

# HHS COVID-19 March 30, 2020 Update

## Private Sector Partnerships and Actions

One of the most inspiring reactions to this crisis is how the private sector has stepped to the challenge with creative innovations to solve problems and provide needed supplies. Here are some recent examples.

Over 1 Million Diagnostic Tests Conducted: With American innovation and a strong commitment from FDA to move quickly, we now have a range of options for testing, including the new toaster size machine that produces test results in as little as five minutes. In fact, FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. Nineteen emergency use authorizations have been issued for diagnostic tests. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**President Meets with Business CEOs:** Today, the President and Vice-President hosted a roundtable discussion with CEOs from manufacturers and technology companies that have partnered with the Administration to provide much-needed aid to our medical personnel and the general public. The companies attending have agreed to donate or manufacture additional gowns, face masks, gloves, Tyvek suits and hand sanitizer.

Insurance Companies Agree to Cover Patient Costs: Cigna and Humana will be covering patient costs related to treatment of COVID-19 for their members. This significant step is designed to help ease the burden on seniors and others who are facing challenging circumstances. Humana notes that member copays, deductibles and coinsurance cost sharing will be waived for covered services for COVID-19-related tests and treatments, regardless of where they take place. This could include telehealth, primary care physician visits, specialty physician visits, facility visits, labs, home health and ambulance services. Humana also intend to cover the cost of FDA-approved vaccines and medications when they become available for members for whom we provide prescription drug coverage.

**Slow the Spread Campaign Extended**: Yesterday the President extended the nation's **Slow the Spread** campaign until April 30. The American people play a key role in the campaign to help slow the virus' spread and helping to keep our most high-risk populations safe.

CMS Expanding Flexibilities to Respond to COVID-19: CMS announced an array of rule changes that will help equip the American healthcare system with maximum flexibility to

- respond to the COVID-19 pandemic. CMS is moving quickly to temporarily lift regulatory barriers during the emergency to:
- *Promote telehealth in Medicare:* Following action to expand reimbursement for telehealth in Medicare, CMS is now allowing providers bill for phone calls with their patients and getting rid of other requirements in Medicare for face to face visits.
- *Increase & Support Healthcare Workforce*: Allow hospitals and other healthcare facilities to temporarily beef up their workforces;
- *Expand In-Place Testing*: Tests to be performed on people at home and in other community-based settings, so that hospitals and other vital facilities can focus on COVID-19 patients;
- *Hospitals Without Walls*: Hospitals to shift some patients to ambulatory surgery centers and other community facilities to prepare for a possible surge of COVID-19 patients;
- Patients Over Paperwork: Providing relief from paperwork, reporting and audit requirements, so providers, health care facilities, MA and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries impacted by COVID-19.
  Additional, CMS has now approved 38 state Medicaid Section 1135 waivers, offering states additional tools and flexibilities to address the crisis.

#### An Update on PPE Supplies:

**Additional Supplies Arriving:** FEMA coordinated an air bridge for flights from Asia beginning on Sunday, March 29, with the first delivery of 80 tons of much needed PPE supplies including 130,000 N95 respirators, 1.8 million face masks and gowns, 10.3 million gloves and thousands of thermometers for New York, New Jersey and Connecticut. Additional flights are contracted to go to Illinois today and to Ohio tomorrow. FEMA has scheduled additional flights and is adding more daily.

**4-Pronged Strategy for Supply Chain of PPE:** FEMA released their 4-part strategy to address the supply chain for securing needed supplies and equipment. The strategy focuses on preservation, acceleration, expansion and allocation of resources and supplies. To make effective decisions about resources, a National Resource Prioritization Cell was established to unify government and private industry prioritization recommendations. These recommendations will further inform federal, state and private sector operations.



Looking for More Information about the Strategic National Stockpile: ASPR, in coordination with the Strategic National Stockpile (SNS) and the Unified Command's Supply Chain Task Force, developed a webpage devoted to the SNS to assist stakeholders with requests for SNS supplies. Information on the page includes general history and mission of the SNS, how jurisdictions (to include territories) can request supplies, a frequently asked questions section, and B-roll footage.

**Mask Sterilization System Approved:** The FDA approved a decontamination system for N95 respirator masks in an effort to be able to reuse the masks and extend the supply of the needed respirators.

