



## CMS Snapshot

### November 19-December 3, 2020

Delivered to you by the Partner Relations Group in the Office of Communications

All releases below are from 2pm Thursday, November 19 through 2pm Thursday, December 3, 2020.

#### News Releases

\*November 19- [HHS Provides \\$25 Million to Siemens Healthineers to Develop and Produce COVID-19 Antigen Diagnostic Tests](#). Today, the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DoD) awarded Siemens Healthineers a \$12 million contract to support domestic production of two diagnostic tests for SARS-CoV-2, the virus that causes COVID-19. The funding is in addition to a \$13 million HHS contract awarded Nov. 2 to enable the company to develop the tests.

\*November 20- [HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter](#). Today, in response to President Trump's July 24, 2020 Executive Order on "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen," HHS Secretary Alex Azar and the HHS Office of Inspector General finalized a regulation to eliminate the current system of drug rebates in Medicare Part D, in order to create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs by delivering discounts directly at the pharmacy counter.

\*November 20- [Trump Administration Announces Prescription Drug Payment Model to Put American Patients First](#). In support of President Trump's historic commitment to lowering drug prices for American patients, HHS Secretary Alex Azar announced a drug payment model through the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services that will lower Medicare Part B payments for certain drugs to the lowest price for similar countries and save American taxpayers and beneficiaries more than \$85 billion over seven years.

\*November 20- [Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen](#). President Trump has made it a priority to decrease the costs of prescription drugs for Americans, and he has never wavered from this commitment. The President has taken bold action from protecting the ability of pharmacists to help patients fill prescriptions at the lowest available cost to fixing loopholes in Medicare that allowed hospitals to keep prescription drug discounts meant for patients. None of these

actions was easy, and the President is working each day to stand up for the American people against entrenched interests.

\*November 20- [Statement from HHS Chief of Staff Brian Harrison on Unapproved Drugs Initiative](#). Today, the Department of Health and Human Services (HHS) through a Notice published in the Federal Register announced the withdrawal of guidance documents issued as part of the Unapproved Drugs Initiative. HHS Chief of Staff Brian Harrison issued the following statement.

\*November 20- [HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care](#). Today, the Department of Health and Human Services (HHS) published two final rules that aim to reduce regulatory barriers to care coordination and accelerate the transformation of the healthcare system into one that pays for value and promotes the delivery of coordinated care.

\*November 20- [Secretary Azar Statement on Final Rule to Increase Access to Lifesaving Organs](#). Today, the Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), is finalizing a rule that is designed to increase the supply of lifesaving organs available for transplant in the United States by requiring that the organizations responsible for organ procurement be transparent in their performance, highlighting the best and worst performers, and requiring them to compete on their ability to successfully facilitate transplants.

\*November 20- [CMS Finalizes Policy that will Increase the Number of Available Lifesaving Organs by Holding Organ Procurement Organizations Accountable through Transparency and Competition](#). Today, the Centers for Medicare & Medicaid Services (CMS) is finalizing a rule that is designed to increase the supply of lifesaving organs available for transplant in the United States by requiring that the organizations responsible for organ procurement be transparent in their performance, highlighting the best and worst performers, and requiring them to compete on their ability to successfully facilitate transplants.

\*November 20- [CMS Announces Historic Changes to Physician Self-Referral Regulations](#). Today, the Centers for Medicare & Medicaid Services (CMS) finalized changes to outdated federal regulations that have burdened health care providers with added administrative costs and impeded the health care system's move toward value-based reimbursement. The Physician Self-Referral Law, also known as the "Stark Law," generally prohibits a physician from making referrals to an entity for certain healthcare services, if the physician has a financial relationship with the entity.

\*November 20- [Trump Administration Announces Prescription Drug Payment Model to Put American Patients First](#). In support of President Trump's historic commitment to lowering drug prices for American patients, HHS Secretary Alex Azar announced a drug payment model through the Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services that will lower Medicare Part B payments for certain drugs to the lowest

price for similar countries and save American taxpayers and beneficiaries more than \$85 billion over seven years.

\*November 23- [HHS Allocates Regeneron Therapeutic to Treat Patients With Mild to Moderate COVID-19](#). The U.S. Department of Health and Human Services today announced plans to allocate initial doses of Regeneron's investigational monoclonal antibody therapeutic, casirivimab and imdevimab, which received [emergency use authorization](#) from the U.S. Food and Drug Administration on November 21, 2020, for treatment of non-hospitalized patients with mild or moderate confirmed cases of COVID-19 at high risk of hospitalization.

