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Fact Sheet: End of the COVID-19 Public Health Emergency

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023.

Since HHS Secretary Xavier Becerra's February 9, 2023, letter to Governors <https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html> announcing the planned end of the COVID-19 PHE, the

Department has been working closely with partners—including Governors; state, local, Tribal, and territorial agencies; industry; and advocates—to ensure an orderly transition out of the COVID-19 PHE.

Today, HHS is releasing a Fact Sheet with an update on current flexibilities enabled by the COVID-19 emergency declaration and how they will be impacted by the end of the COVID-19 PHE on May 11.

What has been accomplished:

Due to the Biden-Harris Administration's whole-of-government approach to combatting COVID-19, we are now in a better place in our response than at any point of the pandemic and well-positioned to transition out of the emergency phase and end the COVID-19 PHE. Over the last two years, the Biden-Harris Administration has effectively implemented the largest adult vaccination program in U.S. history, with over 270 million people receiving at least one shot of a COVID-19 vaccine. The Administration has also made lifesaving treatments widely available, with more than 15 million courses administered. And through COVIDTests.gov, the Administration has distributed more than 750 million free COVID-19 tests shipped directly to more than 80 million households. The Administration has also administered more than 50 million diagnostic tests in-person at pharmacy and community-based sites. As a result of these and other efforts, COVID-19 is no longer the disruptive force it once was. Since January 2021, COVID-19 deaths have declined by 95% and hospitalizations are down nearly 91%.

As we approach the end of the COVID-19 PHE:

- We have successfully marshalled a whole-of-government response to make historic investments in vaccines, tests, and treatments that are broadly available to help us combat COVID-19.

- Our health care system and public health resources throughout the country are now better able to respond to any potential surge of COVID-19 cases without significantly affecting an individual's ability to access resources or care.

- Our public health experts have issued guidance that allows individuals to understand mitigation measures, such as masking and testing to protect themselves and those around them.

- We have the tools to detect and respond to the potential emergence of a variant of high consequence as we continue to monitor the evolving state of COVID-19 and the emergence of virus variants.

Still, we know so many people continue to be affected by COVID-19, particularly seniors, people who are immunocompromised, and people with disabilities. That is why our response to the spread of SARS-CoV-2, the virus that causes COVID-19, remains a public health priority. To ensure an orderly transition, we have been working for months so that we can continue to meet the needs of those affected by COVID-19.

Even beyond the end of the COVID-19 PHE, we will continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID-19 vaccines, treatments, and tests, including for people without health insurance. We will continue to advance research into new, innovative vaccines and treatments through an investment of $5 billion in Project NextGen, a dedicated program to accelerate and streamline the rapid development of the next generation of vaccines and treatments, including investments in research, development, and manufacturing capacity and advancing critical science. And we are continuing to invest in efforts to better understand and address Long COVID and to help mitigate the impacts.

What will not be affected by the end of the COVID-19 PHE:

The Administration's continued response to COVID-19 is not fully dependent on the emergency declaration for the COVID-19 PHE, and there are significant flexibilities and actions that will not be affected when we transition from the current phase of our response on May 11.

Access to COVID-19 vaccinations and certain treatments, such as Paxlovid and Lagevrio, will generally not be affected. To help keep communities safe from COVID-19, HHS remains committed to maximizing continued access to COVID-19 vaccines and treatments.

At the end of the COVID-19 PHE on May 11, Americans will continue to be able to access COVID-19 vaccines at no cost, just as they have during the COVID-19 PHE, due to the requirements of the CDC COVID-19 Vaccination Program Provider Agreement. <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html> people will also continue to be able to access COVID-19 treatments just as they have during the COVID-19 PHE.

Once the federal government is no longer purchasing or distributing COVID-19 vaccines and treatments, payment, coverage, and access may change. In order to prepare for that transition, partners across the U.S. Government (USG) are planning for and have been developing plans to ensure a smooth transition for the provision of COVID-19 vaccines and certain treatments as part of the traditional health care market, which will occur in the coming months.

When that transition to the traditional health care market occurs, to protect families, the Administration has facilitated access to COVID-19 vaccines with no out-of-pocket costs for nearly all individuals and will continue to ensure that effective COVID-19 treatments, such as Paxlovid, are widely accessible.

