COVID-19 NATIONAL PUBLIC HEALTH EMERGENCY TERMINATION

Issue Brief

May 24, 2023

Legal and Health Care Repercussions of the End of the National Public Health Emergency

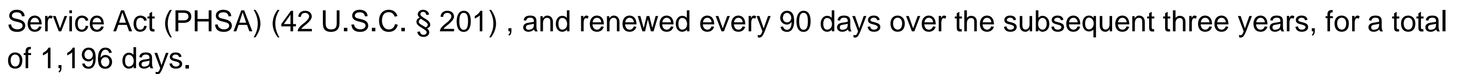
After three years of substantial, national public health impacts extending from COVID-19, the White House announced on January 30, 2023 that it would end the COVID-19 national public health emergency (PHE) (declared via the Department of Health and Human Services (HHS)) on May 11, 2023. Shortly thereafter, the U.S. House of Representatives voted to end the National Emergency that had initially been declared by former President Trump. With Senate agreement in March 2023, President Biden signed Congress' resolution on April 10, 2023 ending the national emergency declaration immediately. Internationally, the World Health Organization announced on May 5 that COVID-19 was no longer a "public health emergency of international concern." Within a week of the termination of HHS' national PHE, remaining U.S. states with active declarations ended their own emergencies.

The termination of these and other national emergency declarations are not merely symbolic. Despite COVID-related deaths, infections, and hospitalizations consistently trending lower, COVID-19 remains a top cause of U.S. deaths, with sub-variants threatening to emerge. While select national emergency declarations continue, closing out national and regional emergencies brings rapid changes to the legal landscape as a return to normalcy takes precedence.

As documented in this Issue Brief, the end of multiple COVID-19 enhanced government authorities carries significant implications related to the cost and availability of COVID-19 vaccines and tests, telehealth and HIPAA flexibilities, Medicare and Medicaid expansions, private health insurance coverages, and immigration policies. Some COVID-era legal measures that have proven efficacious and beneficial may extend beyond the end of emergency declarations. Other emergency interventions and protections, however, conclude abruptly. Key changes among various defined emergency authorities tied to national emergency declarations ending on or before May 11, 2023 are examined below.

Public Health Emergency (PHE)

The national PHE was the first of multiple national emergencies declared in response to COVID-19. It was initially declared by former HHS Secretary Alex Azar on January 31, 2020, pursuant to Section 319 of the Public Health



Service Act (PHSA) (42 U.S.C. § 201) , and renewed every 90 days over the subsequent three years, for a total of 1,196 days.

Pursuant to Congressional authorities laid out in PHSA, the national PHE permitted waivers of select federal laws (coupled with national emergency declarations that came later) and allowed certain flexibilities. PHSA also facilitated interjurisdictional (e.g., federal, state, local) coordination and supported medical countermeasures and social distancing via federal quarantine authorities.

On February 9, 2023, current HHS Secretary Xavier Becerra informed U.S. governors that his next renewal of the PHE would be the last, officially providing 90 days' notice of the changing legal landscape. Advance notice was intended to provide sufficient time for governments, health care systems, and others to prepare for the repercussions of ending the various federal declarations beginning May 11.

Public Readiness and Emergency Preparedness (PREP) Act

On February 4, 2020, former HHS Secretary Azar issued an emergency declaration pursuant to the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act declaration authorized a series of medical countermeasures (MCMs) and associated legal allowances during the COVID-19 pandemic including (1) liability protections for manufacturers, retailers, and others distributing authorized MCMs (notably vaccines); (2) expansive scopes of practice for select providers to increase the number of HCWs able to administer vaccinations; and (3) preemption of conflicting state laws and policies inhibiting federal response efforts.

Pursuant to PREP Act interventions, pharmacists and interns were able to administer COVID-19 and other immunizations to children between the ages of three and 18, circumventing contrary state laws setting other age limits. HCWs licensed in one state were able to provide COVID-19 vaccinations in other states (often labeled "licensure reciprocity"). Select HCWs whose licenses expired in the last five years were able to administer COVID-19 vaccines in any state as well. On April 14, HHS Secretary Becerra confirmed that the PREP Act declaration would extend through December 2024.