\*November 23- [HHS and DOD Award \\$11.6 Million Contract to Puritan Medical Products to Boost U.S. Production of Swabs for Cue Health COVID-19 Tests](#). The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DOD) have jointly awarded an \$11.6 million contract to Puritan Medical Products Company, LLC, to expand domestic production capacity of Cue Sample Wands, the nasal swabs used exclusively with the COVID-19 cartridge-based molecular testing system developed and manufactured by Cue Health, Inc. The test generates results in about 20 minutes at the point-of-care (POC).

\*November 24- [Statement from HHS Chief of Staff Brian Harrison on Efforts to Increase Transparency at HHS](#). Today, the Department of Health and Human Services (HHS) through a [Notice published in the Federal Register](#) announced a policy to enhance transparency at HHS by requiring that all assumptions, working papers, models, and other information used as part of any impact analysis associated with a rule or demonstration project are shared at the time the results of that analysis are publicly disclosed.

\*November 25- [CMS Proposed Rule Seeks to Reduce Exchange Fees Again to Lower Premiums for Plans Using the Federal Enrollment Platform](#). Today, the Centers for Medicare & Medicaid Services (CMS) released the proposed annual Notice of Benefit and Payment Parameters for the 2022 benefit year (proposed 2022 Payment Notice). Building on three years of declining premiums and increasing coverage options on HealthCare.gov, this proposed rule updates the regulatory and financial standards that govern issuers and the Exchanges by proposing a broad set of regulatory changes to advance President Trump's commitment to deliver more affordable health insurance choices for all Americans.

\*November 25- [CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge](#). Today, the Centers for Medicare & Medicaid Services (CMS) outlined unprecedented comprehensive steps to increase the capacity of the American health care system to provide care to patients outside a traditional hospital setting amid a rising number of coronavirus disease 2019 (COVID-19) hospitalizations across the country. These flexibilities include allowances for safe hospital care for eligible patients in their homes and updated staffing flexibility designed to allow ambulatory surgical centers (ASCs) to provide greater inpatient care when needed.

\*December 1- [Secretary Azar Statement on World AIDS Day](#). On the occasion of the 32nd annual World AIDS Day, December 1, 2020, HHS Secretary Alex Azar issued the following statement.

\*December 1- [Tribal Health Programs and Urban Indian Organizations Choose How They Will Access the COVID-19 Vaccine](#). The Department of Health and Human Services is laying the necessary groundwork for the distribution of a safe and effective COVID-19 vaccine by ensuring that all tribal health programs and urban Indian organizations have the choice on how they receive the COVID-19 vaccine. Today, HHS is announcing that all tribal health programs and UIOs have chosen their preferred method for receiving the vaccine.

\*December 1- [Speech: Remarks by CMS Administrator Seema Verma at the ONC API Event](#). Thank you for inviting me today. Let me start by extending special thanks to Dr. Rucker and Matt Lira for organizing this event, and the CMS team Shannon Sartin, and Alex Mugge for their tireless efforts over the last four years. Speaking of four years, this week marks the anniversary of the date that I accepted President Trump's nomination to become the CMS Administrator. I did so because it was clear to me that this administration wasn't afraid to disrupt the status quo to make lasting, transformative changes on behalf of the American people.

\*December 1- [CMS Updates Coverage Policies for Artificial Hearts and Ventricular Assist Devices \(VADs\)](#). Today, the Centers for Medicare & Medicaid Services (CMS) finalized updates to Medicare coverage policies for artificial hearts and ventricular assist devices (VADs), both of which are used to treat patients with life-threatening advanced heart failure.

\*December 2- [Trump Administration Finalizes Policies to Give Medicare Beneficiaries More Choices around Surgery](#). Today, the Centers for Medicare & Medicaid Services (CMS) is finalizing policy changes that will give Medicare patients and their doctors greater choices to get care at a lower cost in an outpatient setting. The Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) final rules will increase value for Medicare beneficiaries and reflect the agency's efforts to transform the healthcare delivery system through competition and innovation.

