

**Monday COVID-19 Snapshot** – Below, you will find our weekly snapshot. The bottom line is that cases, deaths, and hospitalizations continue to climb, but not as steeply as last week (ex: new cases up 17% this week compared to 49% last week). Mitigation strategies and conservative Thanksgiving plans can't be stressed enough.

**This Monday's Bucket of HHS Actions is Full to Overflowing:** From Friday of last week to today, HHS has issued a number important announcements and policies. Here is the cheat-sheet list, with greater detail in the text of the email:

**COVID-Items:**

1. FDA Announces [Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate](#) – December 10<sup>th</sup>!
2. HHS Provides [\\$25 Million to Siemens Healthineers](#) to Develop and Produce COVID-19 Antigen Diagnostic Tests
3. 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
4. HHS [Allocates Regeneron Therapeutic](#) to Treat Patients with Mild to Moderate COVID-19
5. FDA Authorizes [Monoclonal Antibodies for Treatment of COVID-19](#)
6. Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program [Vaccine Toolkit](#)
7. Three New MMWRs

**Non-COVID Items:**

1. HHS Makes [Stark Law and Anti-Kickback Statute Reforms](#) to Support Coordinated, Value-Based Care
2. Drug Pricing:HHS
  - Prescription Drug Payment Model to Put American Patients First – [Most Favored Nation Model](#)
  - HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter – [Lowering Prices for Patients by Eliminating Kickbacks to Middlemen](#)
  - [Unapproved Drugs Initiative](#)

HHS [Drug Pricing Fact Sheet](#) which conveys all of our work in this area.

3. CMS Policy that will [Increase the Number of Available Lifesavings Organs](#) by Holding Organ Procurement Organizations Accountable through Transparency and Competition
4. FDA Expands [Approval of Influenza Treatment](#) to Post-Exposure Prevention

Don't stop scrolling. More information below!

**Public Health Thank You Day!** Thank you all for your hard work battling this pandemic each day. We appreciate you!



Secretary Alex Azar  
@SecAzar

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This #PublicHealthThankYouDay, we thank all the public health professionals, including those working across @HHSGov, for their incredible, tireless work to to combat COVID-19 throughout this year and protect the health of Americans every day. #PHTYD



### Monday COVID-19 Data Snapshot

Takeaway: The surge continues its climb. Cases have now surpassed the summer peak.

#### New Cases (based on 7-day rolling average)

- **17% increase in new cases** (7-day average), as of November 14; (was 49% last week, 24% the week before that)
- Trends in states/cities (64 jurisdictions)
- **4%** of jurisdictions are in a **downward trajectory** (was 0% last week; 5% week before that)
- **2%** are in **plateau** (was 2% last week; 9% the week before)
- **94%** are in **upward trajectory** (was 98% last week; 86% the week before that)

#### Deaths

- **24%** increase in new deaths from previous week (was 26% increase in deaths last week)

#### National Positivity Rate

- **10.0%** positive test rate (was 10.3% last week, 7.6% the week before that)

#### Hospitalizations from COVID

- **22.6%** increase (7-day average) of inpatients have COVID (was 40% last week, 30.9% the week before)

## Testing

- In the past 7 days, **88%** of commercial lab tests were completed within 3 days and **98%** were completed within 5 days, as of November 23

## **Vaccines & Operation Warp Speed**

**FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate:** FDA has scheduled [a meeting of its Vaccines and Related Biological Products Advisory Committee \(VRBPAC\) on Dec. 10](#) to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.

**Vaccine Development 101:** The FDA has updated a webpage, [Vaccine Development – 101](#), to provide an overview of the vaccine development process.

**Emergency Use Authorizations for Vaccines Explained:** In a new webpage, [Emergency Use Authorization for Vaccines Explained](#), the FDA offers answers to questions about EUAs, in general, and more specifically, about EUA requests for a vaccine intended to prevent COVID-19.