Emergency Use Authorizations (EUAs)

On February 7, 2020, former HHS Secretary Azar issued a notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act to allow emergency use authorizations (EUAs) of "in vitro diagnostics" for the detection and diagnosis of COVID-19 through the Food and Drug Administration (FDA). EUAs typically require a pre-determined emergency—specifically the afore-mentioned national PHE issued on January 31, 2020. Diagnostics and other products authorized via EUAs allow for their use and deployment prior to formal FDA approval. Dozens of EUA products, tests, and medications emerged during the COVID-19 pandemic. In February 2020, for example, FDA issued an EUA for CDC 's COVID-19 test kits. In December 2020, the first EUA was issued for a COVID-19 vaccine (Pfizer-BioNTech).

In March 2023, FDA issued Guidance for EUAs and other devices affected by the PHE outlining a three-phase transition plan. Manufacturers may follow these guidelines to ensure devices are fully compliant with post-PHE FDA requirements.

National Emergencies Act and Stafford Act

On March 13, 2020, former President Donald Trump declared dual national emergencies pursuant to the National Emergencies Act (50 U.S.C. § 1601-1651) and the Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) (42 U.S.C. ch. 68 § 5121 et seq). These national emergencies may be terminated by a joint resolution of Congress, direct rescission or non-renewal by the president, or other factors. Among other powers,

national emergencies (1) authorize direct federal agency coordination via the president, (2) allocate federal funds toward state response efforts through the Federal Emergency Management Agency (FEMA) Disaster Relief Fund, (3) allow reimbursement for eligible state response measures, (4) permit select federal law waivers and flexibilities, and (5) facilitate National Guard assistance to states.

After the House of Representatives and Senate voted in favor of the Pandemic is Over Act President Biden signed House Joint Resolution 7 on April 10, 2023, effectively ending the National Emergency.

Defense Production Act (DPA)

The Defense Production Act (DPA) (50 U.S.C. ch. 55) authorizes the president to compel U.S. businesses and manufacturers to prioritize contracts deemed necessary for national defense. Former President Trump first invoked DPA on March 20, 2020 to require select manufacturers to produce scarce resources including ventilators and personal protective equipment (PPE), based on his March 18 executive order defining these goods as "essential to the national defense." In subsequent months, President Trump utilized DPA to spur U.S. production of N95 respirators. President Biden invoked DPA to produce additional PPE and COVID-19 vaccines. DPA operates under distinct legal authority separate from the PHE and is unaffected by the end of the emergency declarations. As of May 2023, there is no announced end date concerning this declaration.

Title 42

On March 21, 2020, former President Trump and the Centers for Disease Control and Prevention (CDC) invoked PHSA "Title 42" authorities (42 U.S.C. § 265) to address possible spread of COVID-19 across the northern Canadian and southern Mexico borders. Title 42 allows federal authorities to turn away immigrants at U.S. borders, airports, and ports of entry to prevent risks of COVID-19 spread. Expulsions are not based on immigration status and are tracked separately from actual deportations. Although CDC has distinct legal authorities to implement Title 42 orders, the Biden administration announced the end of Title 42 immigration policies on May 11, 2023 coupled with the end of the PHE. On May 18, 2023, the U.S. Supreme Court dismissed a Title 42 case it had agreed previously to hear, determining that the end of the PHE rendered related litigation moot.

Figure 1, below, provides a legal snapshot of the aforementioned federal emergency declarations evoked during the COVID-19 pandemic (2020-2023) including the declaration name and citation, key components, and effective beginning and end dates.

