

Memo

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RE: Implications of PHE Expiration

On January 31, 2020, Health and Human Services (HHS) Secretary Alex Azar signed a determination of a nationwide public health emergency (PHE) regarding the novel coronavirus, using his authorities under Section 319 of the Public Health Service Act.¹ This emergency has been extended every 90 days by HHS since, with the current extension lasting through April 11, 2023.² On January 30, 2023, however, the White House issued a Statement of Administration Policy stating that the Biden Administration plans to extend both the PHE and the COVID-19 national emergency to May 11, 2023, on which date both emergencies will end.³

This memo lays out the current state of various policy matters relevant to Argentum that hinge on the legal status of the COVID-19 emergency—both the Section 319 determination and other emergency declarations. Including Section 319, there are three main federal legal authorities that can affect emergency health policies and powers:

- *Section 319 Public Health Emergency (PHE)*: This determination by the Secretary of HHS gives HHS divisions such as CMS and FDA various flexibilities within their programs, such as waiving or suspending certain regulatory provisions in Medicare and Medicaid. Section 319 determinations expire 90 days after issuance unless extended.

¹ Determination that a Public Health Emergency Exists, Dep't of Health & Human Servs. (HHS) (Jan. 31, 2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Determination that a Public Health Emergency Exists, HHS (January 11, 2023), <https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx>.

³ Executive Office of the President, *Statement of Administration Policy (H.R. 382, H.J. Res. 7)* (Jan. 30, 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>.

- *PREP Act Declaration*: On March 17, 2020, Secretary Azar issued a declaration under the PREP (Public Readiness and Emergency Preparedness) Act,⁴ making a separate declaration that a public health emergency exists and providing certain liability protections for covered entities with regard to the use of countermeasures in the emergency.⁵ The duration of a PREP Act declaration is determined in the declaration.
- *Section 564 Determination*: On February 4, 2020, Secretary Azar made a determination under Section 564 of the Food, Drug, and Cosmetic Act (FDCA) that a public health emergency existed with the potential to affect national security or the health of citizens living abroad, allowing the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs) for countermeasures.⁶ Section 564 determinations last until they are rescinded by the Secretary.

Emergency policies can also be affected by the status of a national emergency declaration by the President under the National Emergencies Act (a state-by-state determination, which currently exists for all 50 states regarding COVID-19, extended for another year in February 2022⁷), as well as states' own emergency declarations. Under the January 30th, 2023 Statement of Administration Policy, the Biden Administration would allow both the Section 319 PHE and the COVID-19 national emergency (issued pursuant to the National Emergencies Act) to expire on May 11, 2023. The other two key federal emergency policies, however—under the PREP Act and Section 564 of the FDA—would be unaffected by the planned lapse of the other two declarations.

As of late January 2023, eight states still have public health emergency declarations in effect,⁸ although states may still have other temporary orders in effect that are not dependent on the state's public health emergency declaration.

I. PREP ACT AND OTHER LIABILITY SHIELDS

PREP Act declarations related to COVID-19 provide liability protections for certain entities in relation to the use of countermeasures, and states have also enacted broader liability protections related to COVID-19, some of which hinge on federal and/or state emergency status.

A. PREP Act Protections

1. Extent of PREP Act Protections

⁴ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, HHS, 85 Fed. Reg. 15,198 (Mar. 17, 2020).

⁵ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, HHS, 85 Fed. Reg. 15,198 (Mar. 17, 2020).

⁶ Determination of a Public Health Emergency, HHS, 85 Fed. Reg. 7,316 (Feb. 4, 2020).

⁷ Notice on the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic, Exec. Off. of the President, 87 Fed. Reg. 10,289 (Feb. 18, 2022).

⁸ States' COVID-19 Public Health Emergency Declarations and Mask Requirements, Nat'l Academy for State Health Policy (NASHP) (Jan. 24, 2023), <https://www.nashp.org/governors-prioritize-health-for-all/>.

While the first COVID-19 PREP Act declaration was issued in March 2020, it has been amended ten times since, with the latest amendment coming in January 2022.⁹ The duration of the COVID-19 declaration’s protections varies:

- Some provisions, such as the general protections for persons prescribing, administering, or dispensing countermeasures covered under the declaration, extend through October 1, 2024, or the end of the declaration as determined by the Secretary, “whichever comes first.”
- Some provisions, such as those covering pharmacy technicians and interns administering influenza vaccines, do not currently have an effective end date.

