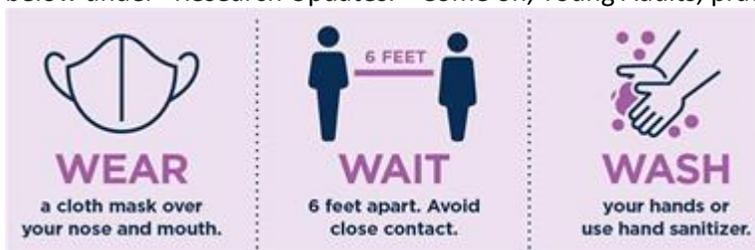


Many of you are watching for information on how the government will prioritize allocation of an eventual FDA-approved COVID vaccine. Well, another step in the process is coming on Friday, when the National Academy of Science will release their final recommendations. More below.

**Framework for Equitable Allocation of COVID-19 Vaccine:** On Friday, October 2, the National Academies will release the final [Framework for Equitable Allocation of COVID-19 Vaccine](#) report during a [free webinar](#) hosted by study committee co-chairs William Foege and Helene Gayle. Sponsored by NIH and CDC, the report will help guide equitable allocation of a limited initial supply of COVID-19 vaccine. The final report follows a [discussion draft](#) that was released on September 1, 2020, to obtain input from the public. In addition to an updated framework for equitable allocation, the report includes recommendations for ensuring equity in distribution, administration, and access to the vaccine; for effective community engagement, risk communication, and strategies to promote vaccine acceptance; and for equitable global allocation.

**How Long Does a Recovered COVID-19 Patient Remain Immune to Reinfection?** We don't know yet, but [NIH Director Francis Collins' new blog](#) looks at data on how long people infected with OTHER less life-threatening coronaviruses stay immune after they recover. A new [study](#) in *Nature Medicine* indicates that "immunity to other coronaviruses tends to be short-lived, with reinfections happening quite often about 12 months later and, in some cases, even sooner." Dr. Collins notes some caveats to interpreting this study or directly extrapolating -- but ultimately concludes that, "the evidence suggests it will be prudent to proceed carefully and with caution when it comes to long-term immunity, whether achieved through naturally acquired infections or vaccination."

**In What Demographic is COVID-19 Growing?** A study looks at cases from August 2 to September 5, 2020 and finds that [cases among persons aged 18–22 years increased 55% nationally](#). Get more info below under "Research Updates." Come on, Young Adults, practice the 3 "Ws"!



**Need a Stat on COVID-19 Quick? Bookmark These Links:**

- **CDC COVID Data Tracker:** This site -- the [COVID-19 data tracker](#) -- will give you the latest data on COVID, including numbers on cases and deaths by state using maps, charts, and data.
- **COVIDView Weekly Summary:** Looking for info on trends in COVID? The CDC [COVIDView Weekly Summary](#) gives each week's surveillance summary, including key updates for the week, positivity rates, emergency and outpatient trends, as well as hospitalization and mortality data.

**Global Health Security Agenda Annual Report Released:** The White House has released the annual report, "[Strengthening Health Security Across the Globe: Progress and Impact of United States Government Investments in the Global Health Security Agenda](#)," which highlights contributions the United States has made as the global health leader to improve the capacity of our international partners to prevent, detect, and respond to infectious disease outbreaks. While this report covers progress

during the period before the COVID-19 pandemic, global health security is undeniably more important now than ever. The pandemic has demonstrated that an infectious disease threat anywhere can be an infectious disease threat everywhere.



Secretary Alex Azar   
@SecAzar

The GHSA Annual Report highlights the committed leadership of the  and the progress and impact of our investments in the [@GHSAGenda](#) to protect against infectious disease threats and their effects on global health, security, and the economy. Read here: [state.gov/wpcontent/uplo...](#)

3:05 PM · Sep 29, 2020 · Twitter Web App

### Vaccine Updates

**NIAID Stops Enrollment of Severely Ill COVID-19 Participants in Clinical Trial of Investigational Treatments:** [The Adaptive COVID-19 Treatment Trial 3 \(ACTT-3\)](#), sponsored by the NIAID, part of the NIH, will [no longer enroll hospitalized participants with severe COVID-19 requiring high-flow oxygen](#), and will not begin to enroll patients requiring non-invasive or invasive mechanical ventilation. This action is being taken after an interim review of safety data by the study's Data and Safety Monitoring Board (DSMB) found an imbalance of serious adverse events among patients on high-flow oxygen/non-invasive mechanical ventilation who received interferon beta-1a versus those who did not receive interferon beta-1a. The DSMB noted no safety concerns among study participants with less severe COVID-19. Therefore, the study will continue to enroll hospitalized patients on low-flow oxygen and those not requiring supplemental oxygen. The DSMB will continue monitoring the trial to ensure participant well-being and safety, as well as study integrity.