The Department announced the "HHS Bridge Access Program For COVID-19 Vaccines and Treatments <https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html>" ("Bridge" Program) on April 18, to maintain broad access to COVID-19 vaccines and treatments for uninsured Americans after the transition to the traditional health care market. For those with most types of private insurance, COVID-19 vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are a preventive health service and will be fully covered without a co-pay when provided by an in-network provider. Currently, COVID-19 vaccinations are covered under Medicare Part B without cost sharing, and this will continue. Medicare Advantage plans must also cover COVID-19 vaccinations in-network without cost sharing, and this will continue. Medicaid will continue to cover COVID-19 vaccinations without a co-pay or cost sharing through September 30, 2024 and will generally cover ACIP-recommended vaccines for most beneficiaries thereafter.

After the transition to the traditional health care market, out-of-pocket expenses for certain treatments, such as Paxlovid and Lagevrio, may change, depending on an individual's health care coverage, similar to costs that one may experience for other covered drugs. Medicaid programs will continue to cover COVID-19 treatments without cost sharing through September 30, 2024. After that, coverage and cost sharing may vary by state.

For more information about the "Bridge" Program, visit Fact Sheet: HHS Announces 'HHS Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured <https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-

announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html>. For more information about access to COVID-19 vaccinations and treatments, visit CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF.

The Food and Drug Administration's (FDA's) Emergency Use Authorizations (EUAs) for COVID-19 products (including tests, vaccines, and treatments) will not be affected. FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use will not be affected by the end of the COVID-19 PHE. To learn more, visit FDA's FAQs: What happens to EUAs when a public health emergency ends? <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends>

Major telehealth flexibilities will not be affected. The vast majority of current Medicare telehealth flexibilities that people with Medicare—particularly those in rural areas and others who struggle to find access to care—have come to rely upon throughout the COVID-19 PHE, will remain in place through December 2024. Additionally, states already have significant flexibility with respect to covering and paying for Medicaid services delivered via telehealth. This flexibility was available prior to the COVID-19 PHE and will continue to be available after the COVID-19 PHE ends. To learn more, visit the Centers for Medicare & Medicaid Services' (CMS) CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF.

Our whole-of-government response to Long COVID will not change. The Department has and will continue to coordinate a whole-of-government response to the longer-term effects of COVID-19, including Long COVID and associated conditions. On April 5, HHS released this Fact Sheet <https://www.hhs.gov/about/news/2023/04/05/fact-sheet-biden-harris-administration-makes-progress-whole-government-response-long-covid.html> outlining the progress made in responding to Long COVID and actions the Department is taking to address the needs of the growing population with Long COVID and associated conditions.

What will be affected by the end of the COVID-19 PHE:

Many COVID-19 PHE flexibilities and policies have already been made permanent or otherwise extended for some time, with others expiring after May 11.

Certain Medicare and Medicaid waivers and broad flexibilities for health care providers are no longer necessary and will end. During the COVID-19 PHE, CMS used a combination of emergency authority waivers, regulations, and sub-regulatory guidance to ensure and expand access to care and to give health care providers the flexibilities needed to help keep people safe. States, hospitals, nursing homes, and others are currently operating under hundreds of these waivers that affect care delivery and payment and that are integrated into patient care and provider systems. Many of these waivers and flexibilities were necessary to expand facility capacity for the health care system and to allow the health care system to weather the heightened strain created by COVID-19; given the current state of COVID-19, this excess capacity is no longer necessary.