It should be noted that PREP Act declarations have remained in effect for long periods of time: As recently as December 2022, HHS amended the PREP Act declaration covering the use of Zika vaccines, first issued in 2016, through 2027.¹⁰

2. Ongoing Litigation

Providers such as assisted living facilities, which have used covered countermeasures made available under Emergency Use Authorizations, could arguably receive liability protection as “covered persons” under the PREP Act declarations that preempt state law liability claims. In August 2020, HHS’s Office of the General Counsel issued a letter confirming that senior living communities are “covered persons” for the purposes of the PREP Act when they “provide a facility to administer or use a covered countermeasure.”¹¹ The PREP Act declaration also requires that activities potentially receiving protection be acting under an authority with jurisdiction under the declaration; HHS’s Office of the Assistant Secretary for Health, acting as such an authority, has published guidance extending this coverage to include healthcare providers administering COVID-19 tests in congregate settings, such as assisted living facilities.¹² In 2020, the HHS Office of the General Counsel issued an advisory opinion arguing that the PREP Act should completely preempt state law claims.¹³

Several federal circuit courts have been presented with claims related to COVID-19 and the PREP Act. Most circuit courts to consider the issue have done so in the context of whether the Act provides complete preemption as a justification for the defendants to remove the case to a federal forum.¹⁴ The Third Circuit found that preemption only extended to the one cause of action created

⁹ Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022).

¹⁰ 87 Fed. Reg. 78,976 (Dec. 23, 2022).

¹¹ Letter from Robert Charrow to Tom Barker (Aug. 14, 2020), HHS Office of the General Counsel.

¹² Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, HHS Office of the Assistant Secretary for Health (Aug. 31, 2020), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf>.

¹³ HHS, General Counsel Advisory Opinion 21-01 (Jan. 8, 2021), <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

¹⁴ Circuit courts have also examined whether the law provides for removal under the federal-officer statute because covered persons are acting under the auspices of government authorities, *see Hudak v. Elmcroft of Sagamore Hills*, 2023 U.S. App. LEXIS 1598 (Jan. 23, 2023) (finding that compliance with federal regulations and mandates did not amount to “acting under” a federal officer), and whether the PREP Act authorized interlocutory appeals to the D.C.

by the PREP Act, covering willful misconduct.¹⁵ The Ninth Circuit, in *Saldana v. Glenhaven Healthcare LLC*, found that the PREP Act was not a “complete preemption statute” because Congress failed to demonstrate intent to preempt state law.¹⁶ Argentum had filed an amicus brief in another case before the Ninth Circuit – *Garcia v. Welltower*¹⁷ – but in November 2022 the Ninth Circuit remanded the case to the lower court for further consideration in light of the *Saldana* decision.¹⁸

On August 31, 2022, defendants in the Ninth Circuit’s *Saldana* case mentioned above filed a writ of certiorari with the Supreme Court appealing the Ninth Circuit’s decision to remand the case to state court based on the conclusion that the PREP Act is not a complete preemption statute,¹⁹ but on Nov. 21, 2022, the Supreme Court declined to consider the case.²⁰ As such, for the time being, the scope of PREP Act preemption will likely continue to be litigated in the lower courts, without further guidance from the Supreme Court.

B. State-Level Liability Shields

Many states have passed some form of liability protections related to COVID-19. For example, the National Conference of State Legislatures found that 22 states had passed liability legislation related to COVID-19 in 2020 alone.²¹

Most (although not all) protections tie the extent of liability protection to the duration of a legal state of emergency by the state, rather than the federal government. Because these provisions vary quite widely, facilities operating in a given state should review whether that state has passed liability legislation and what triggers may bring an end to such protections.

Below are examples of states with varying triggers for their liability protections:

- *Texas*: In June 2021, Texas passed S.B. 6, which provides certain liability protections for healthcare providers, limited only to claims, “arising from care, treatment, or failure to provide care or treatment that occurred during a period beginning on the date that the president of the United States or the governor makes a disaster declaration related to a pandemic disease and ending on the date the declaration terminates.” While many states have let their COVID-19 disaster declarations lapse, as of January 2023, the Texas state

Circuit for cases beyond willful misconduct, *see Cannon v. Watermark Ret. Cmty., Inc.*, 45 F.4th 137 (D.C. Cir. 2022) (finding it did not authorize interlocutory appeals for cases other than willful misconduct).