### Funding

**AHRQ Establishes National Nursing Home COVID Action Network:** The Agency for Healthcare Research and Quality (AHRQ) is partnering with the University of New Mexico's ECHO Institute in Albuquerque and the Institute for Healthcare Improvement (IHI) in Boston to establish a [National Nursing Home COVID Action Network](#). The network will provide free training and mentorship to nursing homes across the country to increase the implementation of evidence-based infection prevention and safety practices to protect residents and staff. The new network is being created under an AHRQ contract worth up to \$237 million that is part of the nearly \$5 billion [Provider Relief Fund](#) authorized earlier this year under the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

**HHS Provides Weekly Update on the Provider Relief Fund Program:** The Provider Relief Fund program supports American families, workers, and the heroic healthcare providers in the battle against the COVID-19 outbreak. HHS is distributing \$175 billion to hospitals and healthcare providers on the front lines of the coronavirus response. To learn more about the Provider Relief Program, visit: [www.hhs.gov/providerrelief](#).

## Recent Updates and Announcements –

- ICYMI - HHS released reporting requirements for Provider Relief Fund (PRF) recipients on Saturday, September 19. The requirements can be found [here](#). A quick summary of the reporting requirements can be found [here](#).
- ICYMI - HHS released the Skilled Nursing Facilities and Nursing Home Incentive Program Methodology on September 16. This methodology describes the criteria nursing homes must meet in order to qualify for a performance-based payment from the PRF. The methodology can be found [here](#).

## Latest Payments –

As of September 23, 2020, HHS has made the following payments under the General and Targeted Distributions:

- \$104,503,230,117 in payments to 525,360 provider TINs.
- Of these payments, 343,593 providers (unique TINs) have attested to the Terms and Conditions for \$87,539,213,030 in payments.
- A listing of PRF distributions to providers that have accepted the Terms and Conditions can be found at [here](#).

As of September 23, 2020, HHS has made COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured payments to 21,765 providers including:

- Testing claims: \$445,316,364
- Treatment claims: \$824,779,522

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 September 21, specifically on nursing home infection control distribution. The FAQ compendium can be found [here](#).

## Testing and Treatment

**CMS Updates COVID-19 Testing Methodology for Nursing Homes:** Today, CMS announced an [update to the methodology the agency employs to determine the rate of COVID-19 positivity in counties](#) across the country. Counties with 20 or fewer tests over 14 days will now move to “green” in the color-coded system of assessing COVID-19 community prevalence. Counties with both fewer than 500 tests and fewer than 2,000 tests per 100,000 residents, and greater than 10 percent positivity over 14 days – which would have been “red” under the previous methodology – will move to “yellow.” This information is critical to nursing homes, which are required to test their staff for COVID-19 at a frequency based on the positivity rate of their respective counties.

**Increasing Domestic Production of APIs:** Yesterday, DoD, in coordination with HHS, [signed a \\$20 million contract award with On Demand Pharmaceuticals](#) (ODP) to develop a domestic production capability for critical active pharmaceutical ingredients (APIs).

**A Closer Look at the FDA’s Center for Devices and Radiological Health’s Unprecedented Efforts in the COVID-19 Response:** The FDA Center that approves vaccines (Biologics Evaluation and Research) gets all the love, but there is another FDA Center that deserves some sunlight: the FDA’s Center for Devices and Radiological Health’s (CDRH). Their response to the pandemic has been unprecedented in terms of volume, speed, and agility – spanning multiple areas, including: regulatory flexibility, Emergency Use Authorizations (EUAs) for devices, shortage mitigation activities, Public Health Service Corps deployment, and extensive engagement with stakeholders. See below for CDRH’s COVID-19 Response by the Numbers:

**Timeline: January 1 - September 18, 2020**

**Regulatory Flexibility:** Proactively issued policies to provide regulatory flexibility to address the pandemic

- 10 EUA templates
- 23 guidance documents
- Including policies intended to help:
  - Car manufacturers making ventilators
  - Apparel manufacturers making masks
  - 3D printing making ventilator components

**Emergency Use Authorizations:** 516 medical products authorized under EUAs (almost 10x the number authorized in all prior national emergencies), including 248 tests, of which:

- 198 are molecular tests
- 4 are antigen tests
- 46 are antibody tests

The FDA received

- 1,734 pre-EUAs
- 3,040 EUAs

**Shortage Mitigation Activities:** Outreach to 1,000+ manufacturing sites across 12 countries to access supply chain vulnerabilities. Result: Identified potential supply chain issues early and worked to minimize disruptions

**Public Health Service Corps Deployment:** 58 CDRH Commissioned Corps officers have been deployed 78 times in support of the COVID-19 mission.