Figure 1. Legal Snapshot of COVID-19 Federal Emergency Declarations

DECLARATION	KEY COMPONENTS	EFFECTIVE DATE	END DATE
Public Health Emergency (PHE) Public Health Service Act sec. 319, 42 U.S.C. § 247d.	Federal law waivers and flexibilities Interjurisdictional coordination Medical countermeasures Social distancing	Jan. 31, 2020	May 11, 2023
PREP Act Public Health Service Act sec. 319F	Liability immunity for COVID-related health care activities and countermeasures	Feb. 4, 2020	Dec. 31, 2024 (anticipated)
Emergency Use Authorizations (EUAs) Federal Food, Drug, and Cosmetic Act sec. 564	Emergency diagnostics for detection and diagnosis of COVID-19	Feb. 7, 2020	To be determined

National Emergency National Emergencies Act, 50 U.S.C. § 1601-1651 Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. ch. 68 § 5121 et seq	FEMA Disaster Relief Fund Federal reimbursement of state response measures Federal law waivers and flexibilities	March 13, 2020	April 10, 2023
Defense Production Act (DPA) 50 U.S.C. ch. 55	U.S. manufacturer production of scarce resources	March 20, 2020	To be determined
Title 42 42 U.S.C. § 265	Deportation of migrants	March 21, 2020	May 11, 2023

COVID-19 Vaccines: Availability, Cost and Mandates

With the first deliveries of COVID-19 vaccines authorized via EUAs beginning on December 14, 2020, Americans have had free access to COVID-19 vaccinations and boosters. As of May 2023, everyone of ages 6 months and older is eligible to be vaccinated for COVID-19. The Biden administration credited the end of the PHE to the largest-ever national vaccination campaign in response to the pandemic.

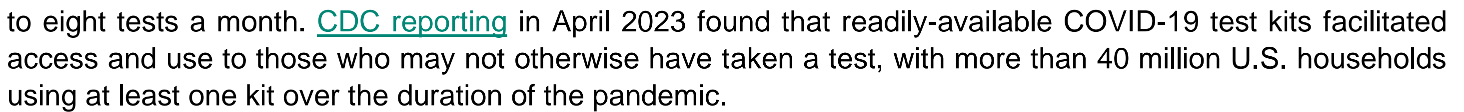
Following the termination of the PHE, the existing federally-purchased supply of COVID-19 vaccines and boosters will remain available with no cost-sharing. As per CDC determinations via the Affordable Care Act (ACA), health insurance plans will continue to cover COVID-19 immunizations at no costs to patients. For those with private health insurance or plans, vaccinations received from an in-network provider (including the associated administration fee) will be available with no out-of-pocket fee. However, insurance plans that were required to cover out-of-network vaccine and administration fees for vaccination during the PHE may no longer elect to do so.

For millions of Americans covered through Medicaid or Medicare, access to COVID-19 vaccines will continue largely unabated. Medicaid will cover COVID-19 vaccinations and boosters through September 30, 2024. Medicare will cover the immunizations under Part B without cost sharing. HHS launched a separate Bridge Program on April 18, 2023 to provide continued access to vaccines and treatment for uninsured Americans.

During the COVID-19 pandemic, various federal vaccine mandates resulted in high vaccination rates for federal employees, contractors, members of the U.S. military, health care workers, and others. Most of these requirements were not fully enforced due to pending litigation challenges. With the end of the national PHE, many remaining federal vaccine mandates expired. For example, the vaccination requirement for federal employees, contractors, and others expired despite never being fully enforced while litigation ensued. Notwithstanding contradictory holdings across several federal appellate courts related to the legality of federal vaccine mandates, the U.S. Supreme Court is unlikely to weigh in given the termination of the PHE. Lacking clear legal authority, the future of federal vaccine mandates remains uncertain. Conversely, state vaccine mandates remain largely intact across most jurisdictions despite select state legislative efforts to crimp vaccine requirements.

COVID-19 Tests

In January 2022, the Biden administration began distributing at-home rapid COVID-19 test kits to U.S. households. These tests were available at no out-of-pocket cost and could be ordered online or picked up from pharmacies or other locations in-person. Proof of out-of-pocket costs for purchasing tests at retail establishments could be submitted to insurance companies for reimbursement. Insurance providers were required to cover up



to eight tests a month. CDC reporting in April 2023 found that readily-available COVID-19 test kits facilitated access and use to those who may not otherwise have taken a test, with more than 40 million U.S. households using at least one kit over the duration of the pandemic.

