



Health Policy Briefing

October 10, 2022

CMS Begins Process of Implementing Drug Inflation Rebate

Several of the *Inflation Reduction Act's* drug pricing provisions went into effect last week, including a measure that will require pharmaceutical manufacturers to rebate the Medicare program if the price of a product rises faster than the rate of inflation. The one-year period that the Centers for Medicare and Medicaid Services (CMS) will use to determine the annual manufacturer price for every unit of a drug sold in Medicare Part D began on October 1. After that year-long period, a product's annual manufacturer price 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. The *Inflation Reduction Act* also included a provision to increase the Average Sales Price add-on percentage for biosimilars, which went into effect last week.

CMS Plans Implementation of Medicare Drug Price Negotiation Program

CMS is aiming to hire 95 full time employees to implement its new drug price negotiation authorities, according to a new report from STAT+. CMS expects to hire individuals with a range of experience in pharmaceuticals, economics, data analytics, regulatory analytics, and management. The hiring process is being directed by Kristi Martin, a CMS senior adviser. Martin previously worked as vice president of healthcare at Arnold Ventures. She also served in the Obama administration at the Center for Consumer Information and Insurance Oversight implementing the Affordable Care Act, the Office of Personnel Management on the Multi-State Plan program, and in the U.S. Department of Health and Human Services (HHS) Office of Health Reform working on public health and prevention policy. While the first round of Medicare negotiated drug prices does not take effect until 2026, a list of drugs selected for negotiation must be published by September 1, 2023.

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Senate Republicans Introduce Legislation to Undo IRA Drug Pricing Measures

Sens. James Lankford (R-Okla.), Mike Lee (R-Utah), Cynthia Lummis (R-Wyo.), and Marco Rubio (R-Fla.) introduced the [Protecting Drug Innovation Act](#) on Friday, which would undo the drug pricing reforms included in the Democrats' landmark *Inflation Reduction Act* passed earlier this year. The Republican legislation would repeal the Medicare drug price negotiation program and drug inflation rebate requirements and eliminate the Medicare Part D benefit redesign capping out-of-pocket costs for seniors. The bill's sponsors have argued that these drug price controls create barriers to effectively bringing down the cost of prescription drugs by reducing innovation and competition.

ACE Kids Act Implemented as of Oct. 1

Implementation of the *Advancing Care for Exceptional (ACE) Kids Act* officially began last week. The *ACE Kids Act* allows children with medically-complex conditions to choose to enroll in a health home – if a state Medicaid program permits – to improve care coordination and health outcomes. The law supports CMS and state Medicaid programs in aligning rules and reimbursement to reduce unnecessary hospitalizations and provide better care coordination for children with complex medical needs. Sen. Chuck Grassley (R-Iowa), the bill's sponsor, praised CMS for meeting the October 1 deadline for implementing the legislation.

Ben Sasse (R-Neb.) Announces Retirement from Senate

Sen. Ben Sasse (R-Neb.) will retire from the Senate by the end of the year to become the president of the University of Florida. Sasse is expected to step down between mid-November and mid-December. Nebraska Governor Pete Ricketts (R) will choose who will fill his seat in the Senate through 2024. Sasse was first elected to the Senate in 2014. He currently serves on the Finance, Judiciary, Budget, and Intelligence committees.

Burr Criticizes FDA Response to Formula Shortages

Senate Health, Education, Labor, and Pensions Committee Ranking Member Richard Burr (R-N.C.) has [written](#) to the Food and Drug Administration (FDA) regarding the agency's response to the infant formula shortage. The letter condemns FDA's internal review of the shortages, which the agency published last month. Burr says the review is a demonstration "that the agency does not take accountability seriously." He argues that before the FDA is provided with additional resources "it needs to show more responsibility and accountability—namely, that the agency can be responsible stewards of the expansive authorities and significant funding Congress has already provided and that it will hold itself accountable for its own mistakes."

President Announces Federal Marijuana Pardons

President Joe Biden announced last week that he will issue an executive order pardoning all individuals convicted of simple marijuana possession under federal law. He called on state governors to consider taking similar action for state offenses. The President also stated that he will be requesting that the Attorney General and HHS Secretary review marijuana scheduling under federal law. The move was praised by House Energy and Commerce Committee Chair Frank Pallone (D-N.J.) as a "welcome step forward as we reconsider our nation's drug policy and how best to expand research as well as access to care and treatment to those struggling with substance use."

NYT Investigates Fraud by MA Insurers

The *New York Times* published an [investigation](#) on Saturday detailing the fraud committed by insurers participating in the Medicare Advantage (MA) program. The report reviewed dozens of fraud lawsuits, inspector general audits, and watchdog investigations into how health insurers exploited MA to increase their own profits by billions of dollars. The *New York Times* found that eight of the ten biggest MA insurers, who represent more than two-thirds of the MA market, have submitted inflated bills to the federal government. Four of the five largest insurers – UnitedHealth, Humana, Elevance, and Kaiser – have faced federal lawsuits over fraudulent efforts by the insurers to over-diagnose patients. CVS Health, the fifth company, is currently under investigation by the Department of Justice. Estimates of the cost of the overpayments range from \$12 billion to \$25 billion in 2020. The insurance industry has responded that these accusations are a reflection of missing documentation rather than willful fraud.

