybersecurity breach of suicide lifelines and quality-adjusted life year (QALY) measures.

### **COVID-19 Emergency Declarations End on May 11, 2023**

The Office of Management and Budget (OMB) on Jan. 30, 2023, announced the national COVID-19 public health emergency (PHE) will end on May 11, 2023. Currently, the national COVID-19 emergency and the PHE – which were first declared by the Trump Administration in January 2020 – are slated to expire on March 1, 2023, and April 11, 2023, respectively. OMB said it intends to "extend the emergency declarations to May 11, and then end both emergencies on that date." The announcement follows resolutions that House Republicans introduced this week to immediately end the COVID-19 PHE. It also follows a declaration from the World Health Organization (WHO) on Jan. 30, 2023, that the coronavirus pandemic remains a global health emergency. The agency also acknowledged the crisis likely was at an "inflection point," where higher levels of immunity soon may lead to lower virus-related deaths.

There are numerous implications to ending these emergency declarations, each of which give the federal government flexibilities to waive or modify certain requirements in a range of areas, including in Medicare and Medicaid programs, Children's Health Insurance Program (CHIP) and private health insurance, as well as to allow for the authorization of medical countermeasures and to provide liability immunity to providers who administer services, among other things. In addition, Congress also enacted legislation – including the Families First Coronavirus Response Act (FFCRA), Coronavirus Aid, Relief, and Economic Security (CARES) Act, American Rescue Plan Act (ARPA), Inflation Reduction Act (IRA) and the Consolidated Appropriations Act of 2023 (CAA) – that provided additional flexibilities tied to one or more of these emergency declarations, and as such they too are scheduled to expire when (or at a specified time after) the emergency period expires.

Fortunately, many of the prominent Medicare telehealth flexibilities are extended through Dec. 31, 2024. The extended flexibilities include:

- the ability to see a patient in their own home regardless of geographic location
- an expanded list of eligible practitioners to furnish telehealth services
- the ability for federally qualified health centers (FQHCs) and rural health clinics (RHCs) to be distant site providers
- the ability to provide audio-only visits to patients
- the delay of the in-person visit requirement before a patient receives mental health visits
- allowing for telehealth to be used for a required face-to-face encounter prior to the recertification of a patient's eligibility for hospice care



In addition to creating telehealth flexibilities under Medicare, the CARES Act established a temporary safe harbor that permitted high deductible health plans (HDHPs) to cover telehealth and remote care services on a first-dollar basis without jeopardizing health savings account (HSA) contributions. The Health Insurance Portability and Accountability Act (HIPAA)-compliant platform and cross-state licensure waivers are not included in the omnibus and will end with the PHE.

Many other waivers will end with the PHE, but legislative or administrative action could extend such waivers. The Centers for Medicare & Medicaid Services (CMS) offers fact sheets by provider type that include information about which waivers and flexibilities have already been terminated, have been made permanent or will end at the end of the PHE.

### **House to Vote on Scaling Back COVID-19 Precautions**

Four health bills will be on the House floor this week that are firmly focused on scaling back COVID-19 precautions. In addition, the House will take up several bills related to pandemic-era policies that would 1) study the impacts of expanded telework and remote work by federal agency employees (H.R. 139), 2) terminate the COVID-19 PHE (H.R. 382) and 3) eliminate the COVID-19 vaccine mandate for healthcare providers (H.R. 497). These bills serve to make the political point that the PHE is over.

### **Committee Rosters Are Taking Shape**

In the House, final committee rosters are set. Taking into account the new ratios and existing committee vacancies, the only committee from which Democrats have been forced to remove members is the Committee on Ways and Means; Reps. Steven Horsford (D-Nev.), Jimmy Gomez (D-Calif.) and Stacey Plaskett (D-Va.) will no longer serve on that committee in the 118th Congress. The Senate is expected to approve an organizing resolution this week once Republicans complete their committee assignments.

Chairwoman Cathy McMorris Rodgers (R-Wash.) recently announced the House Committee on Energy and Commerce's (E&C) subcommittee leadership for the 118th Congress. The Subcommittee on Health will be chaired by Rep. Brett Guthrie (R-Ky.), with Rep. Larry Bucshon (R-Ind.) serving as vice chair. Rep. Guthrie leads the GOP's Healthy Future Task Force along with Rep. Vern Buchanan (R-Fla.). On the other side of the aisle, Rep. Anna Eshoo (D-Calif.) will serve as the ranking member of the Health Subcommittee.

Rep. Guthrie aims to address medical product innovation, price competition and transparency, and oversight of health agencies. He also has signaled his intent to examine the U.S. Food and Drug Administration's (FDA) implementation of emergency use authorization (EUA) as well as the agency's handling of drug supply chain issues and reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

The following members will serve on the E&C Health Subcommittee:

- Brett Guthrie, Chair (R-Ky.)
- Larry Bucshon, Vice Chair (R-Ind.)
- Gus Bilirakis (R-Fla.)
- Michael Burgess (R-Texas)
- Buddy Carter (R-Ga.)
- Dan Crenshaw (R-Texas)
- Neal Dunn (R-Fla.)
- Morgan Griffith (R-Va.)
- Diana Harshbarger (R-Tenn.)
- Richard Hudson (R-N.C.)

- Anna Eshoo, Ranking Member (D-Calif.)
- Lisa Blunt Rochester (D-Del.)
- Tony Cárdenas (D-Calif.)
- Angie Craig (D-Minn.)
- Nanette Diaz Barragán (D-Calif.)
- Debbie Dingell (D-Mich.)
- Robin Kelly (D-III.)
- Annie Kuster (D-N.H.)
- Raul Ruiz (D-Calif.)
- John Sarbanes (D-Md.)