\*December 3- [HHS Outlines New Plans and a Partnership to Reduce U.S. Pregnancy-related Deaths](#). Today, the U.S. Department of Health and Human Services (HHS) released an important [HHS Action Plan - PDF](#) and announced a partnership to reduce maternal deaths and disparities that put women at risk prior to, during, and following pregnancy. The U.S. Surgeon General Jerome M. Adams issued a complementary [Call to Action to Improve Maternal Health - PDF](#) outlining the critical roles everyone can play to improve maternal health.

\*December 3- [Secretary Azar Statement on Maternal Health Actions](#). On Thursday, the Department of Health and Human Services announced an HHS Action Plan, a Surgeon General's Call to Action, a new public-private partnership to reduce maternal mortality and morbidity. HHS Secretary Alex Azar issued the following statement.

\*December 3- [CMS Announces New Model to Advance Regional Value-Based Care in Medicare](#).

Today, the Centers for Medicare & Medicaid Services announced a new and transformative voluntary payment model that builds on CMS' focus to deliver Medicare beneficiaries value through better care and improved quality. The Geographic Direct Contracting Model (the "Model") will test an approach to improving health outcomes and reducing the cost of care for Medicare beneficiaries in multiple regions and communities across the country.

\*December 3- [HHS Amends PREP Act Declaration, Including to Expand Access to COVID-19 Countermeasures Via Telehealth](#). Today, the U.S. Department of Health and Human Services (HHS) issued a fourth amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to critical countermeasures against COVID-19.

\*December 3- [HHS Finalizes Good Guidance Practices Rule and Issues Advisory Opinion Regarding Compliance with Notice-and-Comment Obligations](#). Today, the Department of Health and Human Services (HHS) finalized a Good Guidance Practices rule to help ensure that the public receives appropriate notice of new guidance documents and that HHS guidance documents do not impose obligations on regulated parties that are not already reflected in statutes or regulations. This final rule implements [Executive Order 13891](#) and is part of a broader regulatory reform initiative within HHS.

## Fact Sheets

\* November 20- [HHS Drug Pricing Fact Sheet](#). President Trump is delivering on his promise to cut down on foreign freeriding through the Most Favored Nation Model that will substantially lower drug prices without restricting access.

\*November 20- [Fact Sheet: Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients](#). Directed by President Trump's July 24, 2020 Executive Order on "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen," the Department of Health and Human Services Secretary Alex Azar and the HHS Office of Inspector General (OIG) have finalized a regulation that encourages lower list prices and reduced out-of-pocket spending on prescription drugs.

\*November 20- [Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule \(CMS-1720-F\)](#). On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a final rule to modernize and clarify the regulations that interpret the Medicare physician self-referral law (often called the "Stark Law"), which has not been significantly updated since it was enacted in 1989. The final rule supports the CMS "Patients over Paperwork" initiative by reducing the unnecessary regulatory burdens on physicians and other healthcare providers while reinforcing the Stark Law's goal of protecting patients from

unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest.

\*November 20- [FACT SHEET: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period](#). The Centers for Medicare & Medicaid Services (CMS) is announcing a new payment model, the Most Favored Nation (MFN) Model (or the "MFN Model"), and issuing a corresponding Interim Final Rule with Comment Period (IFC). The MFN Model will lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals (hereinafter called "drugs") than the lowest price that drug manufacturers receive in other similar countries.

\*November 20- [Organ Procurement Organization \(OPO\) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F](#). On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that updates the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) that OPOs must meet to receive Medicare and Medicaid payment. This final rule is an outcome of President Trump's [Executive Order on Advancing American Kidney Health](#) and applies to the procurement of all organs from deceased donors.

\*November 24- [CMS Issues Final Rule to Amend the U.S. Department of Health and Human Services' Risk Adjustment Data Validation Program](#). Today, the Centers for Medicare & Medicaid Services (CMS) issued a final rule to amend the methodology and other program parameters for the U.S. Department of Health and Human Services' risk adjustment data validation (HHS-RADV) program. HHS-RADV was created to strengthen the integrity of the HHS-operated risk adjustment program by validating the accuracy of data submitted by issuers that is used to calculate the amount of funds transferred among insurers based on the actuarial risks of the individuals they enroll.