New ACA Premium Tax Credit Rule Clears OMB

The White House Office of Management and Budget (OMB) has cleared its review of a final rule to ensure that Internal Revenue Service regulations are consistent with the administration's policy to protect and strengthen the Affordable Care Act (ACA). President Joe Biden issued an executive order in January 2021 calling for a review of certain federal regulations to determine if they undermine protections for people with pre-existing conditions. Current ACA premium tax regulations require that employers offer affordable coverage based on the cost of employee coverage. The new forthcoming rule is expected to require the affordability of plans to be based on both the employee's share plus their family members. The final rule can now be issued at any time.

NIH Personnel Update

Dr. Monica Bertagnolli began work as the new director of the National Cancer Institute (NCI) on October 3. She is NCI's first female director and most recently served as the Richard E. Wilson Professor of Surgery in the field of surgical oncology at Brigham and Women's Hospital in Boston. She recently outlined three goals for her work at NCI: "understanding how cancer arises and what biological processes it disrupts; developing and testing new prevention and therapy approaches; and partnering with patients to develop ways for all people to receive the care that best meets their needs and, if they wish, to participate in research." Andrea Norris, Director of the Center for Information Technology and National Institutes of Health (NIH) Chief Information Officer announced that she plans to retire in December. In this role Norris led a \$1.6 billion technology portfolio supporting the research of NIH's 27 Institutes and Centers as well as more than 2,500 universities and medical centers across the country that receive NIH funding support.

Recently Introduced Health Legislation

S.Res.816 — A resolution designating September 4, 2022, as “National Polycystic Kidney Disease Awareness Day”, and raising awareness and understanding of polycystic kidney disease; Sponsor: Blunt, Roy [Sen.-R-MO]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.5002 — A bill to allow for alternatives to animal testing for purposes of drug and biological product applications; Sponsor: Paul, Rand [Sen.-R-KY]; Introduced in the Senate, read twice, considered, read the third time, and passed without amendment by Unanimous Consent.

S.5008 — A bill to promote affordable access to evidence-based opioid treatments under the Medicare program and require coverage of medication assisted treatment for opioid use disorders, opioid overdose reversal medications, and recovery support services by health plans without cost-sharing requirements; Sponsor: Casey, Robert P., Jr. [Sen.-D-PA]; Committees: Senate – Finance

S.5011 — A bill to amend title XIX of the Social Security Act to establish a demonstration project testing Whole Child Health Models, and for other purposes; Sponsor: Carper, Thomas R. [Sen.-D-DE]; Committees: Senate – Finance

S.5015 — A bill to amend titles XIX and XXI of the Social Security Act to improve maternal health coverage under Medicaid and CHIP, and for other purposes; Sponsor: Grassley, Chuck [Sen.-R-IA]; Committees: Senate – Finance

S.5027 — A bill to address the health needs of incarcerated women related to pregnancy and childbirth, and for other purposes; Sponsor: Klobuchar, Amy [Sen.-D-MN]; Committees: Senate – Judiciary

S.5041 — A bill to amend title XVIII of the Social Security Act to provide for the distribution of additional residency positions in psychiatry and subspecialties; Sponsor: Stabenow, Debbie [Sen.-D-MI]; Committees: Senate – Finance

S.5042 — A bill to amend title XVIII of the Social Security Act to expand eligibility for incentives under the Medicare health professional shortage area bonus program to practitioners furnishing mental health and substance use disorder services; Sponsor: Stabenow, Debbie [Sen.-D-MI]; Committees: Senate – Finance

S.5043 — A bill to require the Secretary of Health and Human Services to issue guidance to States on strategies under Medicaid and CHIP to increase mental health and substance use disorder care provider education, training, recruitment, and retention; Sponsor: Stabenow, Debbie [Sen.-D-MI]; Committees: Senate – Finance

S.5061 — A bill to amend title XVIII of the Social Security Act to provide for Medicare coverage and coding for qualified psychologist services furnished by advanced psychology trainees; Sponsor: Daines, Steve [Sen.-R-MT]; Committees: Senate – Finance

S.5062 — A bill to amend title XVIII of the Social Security Act to increase access to mental health programs for physicians; Sponsor: Daines, Steve [Sen.-R-MT]; Committees: Senate – Finance

H.R.9028 — To reauthorize the Assistive Technology Act of 1998, and for other purposes; Sponsor: DeSaulnier, Mark [Rep.-D-CA-11]; Committees: House - Education and Labor