¹⁵ *Estate of Maglioli v Alliance HC Holdings LLC, et al.* (3rd Cir. 2021), <http://www2.ca3.uscourts.gov/opinarch/202833p.pdf>. See also *Mitchell v. Advanced HCS, L.L.C.* (5th Cir. 2022) (removal to federal court is not justified because the PREP Act is not a complete preemption statute); *Mitchell v. Advanced HCS, L.L.C.* (7th Cir. 2022) (claims do not all under PREP Act preemption because claims related to inaction by nursing homes rather than use of covered countermeasures).

¹⁶ *Saldana v. Glenhaven Healthcare LLC* (9th Cir. 2022), <https://cdn.ca9.uscourts.gov/datastore/opinions/2022/02/22/20-56194.pdf>.

¹⁷ *Garcia v. Welltower*, 522 F. Supp. 3d 734 (C.D. Cal. 2021).

¹⁸ *Garcia v. Welltower*, 2022 U.S. App. LEXIS 31913.

¹⁹ Petition for Writ of Certiorari, Supreme Court, https://www.supremecourt.gov/DocketPDF/22/22-192/236585/20220829141712084_Glenhaven%20Saldana%20Cert%20Petition.pdf.

²⁰ *Glenhaven Healthcare LLC, et al. v. Jackie Saldana, et al.* No. 22-192, S.Ct. (Nov. 21, 2022).

²¹ Nat’l Conference of State Legislatures, Fiscal Brief: COVID-19 Liability Legislation (Feb. 2021), https://www.ncsl.org/Portals/1/Documents/fiscal/NCSLFebruaryFiscalBrief_COVID-19_Liability_Legislation.pdf.

declaration is still in effect,²² while the national emergency is now scheduled to expire on May 11.

- *Florida*: In March 2021, Florida passed S.B. 72, which provides certain liability protections with regard to COVID-19, most of which are tied to a claim’s relation to COVID-19, rather than to a particular state or federal emergency declaration. The bill provides certain protections, untied to any emergency declaration, for claims relating to “[d]iagnosis or treatment of, or failure to diagnose or treat, a person for COVID-19; ... [p]rovision of a novel or experimental COVID-19 treatment; [or t]ransmission of COVID-19,” subject to requirements such as a finding that the defendant acted in good faith to comply with government-issued standards in effect at the time.
- *Georgia*: In August 2020, Georgia passed S.B. 359,²³ which provided certain liability protections for claims arising from COVID-19, scheduled to sunset in 2021. In 2021, Georgia’s legislature passed an extension of the legislation extending liability protections through July 2022, but the legislature has now allowed the statute to lapse, thereby covering claims occurring only up to July 14, 2022.²⁴
- *Illinois*: While Illinois has not passed legislation to provide COVID-19-related liability protections, the governor issued an executive order in April 2020²⁵ citing existing Illinois statutes to provide certain emergency liability protections “for the duration of the Gubernatorial Disaster Proclamations” related to the virus (which remain in effect through February 4, 2023²⁶).

II. SECTION 319 PHE POWERS AND FLEXIBILITIES

A. Medicaid Continuous Enrollment

The Families First Coronavirus Response (FFCRA) significantly expanded Medicaid rolls by offering to states an additional federal funding contribution, as long as the state does not remove any beneficiaries from its rolls (except for voluntary termination or departure from the state)²⁷ and does not narrow its eligibility criteria²⁸ for the duration of the Section 319 PHE. As discussed below, this legislation was modified by the Consolidated Appropriations Act of 2023 to detach the unwinding of this enhanced funding and attendant requirements from the Section 319 PHE, allowing states to begin the redetermination process starting April 1, 2023.

CMS guidance provides states with 12 months to initiate redeterminations of beneficiaries’ eligibility, recommending that states prioritize redeterminations by likelihood of current

²² Governor Abbott Renews COVID-19 Disaster Declaration In January 2023 (Jan. 15, 2023), <https://gov.texas.gov/news/post/governor-abbott-renews-covid-19-disaster-declaration-in-january-2023>.

²³ S.B. 359 (2020), <https://www.legis.ga.gov/legislation/57192>.

²⁴ H.B. 112 (2021), <https://gov.georgia.gov/document/2021-signed-legislation/hb-112/download>.

²⁵ Executive Order 2020-37 (May 13, 2020), <https://www.illinois.gov/government/executive-orders/executive-order.executive-order-number-37.2020.html>.

²⁶ Executive Order 2023-1 (Jan. 6, 2023), <https://www.illinois.gov/government/executive-orders/executive-order.executive-order-number-01.2023.html>.

²⁷ Families First Coronavirus Response Act (FFCRA) Sec. 6008(b)(3) (P.L. 116–127).

