



H&K Health Dose: October 11, 2022

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Congress This Week

Congress is in recess until after the Nov. 8 midterm elections.

Bill Introduced Requires CMS to Evaluate Drug Coverage Individually

Reps. Vern Buchanan (R-Fla.) and Nanette Barragán (D-Calif.) on Oct. 4, 2022, [introduced](#) the Mandating Exclusive Review of Individual Treatments (MERIT) Act ([H.R. 9127](#)), to require the Centers for Medicare & Medicaid Services (CMS) to evaluate any new drugs or treatments individually instead of an entire class as in the Aduhelm decision. Notably, if Republicans take the House, Rep. Buchanan would be in line to lead the health subcommittee on the Ways and Means Committee, which could help prioritization in the next session of Congress.

Senate Republicans Introduce Legislation to Repeal Medicare Negotiation

Sens. James Lankford (R-Okla.), Mike Lee (R-Utah), Cynthia Lummis (R-Wyo.) and Marco Rubio (R-Fla.) on Oct. 7, 2022, introduced the [Protecting Drug Innovation Act](#), which would repeal the drug pricing reforms included in the Inflation Reduction Act (IRA) passed earlier this year. The legislation would repeal the Medicare drug price negotiation program and drug inflation rebate requirements as well as eliminate the Medicare Part D benefit redesign capping out-of-pocket costs for seniors.

REGULATORY UPDATES

Forthcoming Annual Fee Schedules

The Medicare Physician Fee Schedule (MPFS) and the Hospital Outpatient Prospective Payment System (HOPPS) 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.

Inflation Reduction Act Resources and Implementation Activity

Centers for Medicare & Medicaid Services (CMS) on Oct. 5, 2022, released a [fact sheet](#) on the Inflation Reduction Act (IRA) that contains information about the Medicare, Medicaid, Children's Health Insurance Program and Health Insurance Marketplace provisions of the IRA. CMS also released an [IRA implementation timeline](#) and [frequently asked questions](#) document.



Additionally, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra and Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure [issued statements](#) on implementing Medicare Part B payment changes for certain biosimilars – one of the Inflation Reduction Act's (IRA) first Medicare provisions to take effect. The IRA provides a temporary increase in the add-on payment for qualifying biosimilars whose average sales price (ASP) is not more than the associated reference biological product price. Additionally, regarding the IRA's inflation rebates, the one-year period that the CMS will use to determine the annual manufacturer price (AMP) for every drug unit sold in Medicare Part D began on Oct. 1, 2022. After that year-long period, a product's AMP will then be compared to a benchmark price from the prior year. A similar rebate program for Medicare Part B will go into effect at the beginning of 2023.

FDA Aims to Speed Approval of New Treatments; Drastically Expands AI Devices List

In line with previous comments to continue leveraging expedited approval pathways, the U.S. Food and Drug Administration (FDA) announced various new pilot programs and guidance to help bring novel therapies to market more quickly. The [Split Real-Time Application Review \(STAR\)](#) pilot program aims to shorten the time from submission-to-market access by splitting it into a two-phase approval process. It will be available for certain supplemental new drug applications and supplemental biologics license applications.

The [Rare Disease Endpoint Advancement](#) pilot program will support the development of rare disease treatments by seeking private sponsors for FDA collaboration, facilitating information sharing and expanding FDA staff capacity to evaluate new therapies. Through that program, the FDA will accept up to three yearly proposals starting in July 2023. The agency also released a slate of new guidance on [abbreviated new drug applications](#) for complex products, [post-approval studies](#) for approved medical devices and [post-market surveillance](#) of certain Class II or III devices to improve applicant-FDA communication and enhance patient safety. Also on Oct. 5, the FDA [added 178 devices](#) to the list of artificial intelligence and machine learning-enabled devices legally marketed in the U.S.

CMS Seeks Input on Payment Policies, Quality Programs, and Possible National Provider and Service Database

The Centers for Medicare & Medicaid Services (CMS) released a pair of Requests for Information (RFI). The first [seeks input](#) on CMS payment policies and quality programs emphasizing access, health equity, provider experience and flexibilities tied to the COVID-19 public health emergency. Feedback is due on or before Nov. 4, 2022. The second [solicits feedback](#) on potentially creating a national directory of healthcare providers and services. Ideally, providers could update it seamlessly through their systems with the help of application programming interfaces. Comments are due on or before Dec. 6, 2022.

CMS Releases 2023 MA, Part D Quality Star Ratings

Centers for Medicare & Medicaid Services (CMS) [released](#) its 2023 quality star ratings for Medicare Advantage (MA) and Part D prescription drug plans to help Medicare beneficiaries compare quality across plans during the open enrollment, which begins Oct. 15, 2022, and ends Dec. 7, 2022. There were some methodological changes including new caps on year-to-year changes in scoring thresholds, doubling the weight of patient experience/complaints and access to care measures, and removing COVID-19 specific adjustments to several measures. Half of MA plans with prescription drug coverage have four stars or greater (out of 5), and 72 percent of current MA beneficiaries are enrolled in such plans. On Sept. 29, 2022, CMS [announced](#) lower premiums for MA and Part D plans (declines of 8 percent and 1.8 percent, respectively), plus a new \$35 monthly cost-sharing limit on insulin products.



New Director at National Cancer Institute

Monica Bertagnolli is the [new director](#) of the National Cancer Institute, housed within the National Institutes of Health. Dr. Bertagnolli is the first woman to hold the role. She came from Harvard Medical School and served as a professor of Surgical Oncology at Brigham and Women's Hospital in Boston.