Existing supplies of federally-purchased COVID-19 test kits are still available post-PHE. Households may order up to four at-home tests on the federal covid.gov/tests website. Additionally, FDA extended the expiration date for many tests. Once remaining supplies run out, however, free COVID-19 test kits will no longer be available to all. Private insurers are not required to cover them with $0 cost-sharing. Some states have chosen to extend access to free COVID-19 tests. North Carolina created a program allowing state residents to order free tests through June 2023.

Free at-home tests will remain available for Medicaid enrollees until September 30, 2024 after which state Medicaid programs may determine whether to continue providing them. Medicaid and Medicare beneficiaries receiving COVID-19 lab (e.g., blood) tests ordered by a doctor remain covered, subject to possible cost sharing.

Telehealth

Prior to the COVID-19 pandemic, telehealth services were generally limited to select services or restricted based on provider type or location. However, social distancing and stay-at-home orders in early 2020 necessitated rapid expansion of telemedicine technologies, capabilities, and coverage. Beginning in March 2020, emergency authorities enabled waivers of existing telehealth requirements, leading to a massive uptake in telehealth service usage.

Many of these emergency interventions may continue past the PHE. In December 2022, a congressional omnibus budget bill de-coupled telehealth flexibilities from the PHE, extending COVID-era flexibilities through December 2024 for most Americans. On May 9, the U.S. Drug Enforcement Administration announced an extension until November 11, 2023 of policies allowing providers to prescribe controlled substances via telehealth without an in-person appointment. Patient-physician prescribing relationships established by that date will be further extended through November 11, 2024.

Medicare

During the PHE, hospitals receiving Medicare funding received a 20% increase in the Medicare payment rate. This increased payment ended on May 11. On May 5, 2023, CMS issued a FAQ document expounding on key changes post-PHE. For example, pre-pandemic, Medicare only covered skilled nursing stays following a three day inpatient hospital stay. This requirement was waived during the PHE but is now back in effect. Medicare Part D prescription drug plans will no longer cover up to a 90-day supply of covered drugs if requested by the beneficiary. Medicare Advantage plans are no longer required to cover out-of-network facility fees at in-network rates.

Medicaid & Children's Health Insurance Program (CHIP)

COVID-era Medicaid expansions resulted in record numbers of Americans with health insurance coverage, decreasing the national uninsured rate to approximately 8% as more individuals qualified for emergency Medicaid coverage largely paid for by the federal government and could not be dis-enrolled for ineligibility. In December 2022, a congressional omnibus budget bill de-coupled Medicaid enrollment from the PHE, setting a March 31, 2023 deadline for states losing COVID-era federal funding that helped pay for the expanded programs. By April 1, five states began to remove individuals from state Medicaid legers. In August 2022, HHS estimated

that 15 million Americans would lose coverage under Medicaid or CHIP following the end of the COVID-era policies. Americans may sign up for an ACA plan during a special post-PHE enrollment period by June 9, 2023.

Health Care Worker (HCW) Liability

Multiple federal laws, including the PREP Act, provided layers of liability immunity for HCWs responding to the COVID-19 crisis and administering countermeasures. Many states adopted their own COVID-specific immunity provisions via gubernatorial executive order or state legislation, although considerable protections at the state level ended with their formal rescission of their declared emergencies. In April 2023, HHS confirmed that the PREP Act declaration will extend through December 2024, likely including liability protections for multiple entities and HCWs administering COVID-19 MCMs. However, vaccination by non-traditional providers, vaccinations across state lines, and in-pharmacy routine childhood vaccinations are no longer covered.

Data Collection

The PHE provided legal authorities for CDC to require all U.S. laboratories to report COVID-19 testing results federally. State-level emergency authorities permitted some states to collect COVID-19 data. As emergency authorities end, public health agencies may lack direct authority or funds to collect these data directly. Post-PHE, data will be tracked through hospitals reporting positive cases, wastewater surveillance, and voluntary reporting from labs. CDC will continue to update COVID-19 data online weekly.

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