\*November 25- [Federal Health Insurance Exchange Weekly Enrollment Snapshot: Week Three](#). In Week Three of the 2021 Open Enrollment period, 758,421 people selected plans using the HealthCare.gov platform. As in past years, enrollment weeks are measured Sunday through Saturday.

\*December 1- [Final Policies for the Medicare Diabetes Prevention Program \(MDPP\) Expanded Model for the Calendar Year 2021 Medicare Physician Fee Schedule](#). On December 1 2020, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2021 Physician Fee Schedule (PFS) final rule, which revises certain MDPP policies during the remainder of the COVID-19 Public Health Emergency (PHE) and any future applicable 1135 waiver event.

\*December 1- [Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021](#). On December 1, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that includes updates on policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, on or after January 1, 2021. The calendar year (CY) 2021 PFS final rule is one of several rules

that reflect a broader Administration-wide strategy to create a healthcare system that results in better accessibility, quality, affordability, empowerment, and innovation.

\*December 2- [CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule \(CMS-1736-FC\)](#). On December 2, 2020, the Centers for Medicare & Medicaid Services (CMS) finalized policies that are consistent with the directives in President Trump's Executive Order, entitled "Protecting and Improving Medicare for Our Nation's Seniors," that aim to increase choice, lower patients' out-of-pocket costs, empower patients, and protect taxpayer dollars.

\*December 3- [Geographic Direct Contracting Model \("Geo"\)](#). The Geographic Direct Contracting Model (also known as the "Model" or "Geo") is a new payment and care delivery model being tested by the Centers for Medicare & Medicaid Services (CMS) Innovation Center. The Model will test whether a geographic-based approach to value-based care can improve quality of care and reduce costs for Medicare beneficiaries across an entire geographic region.

\*December 3- [Federal Health Insurance Exchange Weekly Enrollment Snapshot: Week Four](#). In Week Four of the 2021 Open Enrollment period, 523,020 people selected plans using the HealthCare.gov platform. As in past years, enrollment weeks are measured Sunday through Saturday.

## Podcast

\*November 19- [Nursing Home Series for Front Line Clinicians and Staff](#). Today, the Centers for Medicare & Medicaid Services (CMS) is releasing the first episode in a series of short podcasts for frontline nursing home staff "*CMS Beyond the Policy*". Today's edition is titled "Nursing Home Series for Front Line Clinicians and Staff." Dr. Shari Ling, Deputy Chief Medical Office for The Centers for Medicare and Medicaid Services and geriatrician is joined by David Wright, Director of the Quality Safety & Oversight Group to discuss training and infection control practices in nursing homes to help combat the spread of coronavirus disease 2019 (COVID-19).

## Blogs

\*November 20- [3 ways to save on Medicare costs](#). Everyone likes to save money. We can help. You may be able to get help paying for your health and prescription drug costs. If you aren't sure if you're eligible, it's worth learning more about these 3 ways to save on Medicare costs.

\*November 25- [This Thanksgiving, get peace of mind with 2021 health insurance](#). This holiday season, gift yourself the peace of mind that comes with having health coverage. You have until **Tuesday, December 15, 2020** to enroll in or change health insurance for 2021.

\*December 1- [Time is running out: Update, compare & enroll by Dec 15](#). You have 2 weeks to enroll in Marketplace health insurance for 2021. If you enrolled for 2020, you have until **December 15** to change or update your plan for 2021. If you don't take action you may be automatically enrolled for 2021, but may miss out on new options.

\*December 1- [Support World AIDS Day – Get your HIV screening today](#). Did you know that nearly 40,000 people are diagnosed with HIV in the U.S. each year? Of the 1.2 million people currently living with HIV in the U.S., 1 in 7 don't even know they have it. Medicare covers [HIV screenings](#) for people with Medicare 15-65 years old who ask for the test, people younger than 15 or older than 65 who are at increased risk, and pregnant women.

\*December 1- [Act fast! Review your Medicare plan by December 7](#). Medicare Open Enrollment is almost over. If you're thinking about changing your Medicare plan, you have until **December 7** to take [these actions](#).

*CMS has developed a [Virtual Toolkit](#) to help you stay informed on CMS and HHS materials available on the COVID-19. Please share these materials, bookmark the page, and check back often for the most up-to-date information. For more information, please email [partnership@cms.hhs.gov](mailto:partnership@cms.hhs.gov)*