For Medicaid, some additional COVID-19 PHE waivers and flexibilities will end on May 11, while others will remain in place for six months following the end of the COVID-19 PHE. But many of the Medicaid waivers and flexibilities, including those that support home and community-based services, are available for states to continue beyond the COVID-19 PHE, if they choose to do so. For example, states have used COVID-19 PHE-related flexibilities to increase the number of individuals served under a waiver, expand provider qualifications, and other flexibilities. Many of these options may be extended beyond the COVID-19 PHE. To learn more, visit CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF

Coverage for COVID-19 testing will change, but USG is maintaining a strong stockpile and distribution channels so that tests remain accessible at no cost in certain community locations, and the USG will continue to distribute tests through COVIDtests.gov through the end of May. People with Traditional Medicare can continue to receive COVID-19 PCR and antigen tests with no cost-sharing when the lab tests are ordered by a physician or certain other health care providers, such as physician assistants and advanced practice registered nurses. People enrolled in Medicare Advantage plans can continue to receive COVID-19 PCR and antigen tests when the test is covered by Medicare, but their cost-sharing may change when the COVID-19 PHE ends. Additionally, the program that allowed Medicare coverage and payment for over-the-counter (OTC) COVID-19 tests will end when the COVID-19 PHE ends on May 11; Medicare Advantage plans may continue to cover the tests, and beneficiaries should check with their plan for details.

State Medicaid programs must provide coverage without cost sharing for COVID-19 testing until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. That means with the COVID-19 PHE ending on May 11, 2023, this mandatory coverage will end on September 30, 2024, after which coverage may vary by state.

The requirement for private insurance companies to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end at the expiration of the PHE. However, coverage may continue if plans choose to do so. The Administration is encouraging private insurers to continue to provide such coverage going forward. For more information visit Coverage for COVID-19 Tests - PDF, Frequently Asked Questions: CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency - PDF <https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf>, FAQs About Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act, and Health Insurance Portability and Accountability Act Implementation Part 58 - PDF <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf>.

Additionally, the USG may continue to distribute free COVID-19 tests from the Strategic National Stockpile through states and other community partners. Pending resource availability, the Centers for Disease Control and Prevention's (CDC) Increasing Community Access to Testing (ICATT) program will continue to focus on no-cost testing for uninsured individuals and areas of high social vulnerability through pharmacies and community-based sites. For more information, visit CDC's ICATT website <https://www.cdc.gov/icatt/index.html>.

Certain COVID-19 data reporting and surveillance will change. CDC COVID-19 data surveillance has been a cornerstone of our response, and during the PHE, HHS had the authority to require lab test reporting for COVID-19. At the end of the COVID-19 PHE, HHS will no longer have this express authority to require this data from labs, which will affect the reporting of negative test results and impact the ability to calculate percent positivity for COVID-19 tests in some jurisdictions. Hospital data reporting will continue as required by the CMS conditions of participation through April 30, 2024, but reporting will be reduced from the current daily reporting to weekly.

Despite these changes, CDC will continue to report valuable data to understand COVID-19 trends and to inform individual and community public health actions to protect those at highest risk of severe COVID-19. In fact, CDC will still have access to more data than is currently collected for other respiratory illnesses to inform public health action at all levels, with hospital data, which is available at the county level, becoming a primary data source to indicate severe COVID-19 in a community. To learn more, visit this CDC resource: End of the Federal COVID-19 Public Health Emergency (PHE) Declaration <https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html>.

In March, FDA announced a transition plan for certain COVID-19-related guidance documents related to topics such as medical devices, clinical practice and supply chains, including which policies will end or be temporarily extended. To learn more, please visit FDA's COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

FDA's ability to detect shortages of critical devices related to COVID-19 will be more limited. While FDA will still maintain its authority to detect and address other potential medical product shortages, it is seeking congressional authorization to extend the requirement for device manufacturers to notify FDA of interruptions and discontinuances of critical devices outside of a PHE which will strengthen the ability of FDA to help prevent or mitigate device shortages.

Public Readiness and Emergency Preparedness (PREP) Act liability protections will be amended. On April 14, 2023, HHS Secretary Becerra sent a letter <https://www.hhs.gov/about/news/2023/04/14/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html> and Fact Sheet <https://www.hhs.gov/about/news/2023/04/14/factsheet-hhs-announces-amend-declaration-prep-act-medical-countermeasures-against-covid19.html> to the nation's governors announcing his intention to amend the PREP Act declaration to extend certain important protections that will continue to facilitate access to convenient and timely COVID-19 vaccines, treatments, and tests for individuals. The Secretary intends to amend the PREP Act declaration for the COVID-19 countermeasures to extend the protections referenced in that fact sheet as well as others and publish the amendment in the Federal Register as required by the PREP Act.

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