**Vaccines:** Vaccine information for you and your family from the CDC.

- [10 Things Healthcare Professionals Need to Know about U.S. COVID-19 Vaccination Plans](#)
- [8 Things to Know about U.S. COVID-19 Vaccination Plans](#)
- [About COVID-19 Vaccines](#)
- [How CDC Is Making COVID-19 Vaccine Recommendations](#)
- [Ensuring the Safety of COVID-19 Vaccines](#)
- [Ensuring COVID-19 Vaccines Work](#)
- [Frequently Asked Questions about COVID-19 Vaccination](#)

## **Operation Warp Speed Weekly Update:**

*Vaccine Development:*

- Pfizer [submitted a request](#) Friday for Emergency Use Authorization from the Food and Drug Administration. This came days after the company announced the [conclusion of its Phase 3 study](#) and reported its vaccine candidate met all primary efficacy end points, noting its efficacy was consistent across age, gender, race and ethnicity, with more than 94% observed in adults over 65.
- Moderna [announced](#) intent to submit for an Emergency Use Authorization in the coming weeks, following its vaccine candidate showing 94.5% efficacy in its first interim analysis. Preliminary analysis from a Phase 3 study with more than 30,000 participants suggests a broadly consistent safety and efficacy profile across all evaluated subgroups.
- The VA issued a [PSA](#) and announced its nationwide effort to recruit volunteers to test vaccines and treatments for COVID-19 at more than 50 VA facilities. VA's volunteer list is open to veterans and non-veterans, 18 years old or older. Participation in any research study is strictly voluntary. Vaccines being studied at VA sites include candidates developed by Moderna, AstraZeneca, Pfizer and Janssen. VA's trials for COVID-19 treatments include remdesivir, monoclonal antibodies, Tocilizumab and others.

*Therapeutics Development:* As of Thursday, the government has allocated more than 100,000 treatment courses (vials) of bamlanivimab with about 40,000 courses currently being prepared for distribution. The first allocation began Nov. 10. A jurisdiction-by-jurisdiction dashboard of allocations [can be found here](#), and is updated each Wednesday at 11 a.m. ET.

*Distribution:* With distribution of safe and effective COVID-19 vaccines approaching, Operation Warp Speed is refining plans to deliver vaccine doses across the country. Operation Warp Speed's Director of Supply, Production and Distribution Paul Ostrowski [discusses the strategy](#) with [video clips](#) available for use by the media.

## **Testing**

**HHS Provides \$25 Million to Siemens Healthineers to Develop and Produce COVID-19 Antigen Diagnostic Tests:** HHS and 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. The laboratory-based antigen tests under development will use a nose swab sample – or possibly a saliva sample – to detect viral antigens to determine whether a person is infected with the virus.

**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:** HHS and 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). Awarded November 19, the new contract will allow Puritan Medical to expedite upgrades at its Maine facility and increase production capability of Cue's nasal swabs to 3 million per month by March 2021.

**Guidance for SARS-CoV-2 Point-of-Care Testing:** This CDC Web resource provides guidance on the regulatory requirements for [SARS-CoV-2 POC testing](#), using POC tests safely, and information on reporting POC test results.

**Testing and International Air Travel:** [Testing before and after travel](#) can reduce the risk of spreading COVID-19. Testing does not eliminate all risk, but when paired with a period of staying at home and everyday precautions like [wearing masks](#) and [social distancing](#), it can make travel safer by reducing spread on planes, in airports, and at destinations.

**Testing Updates:** As of Nov 18, 289 tests are authorized by the FDA under EUAs; these include 224 molecular tests, 58 antibody tests, and 7 antigen tests.

## **Treatment**

**HHS Allocates Regeneron Therapeutic to Treat Patients with Mild to Moderate COVID-19:** HHS 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. A data-driven system will ensure continued fair and equitable distribution of these new products. Beginning immediately, weekly allocations to state and territorial health departments will be proportionally based on confirmed COVID-

19 cases in each state and territory over the previous seven days, based on data hospitals and state health departments enter into the HHS Protect data collection platform.

**FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19:** FDA issued an [emergency use authorization \(EUA\)](#) for [casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19](#) in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19. This includes those who are 65 years of age or older or who have certain chronic medical conditions. Casirivimab and imdevimab must be administered together by intravenous (IV) infusion. The EUA was issued to Regeneron Pharmaceuticals Inc.