- John Joyce (R-Pa.)
- Bob Latta (R-Ohio)
- Mariannette Miller-Meeks (R-lowa)
- Jay Obernolte (R-Calif.)
- Greg Pence (R-Ind.)

- Kim Schrier (D-Wash.)
- Lori Trahan (D-Mass.)

As chair of the Healthy Future Task Force, Rep. Buchanan has indicated that his priorities for the committee include expanding telehealth accessibility, strengthening Medicare and focusing on preventative care. Rep. Lloyd Doggett (D-Texas) will serve as ranking member of the Health Subcommittee, and minority subcommittee assignments are forthcoming.

The following members will serve on the Ways and Means Health Subcommittee:

- Vern Buchanan, Chair (R-Fla.)
- Brian Fitzpatrick (R-Pa.)
- Kevin Hern (R-Okla.)
- Mike Kelly (R-Pa.)
- Carol Miller (R-W.Va.)
- Blake Moore (R-Utah)
- Greg Murphy (R-N.C.)
- Adrian Smith (R-Neb.)
- Michelle Steel (R-Calif.)
- Claudia Tenney (R-N.Y.)
- Brad Wenstrup (R-Ohio)

### Conservative Push to Do Away with Income Tax and the IRS

The conservative tax proposal to abolish the IRS and replace income, payroll and estate taxes with a federal sales tax has started to gain attention after Speaker Kevin McCarthy (R-Calif.) promised the bill would go through the legislative process while vying for the speakership. Ways and Means Chair Jason Smith (R-Mo.) indicated he would be willing to host a committee hearing allowing for debate on the legislation.

The proposed 30 percent sales tax would have healthcare implications, since healthcare services are considered retail sales. Additionally, prescription drugs would be taxed, a shift from the status quo in most states. The bill would also impact tax subsidies for employer-sponsored health plans. Twenty-four conservatives have cosponsored the bill in the 118th Congress, while many other Republicans are distancing themselves from the proposal. The tax bill would face an uphill battle in the House and would likely be a non-starter in the Democratic-controlled Senate.

### **REGULATORY UPDATES**

#### **HHS Releases Report on Insulin Cost Savings**

On Jan. 24, 2023, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) released a report on insulin cost savings for Medicare beneficiaries as a result of the recently enacted IRA, which included provisions to cap insulin costs at \$35 per month. While the



IRA's insulin provisions did not take effect until January 2023 for Medicare Part D and will take effect in July 2023 for insulin covered by Medicare Part B, the report demonstrated that if the cap had been in place in 2020, 1.5 million Medicare beneficiaries would have saved an average of \$500 on insulin for the year.

### **Remote Monitoring Services Under Coverage Review**

On Feb. 28, 2023, Medicare Administrative Contractors (MACs) are scheduled to jointly host a multijurisdictional contractor advisory committee (CAC) meeting. The purpose of the meeting is to obtain advice from a select panel regarding the strength of published evidence on remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) for non-implantable devices and any compelling clinical data to assist in defining meaningful and measurable patient outcomes (e.g., decreases in emergency room visit and hospitalizations) for Medicare beneficiaries. CAC meetings often, but not always, are held in advance of the publication of a draft local coverage determination (LCD), specifying the circumstances or criteria under which items and services may be covered by Medicare in a particular geographic region. Given the increasing utilization of remote monitoring services, interested stakeholders should consider attending the upcoming CAC meeting and begin gathering data to support the clinical efficacy of non-implantable medical devices for RPM and RTM services. Complete details, including background material, questions, agenda and registration will be available on the MAC sites by Feb. 14, 2023.

### CMS to Crack Down on Medicare Advantage Audits

HHS announced it will extrapolate Medicare Advantage audit data beginning with payment year 2018 as it moves to claw back overpayments with its long-awaited Medicare Advantage Risk Adjustment Data Validation (RADV) rule. RADV audits take a sample of patients on a Medicare Advantage plan, check to see if the diagnosis codes match and then analyze how many errors there were. Originally, the CMS wanted to extrapolate those results to a company's entire contract. The government is still moving forward with that kind of extrapolation – and is still conducting these audits retrospectively – but extrapolation would only apply for audits that cover 2018 and thereafter. Director of the Center for Program Integrity Dara Corrigan said, "HHS anticipates retroactively recouping \$479 million in overpayments from payment year 2018, and forecasts recovering around \$4.7 billion between 2023 and 2032 based on the new audit structure, though the department will not extrapolate data from 2011 through 2017."

#### MACPAC Votes To Recommend Congress Let States Restrict Drug Coverage

On Jan. 27, 2023, the Medicaid and CHIP Payment and Access Commission (MACPAC) voted to approve a recommendation that calls on Congress to amend the Social Security Act to allow states to exclude or restrict coverage of an outpatient drug based on a Medicare national coverage determination (NCD), including any "coverage with evidence development" (CED) requirements. A CED enables Medicare to cover services on the condition that they are "furnished in the context of approved clinical studies and/or with the collection of additional clinical data." A statutory change would allow states to align their coverage criteria with a federal determination of reasonable and necessary coverage. The Commission also approved the recommendation to require managed care plans to follow the state's coverage decision regarding drugs based on CED requirements implemented under a Medicare NCD.

While discussing the recommendations, most commissioners said they were fond of granting states the option to impose CED restrictions. One commissioner raised multiple concerns that allowing Medicaid the same right to restrict coverage as Medicare could impact patient access, because certain patients might not be able to participate in clinical trials.