U.S. Department of Health and Human Services

COVID-19 Public Health Emergency Transition Roadmap

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. Our response to the spread of SARS-CoV-2, the virus that causes COVID-19, remains a public health priority, but thanks to the Administration's whole of government approach to combatting the virus, we are in a better place in our response than we were three years ago, and we can transition away from the emergency phase.

Over the last two years, the Biden Administration has effectively implemented the largest adult vaccination program in U.S. history, with nearly 270 million Americans receiving at least one shot of a COVID-19 vaccine.

As a result of this and other efforts, since the peak of the Omicron surge at the end of January 2022:

- Daily COVID-19 reported cases are down 92%,
- COVID-19 deaths have declined by over 80%, and
- New COVID-19 hospitalizations are down nearly 80%.

We have come to this point in our fight against the virus because of our historic investments and our efforts to mitigate its worst impacts. Addressing COVID-19 remains a significant public health priority for the Administration, and over the next few months, we will transition our COVID-19 policies, as well as the current flexibilities enabled by the COVID-19 emergency declarations, into improving standards of care for patients. We will work closely with partners, including state, local, Tribal, and territorial agencies, industry, and advocates, to ensure an orderly transition.

What will not be affected:

It is important to note that the Administration's continued response to COVID-19 is not fully dependent on the COVID-19 PHE, and there are significant flexibilities and actions that will not be affected as we transition from the current phase of our response. As described below, the Administration is committed to ensuring that COVID-19 vaccines and treatments will be widely accessible to all who need them. There will also be continued access to pathways for emergency use authorizations (EUAs) for COVID-19 products (tests, vaccines, and treatments) through the Food and Drug Administration (FDA), and major telehealth flexibilities will continue to exist for those participating in Medicare or Medicaid.

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.

Partners across the U.S. Government (USG) are developing plans to ensure a smooth transition

for the provision of COVID-19 vaccines and treatments as part of the traditional health care marketplace and are committed to executing this transition in a thoughtful, well-coordinated manner.

Importantly, this transition to more traditional health care coverage is not tied to the ending of the COVID-19 PHE and in part reflects the fact that the federal government has not received additional funds from Congress to continue to purchase more vaccines and treatments.

When this transition to traditional health care coverage occurs later this year, many Americans will continue to pay nothing out-of-pocket for the COVID-19 vaccine. Vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are a preventive health service for most private insurance plans and will be fully covered without a co-pay. Currently, COVID-19 vaccinations are covered under Medicare Part B without cost sharing, and this will continue. Medicaid will continue to cover all COVID-19 vaccinations without a co-pay or cost sharing through September 30, 2024, and will cover ACIP-recommended vaccines for most beneficiaries thereafter.

Out-of-pocket expenses for certain treatments may change, depending on an individual's health care coverage, similar to costs that one may experience for other drugs through traditional coverage. 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.

FDA's EUAs for COVID-19 products (including tests, vaccines, and treatments) will not be affected. The ending of the COVID-19 PHE will not affect the FDA's ability to authorize various products, including tests, treatments, or vaccines for emergency use. Existing EUAs for COVID-19 products will remain in effect under Section 564 of the Federal Food, Drug, and Cosmetic Act, and the agency may continue to issue new EUAs going forward when criteria for issuance are met.

Major Medicare telehealth flexibilities will not be affected. The vast majority of current Medicare telehealth flexibilities that Americans—particularly those in rural areas and others who struggle to find access to care—have come to rely upon over the past two years, will remain in place through December 2024 due to the bipartisan Continuing Appropriations Act, 2023 passed by Congress in December 2022.

Medicaid telehealth flexibilities will not be affected. States already have significant flexibility with respect to covering and paying for Medicaid services delivered via telehealth. State requirements for approved state plan amendments vary as outlined in CMS' Medicaid & CHIP Telehealth Toolkit. This flexibility was available prior to the COVID-19 PHE and will continue to be available after the COVID-19 PHE ends. Similar to Medicare, these telehealth flexibilities can provide an essential lifeline to many, particularly for individuals in rural areas and those with limited mobility.

The process for states to begin eligibility redeterminations for Medicaid will not be affected. During the COVID-19 PHE, Congress has provided critical support to state Medicaid programs by substantially increasing the federal matching dollars they receive, as long as they agreed to important conditions that protected tens of millions of Medicaid beneficiaries, including the condition to maintain Medicaid enrollment for beneficiaries until the last day of the month in which the PHE ends. However, as part of the Continuing Appropriations Act, 2023,

Congress agreed to end this condition on March 31, 2023, independent of the duration of the COVID-19 PHE.