**Warning Letters for Fraudulent COVID-19 Products:**

- As part of the FDA's effort to protect consumers, the agency issued a [warning letter](#) jointly with the Federal Trade Commission (FTC) to Pro Breath MD, LLC dba Dentist Select and OraCare for selling unapproved products with fraudulent COVID-19 claims. The company sells "OraCare Health Rinse" and "OraCare Operatory Pre-Rinsing Set" products with misleading claims that the products can mitigate, prevent, treat, diagnose or cure COVID-19 in people. FDA requested that Dentist Select and OraCare immediately stop selling these unapproved and unauthorized products. Consumers concerned about COVID-19 should consult with their health care provider.
- The FDA and the FTC also issued a joint [warning letter](#) to Vibrant Health Care, Inc., for marketing an unapproved umbilical cord derived cellular product to mitigate, prevent, treat, diagnose or cure COVID-19.

**COVID-19 Response At-A-Glance:** The agency also issued an updated FDA COVID-19 Response [At-A-Glance Summary](#) that provides a quick look at facts, figures, and highlights on the agency's response efforts.

**CMS & COVID-19**

**Medicare Accelerated and Advance Payments Program COVID-19 Public Health Emergency Payment Data:** CMS expanded its [Accelerated and Advance Payment \(AAP\) Program](#) to increase cash flow to Medicare providers and suppliers impacted by the COVID-19 Public Health Emergency. These payments are funded from the Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B) trust funds, which are the same funds used to pay Medicare claims each day. Accelerated and advance payments are loans that providers must pay back.

**Podcast on Nursing Home Series for Front Line Clinicians and Staff:** 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 CMS 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 COVID-19.

**Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program:** CMS released an update to the [Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program vaccine toolkit](#) that was originally released on October 28. This update includes information regarding the Public Readiness and Emergency Preparedness (PREP) Act authorizations related to COVID-19 vaccinations,

implications on Medicaid and Children’s Health Insurance Program coverage and reimbursement, and authorization for pharmacies distributing and administering certain covered countermeasures (including COVID-19 vaccinations).

## **PPE**

**Strategies for Optimizing the Supply of N95 Respirators:** CDC updated guidance on how to [optimize N95 respirators](#) during COVID-19.

**Community Use of Cloth Masks to Control the Spread of SARS-CoV-2:** CDC released a [scientific brief](#) on the community use of cloth masks to control the spread of COVID-19.

## **Information for Specific Populations**

**Preparing for COVID-19 in Nursing Homes:** CDC updated guidance on how to prepare and respond to COVID-19 in [nursing home and long-term care facilities](#). CDC also released an [infection prevention and control assessment tool](#) for nursing homes preparing for COVID-19.

**State Public Health Veterinarians and Animal Health Officials:** CDC updated information for [state vets and animal health officials](#) on protecting themselves and animals from COVID-19.

**Correctional and Detention Facilities:** CDC released guidance for [Correctional and Detention Facilities](#) to ensure continuation of essential public services and protection of the health and safety of incarcerated and detained persons, staff, and visitors.

**Operational Considerations for Non-US Settings:** CDC has developed [operational considerations to help contain and prevent COVID-19](#) in healthcare facilities in non-US settings. These documents were created for healthcare facilities with limited resources (such as staff shortages and supply shortages), particularly in low- and middle-income countries.

**People with Moderate to Severe Asthma:** People with [moderate to severe asthma](#) may be at higher risk of getting very sick from COVID-19. COVID-19 can affect your nose, throat, lungs (respiratory tract); cause an asthma attack; and possibly lead to pneumonia and acute respiratory disease.

**Providing Spiritual and Psychosocial Support to People with COVID-19 at Home:** During the COVID-19 pandemic, the safest means of [providing spiritual and psychological support](#) is by phone, video, or through private social media chat platforms. Spiritual leaders may pray, share theological and scriptural reflections, and share messages of hope.

**Postmortem Guidance:** CDC's guidance on [collection and submission of postmortem specimens](#) from deceased persons under investigation for COVID-19.

**Investigating a COVID-19 Case:** CDC provides a step-by-step guide for conducting a [COVID-19 case investigation](#), including operational questions that a jurisdiction should consider while planning their activities for [contact tracing](#). CDC also updated guidance to health departments regarding prioritization recommendations in [high burden jurisdictions](#) for contact tracing and case investigation and information on prioritizing [COVID-19 contact tracing mathematical modeling methods and findings](#) regarding timeframes for effectiveness.