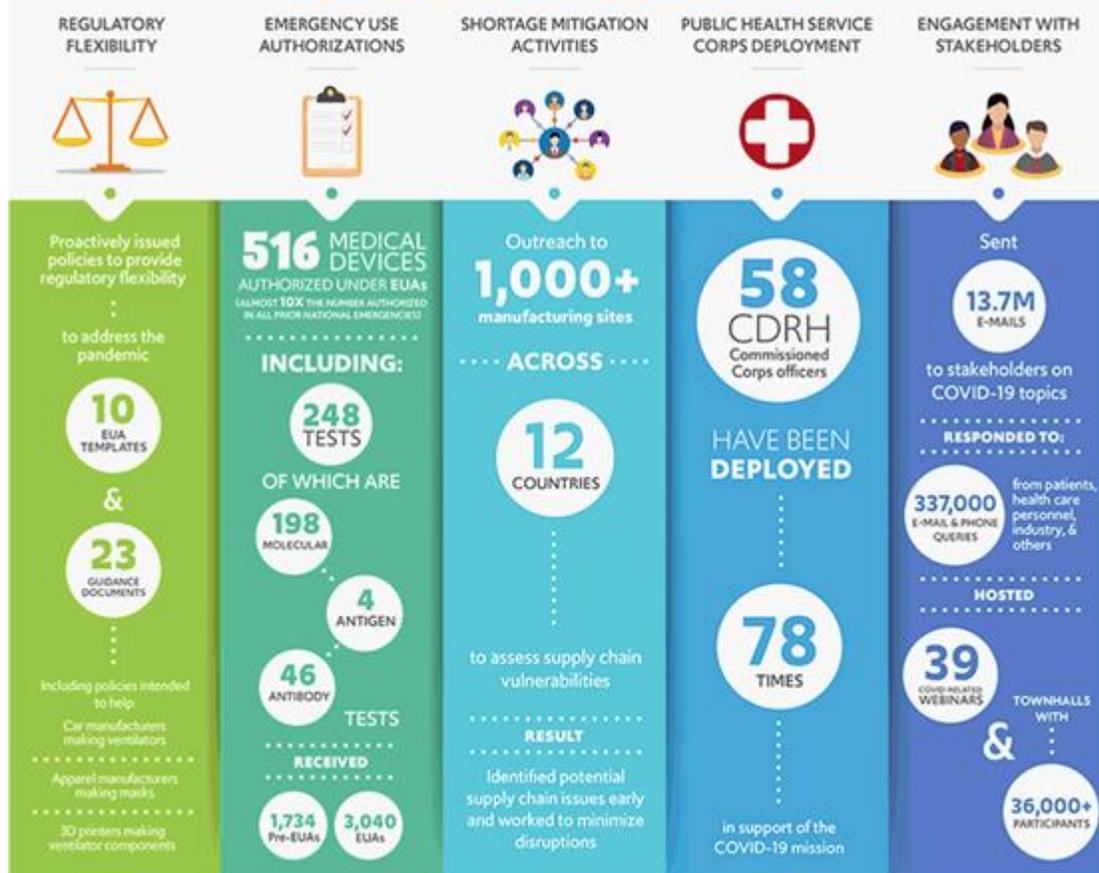
**Engagement with Stakeholders:**

- Sent 13.7 million emails to stakeholders on COVID-19 topics
- Responded to 337,000 email and phone queries from patients, health care personnel, industry, and others
- Hosted 39 COVID-related webinars and townhalls with 36,000+ participants

# Center for Devices and Radiological Health's Response to COVID-19

FDA U.S. FOOD & DRUG ADMINISTRATION

TIMELINE: JANUARY 1 — SEPTEMBER 18, 2020



For more information please visit: [fda.gov/medical-devices](https://fda.gov/medical-devices).

## Research Updates

**Multiple COVID-19 Clusters on a University Campus:** CDC released an MMWR on [Multiple COVID-19 Clusters on a University Campus](#) in North Carolina during August 2020. A North Carolina university experienced a rapid increase in COVID-19 cases and clusters within 2 weeks of opening the campus to students. Student gatherings and congregate living settings, both on and off campus, likely contributed to the rapid spread of COVID-19 in this setting. Enhanced measures are needed to reduce transmission

at institutes of higher education and could include reducing on-campus housing density, ensuring adherence to masking and other mitigation strategies, increasing testing for SARS-CoV-2, and discouraging student gatherings.

**Recent Increase in COVID-19 Cases Reported Among Adults Aged 18–22 Years:** CDC released an MMWR on [Recent Increase in COVID-19 Cases Reported Among Adults Aged 18–22 Years](#) in the U.S. During August 2–September 5, 2020, weekly COVID-19 cases among persons aged 18–22 years increased 55% nationally. Increases were greatest in the Northeast (144%) and Midwest (123%). Increases in cases were not solely attributable to increased testing. Young adults, including those enrolled in colleges and universities, should take precautions, including mask wearing, social distancing, and hand hygiene, and follow local, state, and federal guidance for minimizing the spread of COVID-19. Institutions of higher education should take action to promote healthy environments.

#### **Last & Not COVID-19-Related**

**Secretary Azar – A Healthcare Plan for All Americans:** Secretary Azar released an op-ed in *Townhall* titled "[A Healthcare Plan for All Americans](#)," highlighting President Trump's healthcare plan that was unveiled last week. The op-ed discusses the Administration's actions to have "better care, more choice, lower costs, and a path to a system that puts you, the patient, in control and treats you like a person, not a number."