Access to buprenorphine for opioid use disorder treatment in Opioid Treatment Programs (OTPs) will not be affected. Early in the COVID-19 pandemic, the Substance Abuse and Mental Health Services Administration (SAMHSA) released guidance allowing patients to start buprenorphine in an OTP by telehealth without the required in-person physical examination first. This flexibility has proven to be safe and effective in engaging people in care such that SAMHSA proposed to make this flexibility permanent as part of changes to OTP regulations in a Notice of Proposed Rulemaking that it released in December 2022. SAMHSA has committed to providing an interim solution if the proposed OTP regulations are not finalized prior to May 11.

Access to expanded methadone take-home doses for opioid use disorder treatment will not be affected. Early in 2020, SAMHSA allowed an increased number of take-home doses to patients taking methadone in an OTP. Research and feedback from patients, OTPs, and states have demonstrated that this flexibility has allowed people with opioid use disorder to stay in treatment longer, supported recovery, and has not resulted in increases in methadone-related overdoses. SAMHSA announced it will extend this flexibility for one year from the end of the COVID-19 PHE, which will be May 11, 2024, to allow time for the agency to make these flexibilities permanent as part of the proposed OTP regulations published in December 2022.

What will be affected:

Many COVID-19 PHE flexibilities and policies have already been made permanent or otherwise extended for some time. However, HHS continues to review the flexibilities and policies implemented during the COVID-19 PHE to determine whether others can and should remain in place, even for a temporary duration, to facilitate jurisdictions' ability to provide care and resources to Americans. Still, others will expire. Below is a list of some of the changes people will see in the months ahead.

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 has 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.

CMS developed a roadmap for the eventual end of the COVID-19 PHE, which was published in August 2022, and has been sharing information on what health care facilities and providers can do to prepare for future emergencies. This includes facilities returning to normal operations and meeting CMS requirements that promote the safety and quality of care they provide. CMS will continue to provide updated information and is also offering technical assistance to states and engaging in public education about the necessary steps to prepare for the end of the COVID-19 PHE.

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 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 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 PHE.

Coverage for COVID-19 testing for Americans will change. Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted COVID-19 tests when ordered by a provider, but their current access to free over-the-counter (OTC) COVID-19 tests will end, consistent with the statute on Medicare payment for OTC tests set by Congress.

The requirement for private insurance companies to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end. However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward.

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.

Additionally, dependent on supply and resources, the USG may continue to distribute free COVID-19 tests from the Strategic National Stockpile through the United States Postal Service, 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 working to ensure continued equitable access to testing for uninsured individuals and areas of high social vulnerability through pharmacies and community-based sites.

Reporting of COVID-19 laboratory results and immunization data to CDC will change. CDC COVID-19 data surveillance has been a cornerstone of our response, and during the PHE, HHS has 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 may affect the reporting of negative test results and impact the ability to calculate percent positivity for COVID-19 tests in some jurisdictions. CDC has been working to sign voluntary Data Use Agreements (DUAs), encouraging states and jurisdictions to continue sharing vaccine administration data beyond the PHE. Additionally, hospital data reporting will continue as required by the CMS conditions of participation through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency.

Certain FDA COVID-19-related guidance documents for industry that affect clinical practice and supply chains will end or be temporarily extended. FDA published several dozen guidance documents to address challenges presented by the COVID-19 PHE, including limitations in clinical practice or potential disruptions in the supply chain. FDA is in the process of addressing which policies are no longer needed and which should be continued, with any appropriate changes, and the agency will announce plans for each guidance prior to the end of the PHE.

FDA's ability to detect early shortages of critical devices related to COVID-19 will be more limited. During the PHE, manufacturers of certain devices related to the diagnosis and treatment of COVID-19 have been required to notify the FDA "of a permanent discontinuance in the manufacture of the device" or "an interruption in the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States." This requirement will end when the PHE ends. 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 significant 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 for may be impacted. Currently, the amended PREP Act declaration provides liability immunity to manufacturers, distributors, public and private organizations conducting countermeasure programs, and providers for COVID-19 countermeasure activities related to a USG agreement (e.g., manufacturing, distribution, or administration of the countermeasures subject to a federal contract, provider agreement, or memorandum of understanding). That coverage will not be affected by the end of the PHE. However, PREP Act liability protections for countermeasure activities that are not related to any USG agreement (e.g., products entirely in the commercial sector or solely a state or local activity) will end unless another federal, state, or local emergency declaration is in place for area where countermeasures are administered. HHS is currently reviewing whether to continue to provide this coverage going forward.

The ability of health care providers to safely dispense controlled substances via telemedicine without an in-person interaction is affected; however, there will be rulemaking that will propose to extend these flexibilities. During the PHE, the Drug Enforcement Administration (DEA) and HHS adopted policies to allow DEA-registered practitioners to prescribe controlled substances to patients without an in-person interaction. These policies allowed for audio-only modalities to initiate buprenorphine prescribing. DEA is planning to initiate rulemaking that would extend these flexibilities under certain circumstances without any gap in care and will provide additional guidance to practitioners soon.

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