H.R.9034 — To amend title XVIII of the Social Security Act to provide for reform to and a permanent extension of the Medicare-dependent hospital program, and for other purposes; Sponsor: Arrington, Jodey C. [Rep.-R-TX-19]; Committees: House - Ways and Means

H.R.9036 — To establish a grant program to facilitate peer-to-peer suicide prevention programs for middle school and high school students, and for other purposes; Sponsor: Beyer, Donald S., Jr. [Rep.-D-VA-8]; Committees: House - Education and Labor; Energy and Commerce

H.R.9037 — To amend title XIX of the Social Security Act to establish a demonstration project testing Whole Child Health Models, and for other purposes; Sponsor: Blunt Rochester, Lisa [Rep.-D-DE-At Large]; Committees: House - Energy and Commerce

H.R.9040 — To amend the Public Health Service Act to improve reproductive health care of individuals with disabilities; Sponsor: Bush, Cori [Rep.-D-MO-1]; Committees: House - Energy and Commerce

H.R.9054 — To end COVID-19 lockdowns and COVID-19 vaccine mandates; Sponsor: Gosar, Paul A. [Rep.-R-AZ-4]; Committees: House - Oversight and Reform; Energy and Commerce; Education and Labor

H.R.9067 — To require the Secretary of Health and Human Services to submit a report on the interoperability of medical devices; Sponsor: Miller-Meeks, Mariannette [Rep.-R-IA-2]; Committees: House - Energy and Commerce

H.R.9080 — To amend the Internal Revenue Code of 1986 to establish new community benefit standards for tax-exempt hospital organizations, and for other purposes; Sponsor: Spartz, Victoria [Rep.-R-IN-5]; Committees: House - Ways and Means

H.Res.1413 — Expressing support for designation of September 2022 as “National Dystonia Awareness Month” and raising awareness and understanding of the disorder of dystonia; Sponsor: Smith, Christopher H. [Rep.-R-NJ-4]; Committees: House - Energy and Commerce

H.Res.1419 — Recognizing the roles and the contributions of United States certified nurse-midwives and certified midwives in providing high-quality, evidence-based, and cost-effective health care services to women and childbearing families; Sponsor: Roybal-Allard, Lucille [Rep.-D-CA-40]; Committees: House - Energy and Commerce

H.R.9090 — To amend title XVIII of the Social Security Act to treat certain multimarker testing relating to ovarian cancer as reasonable and necessary for coverage under the Medicare program; Sponsor: Dean, Madeleine [Rep.-D-PA-4]; Committees: House - Energy and Commerce; Ways and Means

H.R.9091 — To authorize the Secretary of Veterans Affairs to carry out an information technology system to manage supply chains for medical facilities of Department of Veterans Affairs; Sponsor: Mann, Tracey [Rep.-R-KS-1]; Committees: House - Veterans' Affairs

H.R.9094 — To amend the Public Health Service Act to enhance efforts to address antimicrobial resistance, and for other purposes; Sponsor: Bera, Ami [Rep.-D-CA-7]; Committees: House - Energy and Commerce

H.R.9099 — To amend the Public Health Service Act to provide for establishment of an Office of Minority and Women Inclusion within each covered agency of the Department of Health and Human Services, and for other purposes; Sponsor: DeLauro, Rosa L. [Rep.-D-CT-3]; Committees: House - Energy and Commerce

H.R.9105 — To amend the Public Health Service Act to authorize the establishment of the National Medical Corps Program to create pathway programs for community college students to pursue premedical training and enter medical school, and for other purposes; Sponsor: Lee, Barbara [Rep.-D-CA-13]; Committees: House - Energy and Commerce

H.R.9109 — To amend the Public Health Service Act to provide support for bereavement services, and for other purposes; Sponsor: Morelle, Joseph D. [Rep.-D-NY-25]; Committees: House - Energy and Commerce

H.R.9117 — To make permanent the authority of the Secretary of Veterans Affairs to make grants for the transportation of highly rural veterans to medical care; Sponsor: Peltola, Mary Sattler [Rep.-D-AK-At Large]; Committees: House - Veterans' Affairs

H.Res.1421 — Expressing support for designation of the week of October 2, 2022, through October 8, 2022, as "Latex Allergy Awareness Week"; Sponsor: Dingell, Debbie [Rep.-D-MI-12]; Committees: House - Oversight and Reform

H.Res.1422 — Supporting the designation of October 1, 2022, as National Ostomy Awareness Day; Sponsor: Payne, Donald M., Jr. [Rep.-D-NJ-10]; Committees: House - Energy and Commerce

H.R.9127 — To amend title XVIII of the Social Security Act to clarify the use of the national coverage determination process under the Medicare program; Sponsor: Buchanan, Vern [Rep.-R-FL-16]; Committees: House - Energy and Commerce; Ways and Means

H.R.9137 — To amend the Public Health Service Act to reauthorize the State offices of rural health program; Sponsor: Mullin, Markwayne [Rep.-R-OK-2]; Committees: House - Energy and Commerce