²⁸ FFCRA Sec. 6008(b)(2).

ineligibility. States have two months following the 12 month period to complete redeterminations, and generally are encouraged by CMS to “mitigate churn for eligible beneficiaries and smoothly transition individuals between coverage programs.”²⁹ A March 2022 survey found that, of 48 states that have begun planning for the redetermination process, 41 expect to initiate the process for enrollees within 9–12 months, while the remaining states expect to do so more quickly.³⁰ A 2022 survey of a sample of states by the Medicaid and CHIP Payment and Access Advisory Commission (MACPAC) found that state planning for resuming coverage determinations was underway, and that states would be grateful for more certainty around the resumption of coverage redeterminations or more time to complete the process, but generally did not feel either was necessary.³¹ In August 2022, HHS’s Assistant Secretary for Planning and Evaluation (ASPE) published an analysis with recommendations for states around best practices for resuming eligibility and reducing “churn” of enrollees, but without recommending or contemplating any significant changes to the planned process.³²

While the FFCRA continuous coverage protections have significantly increased Medicaid rolls, the effect is much more dramatic for working-age adults and children than it is for elderly adults, because the latter category usually experience income changes less frequently. One estimate found that the increase in enrollment due to continuous coverage has amounted to 201,000 elderly and disabled enrollees, out of 4 million elderly and disabled enrollees on Medicaid in general, representing just 6 percent of the increase in Medicaid enrollment during the pandemic.³³ One of the risk-based approaches proposed by CMS for redetermining eligibility would deprioritize populations like the aged “whose eligibility tends to be stable.”³⁴

In the Consolidated Appropriations Act, 2023 (CAA, 2023),³⁵ Congress created a new statutory framework for the unwinding of the enhanced FMAP and continuous coverage requirements, allowing states to begin redeterminations on April 1, 2023.³⁶ During 2023, states may continue to receive an enhanced FMAP in the below amounts for the specified time periods if they meet certain requirements, including existing rules around premium and eligibility standards, attempts to contact beneficiaries facing disenrollment, and other standards for the unwinding process:

- 6.2%: through 3/31/2023

²⁹ State Health Officer Letter 22-001, Ctrs. for Medicare & Medicaid Servs. (CMS) (Mar. 3, 2022), <https://www.medicaid.gov/federal-policy-guidance/downloads/sho22001.pdf>.

³⁰ Medicaid and CHIP Eligibility and Enrollment Policies as of January 2022: Findings from a 50-State Survey, Kaiser Family Foundation (KFF) (Mar. 16, 2022), <https://www.kff.org/medicaid/press-release/states-are-planning-for-the-end-of-the-continuous-enrollment-requirement-in-medicaid-after-the-covid-19-public-health-emergency-expires-but-many-have-not-made-key-decisions/>.

³¹ Medicaid and the Public Health Emergency, MACPAC, July 2022 (presentation available at: <https://www.macapac.gov/publication/medicaid-and-the-public-health-emergency/>).

³² Unwinding the Medicaid Continuous Enrollment Provision: Projected Enrollment Effects and Policy Approaches, HHS ASPE (Aug. 19, 2022), <https://aspe.hhs.gov/reports/unwinding-medicaid-continuous-enrollment-provision>.

³³ Fiscal and Enrollment Implications of Medicaid Continuous Coverage Requirement During and After the PHE Ends, KFF (May 10, 2022), <https://www.kff.org/medicaid/issue-brief/fiscal-and-enrollment-implications-of-medicaid-continuous-coverage-requirement-during-and-after-the-phe-ends/>.

³⁴ State Health Officer Letter 22-001.

³⁵ H.R. 2617 (2022), Pub. L. No: 117-328.

³⁶ CAA, 2023, Sec. 5131.

- 5%: 4/1/2023 – 6/30/2023
- 2.5%: 7/1/2023 – 9/30/2023
- 1.5%: 10/1/2023 – 12/31/2023

B. Home- and Community-Based Services Funding

The American Rescue Plan (ARP) increased the federal funding contribution for Home- and Community-Based Services (HCBS) from April 2021 through March 2022, as long as states met certain maintenance-of-effort requirements.³⁷ Although the ARP increase only extends for one year, states can expend the funds through 2025 and use this flexibility to make longer-term investments in their HCBS programs, such as technology and workforce investments.³⁸ All 50 states have now submitted spending plans to CMS and received permission to claim the full additional increase in HCBS matching funds.³⁹ The House-passed Build Back Better budget-reconciliation legislation in 2021 aimed to extend these investments, including through a permanent six-percentage-point increase in federal matching funds.⁴⁰ However, the Inflation Reduction Act passed in August 2022 using the budget reconciliation process did not include any HCBS-related provisions, nor did the CAA, 2023 include an extension of these increased matching funds.