**Public Health Interpretation and Use of Wastewater Surveillance Data:** CDC updated guidance on the implementation of wastewater-based disease surveillance. CDC also updated information on wastewater surveillance [data reporting and analytics](#), [testing methods](#), [developing a sampling strategy](#), and [targeted wastewater surveillance](#) at facilities, institutions, and workplaces.

**Travel FAQs:** CDC updated a list of [travel FAQs](#) regarding protecting oneself and limiting the spread of COVID-19.



**GLOBAL HEALTH ALERT: COVID-19**

You may have been exposed to COVID-19 while traveling.  
Watch your health for symptoms. Even with no symptoms, you can spread the virus to others.

**PROTECT OTHERS FROM GETTING SICK:**

-   
Keep 6 ft/2 m apart from others.
-   
Wear a mask.
-   
Wash your hands often.

**Close contact activities put you at risk for exposure to COVID-19.**  
If you think you may have been exposed while you traveled, take extra care for 14 days after travel:

- Stay home as much as possible.
- Avoid being around people, especially those at higher risk for severe illness from COVID-19.
- Consider getting tested for COVID-19.

For more information: [www.cdc.gov/COVIDtravel](http://www.cdc.gov/COVIDtravel)

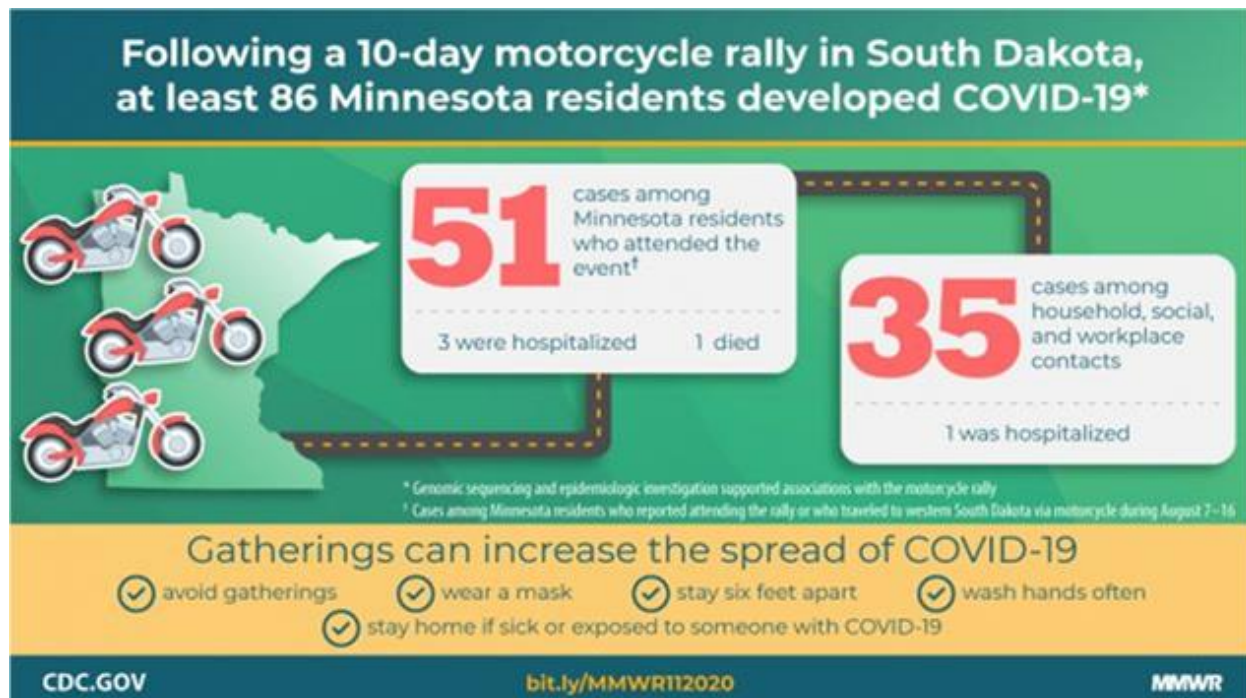


## Research Updates

**NIH Expands Research to Improve COVID-19 Testing Among Underserved and Vulnerable Populations:** NIH has [awarded nearly \\$45 million to expand the research network](#) of the [Rapid Acceleration of Diagnostics Underserved Populations \(RADx-UP\)](#) program, adding 20 institutions and seven states and territories. RADx-UP aims to enable and enhance COVID-19 testing of populations disproportionately affected by the disease, including African Americans, American Indians/Alaskan Natives, Latinos/Latinas, Native Hawaiians, older adults, pregnant women and those who are homeless or incarcerated. This second round of awards brings the total investment in the RADx-UP program to more than \$283 million at 55 institutions across 33 states and territories and the Cherokee Nation.

**COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State:** CDC released an MMWR on [COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State in](#)

[Minnesota](#) between August and September 2020. Following a 10-day motorcycle rally in South Dakota attended by approximately 460,000 persons, 51 confirmed primary event-associated cases, 21 secondary cases, and five tertiary cases were identified in Minnesota residents. An additional nine likely rally-associated secondary or tertiary cases occurred. Four patients were hospitalized, and one died. Genomic sequencing supported the associations with the motorcycle rally. The impact of gatherings as a source of virus transmission underscores the importance of reducing the number of attendees at gatherings, using face masks, and encouraging physical distancing to prevent ongoing transmission of SARS-CoV-2. Furthermore, these findings demonstrate the rationale for consistent mitigation measures across states.



**The Advisory Committee on Immunization Practices’ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine:** CDC released an MMWR on [The Advisory Committee on Immunization Practices’ \(ACIP\) Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine](#). During the period when the U.S. supply of COVID-19 vaccines is limited, the ACIP will make vaccine allocation recommendations. In addition to scientific data and implementation feasibility, four ethical principles will assist ACIP in formulating recommendations for the initial allocation of COVID-19 vaccine:

- 1) maximizing benefits and minimizing harms;
- 2) promoting justice;
- 3) mitigating health inequities; and
- 4) promoting transparency.

Ethical principles will aid ACIP in making vaccine allocation recommendations and state, tribal, local, and territorial public health authorities in developing vaccine implementation strategies based on ACIP’s recommendations.

**Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate:** CDC released an MMWR on [Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate in Kansas](#) between June 1 and August 23, 2020. The governor of Kansas issued an



executive order requiring wearing masks in public spaces, effective July 3, 2020, which was subject to county authority to opt out. After July 3, COVID-19 incidence decreased in 24 counties with mask mandates but continued to increase in 81 counties without mask mandates. Countywide mask mandates appear to have contributed to the mitigation of COVID-19 transmission in mandated counties.



## **Funding**

### **Weekly Update on the Provider Relief Fund Program:**

*Recent Updates and Announcements:* This week, HHS continued the validation and processing of Phase 3 General Distribution applications. HHS remains committed to distributing payments as quickly as possible to providers confronting this pandemic.

*Latest Payments:* As of the week of November 16, HHS has made the following total payments under the General and Targeted Distributions of the PRF program:

- \$106,540,472,343 in payments to 550,612 provider TINs.
- Of these payments, 386,308 providers (unique TINs) have attested to the Terms and Conditions for \$97,681,173,723 in payments. A listing of PRF distributions to providers that have accepted the Terms and Conditions can be found at [here](#).

As of November 18, HHS has made payments to 26,096 providers through the HRSA COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured program including:

- Testing claims: \$847,851,459

- Treatment claims: \$1,217,797,665

A listing of health care entities that have agreed to the Terms and Conditions and received claims reimbursement can be found [here](#).

*Recently Added Frequently Asked Questions (FAQs):*

The Provider Relief Fund issued or updated the following FAQs during the week of November 16. The below and the compendium of all FAQs can be found [here](#).

### **Non- COVID Items**

**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. Read more on the [HHS Drug Pricing Fact Sheet](#).

**HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care:** 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. The rules provide greater flexibility for healthcare providers to participate in value-based arrangements and to provide coordinated care for patients. The final rules also ease unnecessary compliance burden for healthcare providers and other stakeholders across the industry, while maintaining strong safeguards to protect patients and programs from fraud and abuse. The HHS OIG issued the final rule “Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements,” and CMS issued the final rule “Modernizing and Clarifying the Physician Self-Referral Regulations.”