**Executive Order on the Defense Production Act:** The President signed an Executive Order that delegates a number of DPA authorities joining to HHS and DHS. The President directed HHS Secretary Azar to use DPA authorities to require General Motors to prioritize contracts for ventilators.

### An Update on Diagnostic Testing, Treatment and Vaccine Development

**Donations of Drugs for Potential Use to Treat COVID-19:** Last night, HHS announced it had secured large donations of medicine for the Strategic National Stockpile of potential therapeutics for COVID-19. The Department accepted 30 million doses of hydroxychloroquine sulfate donated by Sandoz and 1 million doses of chloroquine phosphate donated by Bayer. The FDA issued an Emergency Use Authorization (EUA) to BARDA to allow the products, typically used as anti-malarial drugs, to be distributed and prescribed by doctors to hospitalized teen and adult patients with COVID-19, as appropriate, when a clinical trial is not available or feasible.

Accelerating Clinical Trials for COVID-19: HHS took steps today to speed the development and manufacturing of vaccines to prevent COVID-19, working with New Jersey-based Janssen Research & Development, part of Johnson & Johnson, and Moderna of Cambridge, Massachusetts. In parallel to initial clinical evaluation, BARDA also will work with Janssen to accelerate advanced clinical trials, regulatory support, and large-scale manufacturing to produce up to 300 million doses of vaccine in the United States each year. At the same time, BARDA will collaborate with Moderna to prepare now for Phase 2 and 3 clinical trials of a vaccine being developed by Moderna and the NIH.

Request to Hospitals to Submit Data to CMS: CMS sent a letter to the nation's hospitals, on behalf of Vice President Pence, requesting they report data in connection with their efforts to fight the 2019 Novel Coronavirus. Specifically, the Trump Administration is requesting that hospitals report COVID-19 testing data to HHS, in addition to daily reporting regarding bed capacity and supplies to the CDC and CDC National Healthcare Safety Network (NHSN) COVID-19 Patient Impact and Hospital Capacity Module. The data will help the Trump Administration obtain this critical information to help identify supply and bed capacity needs, as well as enhance COVID-19 surveillance efforts.

## Information on Handling the Crisis:

Updated Guidance Defining Essential Workers: The Department of Homeland Security updated their guidance on essential workers. This list (which is advisory-only) is intended to help State, local, tribal and territorial officials as they work to protect their communities, while ensuring continuity of functions critical to public health and safety, as well as economic and national security. The guidance and accompanying list identify workers who conduct a range of operations and services that are typically essential to continued critical infrastructure viability, including staffing operations centers, maintaining and repairing critical infrastructure, operating call centers, working construction, and performing operational functions, among others. It also includes workers who support crucial supply chains and enable functions for critical infrastructure. The industries they support represent, but are not limited to, medical and healthcare, telecommunications, information technology systems, defense, food and agriculture, transportation and logistics, energy, water and wastewater, law enforcement, and public works.

Ensuring Protection Against Discrimination: The Office of Civil Rights issued a Bulletin to ensure that entities covered by civil rights authorities keep in mind their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs, including in the provision of health care services during COVID-19. OCR is particularly focused on ensuring that covered entities do not unlawfully discriminate against people with disabilities when making decisions about their treatment during the COVID-19 health care emergency.

**Advice for Caring for Children During the Pandemic:** CDC released information on Caring for Children during the pandemic which outlines best practices to protect the family from getting sick, how to continue to educate children, and tips on keeping everyone healthy as well as an FAQ for families with children on school dismissals and availability of food.

**Resources for Different Types of Facilities:** CDC released updated information and guidance for isolation and alternative care sites, State, Local, Territorial and Tribal Departments and for Correction and Detention Facilities which also includes an FAQ for administrators, staff and people who are incarcerated.

Ensuring Safe Food and Medical Products: The FDA released a statement from Commissioner Hahn that outlines all of the steps FDA has taken with respect to medical devices, human drugs and biologics and animal drugs, blood supply and human and animal food. The FDA issued a Consumer Update, Food Safety and Availability During the Coronavirus Pandemic, to describe the many ways the agency is working to help ensure the foods you, your family, and your pets eat are safe and available.