



H&K Health Dose: October 18, 2022

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Congress This Week

Congress is in recess until after the Nov. 8, 2022, midterm elections. The next votes in the House and Senate are scheduled to occur during the week of Nov. 14.

REGULATORY UPDATES

COVID-19 Public Health Emergency Extended through Mid-January

U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra on Oct. 13, 2022, [extended](#) the COVID-19 public health emergency (PHE) through mid-January 2023. By law, PHEs must be reauthorized in 90-day increments. The administration has not been clear about when it intends to end the PHE but has indicated it would provide 60 days' advance notice so state Medicaid agencies and other stakeholders can prepare. With this renewal that 60-day notice time frame would be the week after the election. Given the need for Congress to address policies tied to the PHE, the PHE may be extended beyond January 2023 – although it is by no means certain. Congress did pass legislation that extended the telehealth flexibilities for another five months after the PHE ends. However, efforts to extend that beyond the five months still need to be taken up by the Senate.

New Executive Order Directs HHS to Leverage CMS Innovation Center to Improve Access to and Lower Drug Costs

President Joe Biden on Oct. 14, 2022, [signed](#) a new Executive Order that directs the Secretary of Health and Human Services (HHS) to issue a report within 90 days outlining plans to improve access to and lower costs for innovative drug therapies for Medicare and Medicaid beneficiaries through innovative payment and delivery models under the Centers for Medicare & Medicaid Services Innovation Center. The HHS Secretary is expected to test models after submitting the report.

IRA Implementation Update

As the U.S. Department of Health and Human Services begins the process of building new price negotiation and inflation rebate programs within Medicare, HHS [announced](#) the establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare to implement the drug price negotiations program and the inflation rebate program.



Medicare 340B Payment Cut Ending for 2022

The Centers for Medicare & Medicaid Services (CMS) on Oct. 13, 2022, [announced](#) that it will end the Medicare outpatient drug payment cut for 340B hospitals for the remainder of calendar year (CY) 2022. This announcement follows the U.S. Supreme Court decision on the drug payment cuts that were included in the 2018 Outpatient Prospective Payment System (OPPS) Final Rule. CMS did not specify whether it will apply OPPS budget-neutrality requirements to the revised payment. However, CMS noted in the 2023 OPPS proposed rule that if the agency was to restore the full 340B drug payment rates for 2023, it would need to offset those increases with corresponding reductions for other Medicare outpatient services to meet OPPS budget-neutrality requirements. The 2023 OPPS Final Rule is with the Office of Management and Budget (OMB) and is expected to be released in the next two weeks.

Forthcoming Rules

The Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS) final rules are expected early next month. The Social Security Act requires the establishment of the fee schedules before Nov. 1 of the preceding year. However, the rules typically are released the first week of November. Both rules are currently at the Office of Management and Budget (OMB). The fee schedules are updated annually by Centers for Medicare & Medicaid Services (CMS), with new rates going into effect on Jan. 1 of each year.

Additionally, the OMB [received](#) a proposed rule focusing on improving interoperability of healthcare data and establishing processes for prior authorization within Medicare, Medicaid and the Marketplace.

FDA Debates Removing Preterm Birth Preventive Drug From Market, Reigniting Criticisms of Accelerated Approval Pathway

The U.S. Food and Drug Administration (FDA) is [convening this week](#) to debate whether to remove Makena, an injection-based drug intended to lower the risk of preterm birth, from the market. The drug was granted approval under the FDA's accelerated approval pathway in 2011 and has now become the latest lightning rod over the increasingly controversial program that allows drugmakers to bring products to market before clinical trials confirming their clinical benefit are complete. Advocates argue that the process gives patients with serious conditions early access to potentially life-changing treatments, while critics argue enforcement is too relaxed and that the program risks jeopardizing patient safety.

This comes after a recent [report](#) from the U.S. Department of Health and Human Services' (HHS) Office of Inspector General (OIG) found that more than a third of drugs granted accelerated approval have at least one trial past their original planned completion date.



FDA Seeks Public Feedback on Distributed and Point-of-Care Drug Manufacturing

The U.S. Food and Drug Administration (FDA) issued a [request for public comments](#) on a recently released discussion paper on areas associated with Distributed Manufacturing and Point-of-Care (POC) Manufacturing of Drugs.

Key issues include:

- How often might a Distributed Manufacturing unit move to a new location and what might an applicant report to the agency when doing so?
- What locations are envisioned for POC unit operation?
- How might a centralized quality system (i.e., at a "parent location") ensure each manufacturing unit complies with regulatory requirements and quality standards?
- What type of business relationships are envisioned between companies developing POC manufacturing platforms and healthcare facilities?

Interested stakeholders can provide input at a public workshop on Nov. 14-16, 2022, and to the public docket.

Treasury Department Finalized Family Glitch Rule

The U.S. Department of the Treasury on Oct. 11, 2022, [finalized a rule](#) that fixes what is known as the "family glitch" rule, which targets an issue that inadvertently raises insurance costs for certain families. The rule goes into effect next month.

Medicare Open Enrollment Oct. 15 through Dec. 7

Medicare open enrollment for 2023 officially [opened](#) Oct. 15, 2022, and will remain open through Dec. 7, 2022. New insulin cost-sharing caps of \$35 per month will apply. Avid health policy followers will watch to see whether enrollment in Medicare Advantage (MA) will eclipse traditional Medicare. In 2022, 48 percent of eligible beneficiaries [were enrolled](#) in an MA plan. Premiums for traditional Medicare, MA and Medicare prescription drug Part D plans all decreased because of lower than expected uptake of an expensive new Alzheimer's drug, Aduhelm.

FDA, CDC Green Light Omicron-Targeted Booster for Young Children; Vaccine Rates Remain Stagnant

The U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control (CDC) have [green-lighted](#) emergency use authorization for Pfizer and Moderna's omicron-targeting boosters for children as young as 5 and 6, respectively. However, overall vaccination rates among children remain low. Only 39 percent of children ages 5-11 have received at least one dose of the two-dose regimen. Bivalent booster adoption also remains low at only 5 percent of eligible Americans.

CMS Extends, Updates BPCI Advanced Model

The Centers for Medicare & Medicaid Services (CMS) on Oct. 13, 2022, [announced](#) that the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model would be extended for two additional years. The BPCI Advanced Model, launched on Oct. 1, 2018, was set to end on Dec. 31, 2023, but will now conclude on Dec. 31, 2025. CMS plans to announce a Request for Applications (RFA) in early 2023. The agency also announced several pricing methodology changes, which are summarized in a new [fact sheet](#) but include reducing the pay cut for episodes of care from 3 percent down to 2 percent and holding providers accountable for episodes of care during which beneficiaries are diagnosed with COVID-19.