- [Read OIG’s final rule](#) and [fact sheet](#)
- [Read CMS’s final rule](#) and [fact sheet](#)

**HHS Finalizes Rule to Bring Drug Discounts Directly to Seniors at the Pharmacy Counter:** 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. Savings to patients may be nearly 30 percent: In 2019, Part D rebates totaled \$39.8 billion, representing an average discount of nearly 30 percent for brand drugs.

- The rebate rule tackles a number of the issues raised in the [American Patients First drug pricing blueprint](#), released by President Trump in May 2018 and developed by HHS under Secretary Azar’s leadership, such as lowering out of pocket costs, improving negotiation, and stimulating competition through generic and biosimilar adoption
- Read [Secretary Azar’s Confirmation In Response to Executive Order](#) on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen
- [Read a fact sheet on the rule](#)
- [Read the rule](#)

### **Trump Administration Announces Prescription Drug Payment Model to Put American Patients First:**

HHS Secretary Alex Azar announced a drug payment model through the Center for Medicare and Medicaid Innovation at CMS 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. Starting in January, the model, known as the Most Favored Nation (MFN) Model, will test an innovative way for Medicare to pay no more for high cost, physician-administered Medicare Part B drugs than the lowest price charged in other similar countries. Following the President's recent Executive Orders to lower drug prices and improve access to life-saving medications, the MFN Model will protect current beneficiary access to Medicare Part B drugs, make them more affordable, and address the disparity of drug costs between the U.S. and other countries.

- The rule tackles a number of issues identified in the [American Patients First drug pricing blueprint](#), released by President Trump in May 2018 and developed by HHS under Secretary Azar's leadership, including high out-of-pocket costs, foreign freeriding, and the need for more biosimilar competition.
- Read the [Fact Sheet on the Most Favored Nation Model](#) by CMS
- The [Most Favored Nation Model Interim Final Rule](#) with Comment Period (CMS-5528-IFC) can be downloaded. Public comments on the rule can be submitted through [www.regulations.gov](http://www.regulations.gov) and must be received no later than 60 days after publication of the IFC in the Federal Register.
- The new ASPE report on rises in [Medicare Part B drug spending and utilization](#)
- The ASPE report on [Medicare Part B drug spending and international price comparisons](#)

**CMS Finalizes Policy that will Increase the Number of Available Lifesavings Organs by Holding Organ Procurement Organizations Accountable through Transparency and Competition:** 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.

- Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: [Revisions to Outcome Measures for OPOs CMS-3380-F](#)
- Read Secretary Azar's [remarks](#) on Trump Administration actions in September to support living donations and promote transplants
- Read Secretary Azar's [Statement](#) on Final Rule to Increase Access to Lifesaving Organs
- Information on the progress on President Trump's [Advancing American Kidney Health initiative](#)
- [Fact sheet](#) on the final rule
- To view the [final rule](#)

**CMS Announces Historic Changes to Physician Self-Referral Regulations:** 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. The old federal regulations that interpret and implement this law were designed for a health care system that reimburses providers on a fee-for-service basis, where the financial incentives are to deliver more services. However, the 21st century American health care system is increasingly moving toward financial

arrangements that reward providers who are successful at keeping patients healthy and out of the hospital, where payment is tied to value rather than volume.

- The [Final Rule](#)
- Modernizing and Clarifying the [Physician Self-Referral Regulations](#) Final Rule (CMS-1720-F)

**Statement from HHS Chief of Staff Brian Harrison on Unapproved Drugs Initiative:** HHS through a Notice published in the Federal [Register announced the withdrawal of guidance documents](#) issued as part of the Unapproved Drugs Initiative. HHS released [Frequently Asked Questions](#) regarding HHS's announcement on the unapproved drug initiative.

**FDA Expands Approval of Influenza Treatment to Post-Exposure Prevention:** FDA expanded the [approved indication for Xofluza \(baloxavir marboxil\)](#) to include post-exposure prevention of influenza (flu) for patients 12 years of age and older after contact with an individual who has the flu.

- “This expanded indication for Xofluza will provide an important option to help prevent influenza just in time for a flu season that is anticipated to be unlike any other because it will coincide with the coronavirus pandemic,” said Debra Birnkrant, M.D., director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research.