C. Medicare and Medicaid Coverage Flexibilities

The Section 319 PHE provides significant flexibilities for CMS and states to expand coverage of services, such as services provided via telehealth, and to waive certain program requirements. These flexibilities generally depend on the existence of the Section 319 PHE, but Congress and CMS have taken a number of steps to preserve some flexibilities for some time after the end of the PHE.

1. Telehealth

Within Medicare, CMS used waiver authority under the PHE to make major expansions of telehealth, such as removing geographic restrictions, type of service restrictions, or requirements for site of service.

Some of these flexibilities have already been extended permanently in statute, with the Consolidated Appropriations Act of 2021 making permanent the availability of mental health services via telehealth for Medicare beneficiaries regardless of where they live. The Consolidated Appropriations Act of 2022 extended many major Medicare flexibilities through 151 days after the eventual end of the Section 319 PHE, including the ability to receive services via audio only

³⁷ American Rescue Plan, Sec. 9817 (P.L. 117–2).

³⁸ State Medicaid Director Letter #22-002, CMS (June 3, 2022), <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22002.pdf>.

³⁹ Strengthening and Investing in Home and Community Based Services for Medicaid Beneficiaries: American Rescue Plan Act of 2021 Section 9817 Spending Plans and Narratives, CMS (Dec. 2021), <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817-spending-plans-and-narratives/index.html>.

⁴⁰ H.R. 5376 (2021), Secs. 30711–30715.

and for beneficiaries to receive services at “any site in the United States at which the eligible telehealth individual is located at the time the service is furnished ... including the home of an individual.”⁴¹

In the CAA, 2023,⁴² Congress extended through December 31, 2024 most of the Medicare-related telehealth flexibilities, such as removals of geographic restrictions, availability of audio-only services, expansions of origination sites, and delays of in-person requirements for mental health services.

The HHS Office for Civil Rights also provided enforcement discretion under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which sets certain standards for the security of technology used for telehealth, to permit the use of commonly available, otherwise non-HIPAA-compliant technologies for telehealth (such as Skype or Zoom), “during the COVID-19 nationwide public health emergency.”⁴³ No action has been taken to make this flexibility permanent, although the American Medical Association has asked HHS to create a post-PHE “glide path” for enforcement.⁴⁴

Within Medicaid, states have had broad discretion to cover telehealth services even prior to the PHE, as laid out in two CMS FAQ documents released in 2020 and 2021, and states have been able to modify their State Plan Amendments rapidly to expand telehealth options through disaster-related waivers allowed by CMS during the PHE.⁴⁵ State plans for the future of these flexibilities vary: California, for instance, extended COVID-19-related Medicaid telehealth flexibilities throughout the end of the PHE and is currently in the process of updating its provider manual for permanent policies,⁴⁶ while New York State has extended flexibilities through the end of the Section 319 PHE or the issuance of future guidance by the state.⁴⁷

Many states also took temporary steps to allow provision of services through telehealth by providers not licensed within the state, although a recent survey found that only four states still have such emergency waivers in effect.⁴⁸ Some states, such as Arizona⁴⁹, have taken steps to make

⁴¹ Consolidated Appropriations Act, 2022, Sec. 301 (P.L. 117–203).

⁴² CAA, 2023, Sec. 4113.

⁴³ Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, HHS, <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>.

⁴⁴ RE: Glide Path for HIPAA Enforcement Discretion on Use of Telemedicine Platforms, Am. Med. Ass’n (Oct. 25, 2021), <https://www.ama-assn.org/practice-management/digital/need-glide-path-hipaa-telehealth-rules-pandemic-s-end>.

⁴⁵ State Medicaid & CHIP Telehealth Toolkit, CMS (2020), <https://www.medicare.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>; State Medicaid & CHIP Telehealth Toolkit Supplement #1, CMS (2021),

<https://www.medicare.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf>.

⁴⁶ Telehealth Flexibilities and Revisions to the Telehealth Provider Manual, Calif. Dep’t of Health Care Servs. (Jan. 6, 2023), https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_31960_06.aspx.

⁴⁷ Medicaid Update, N.Y. Dep’t of Pub. Health (June 2021), https://health.ny.gov/health_care/medicaid/program/update/2021/docs/mu_no07_jun21_speced_telehealth_pr.pdf.

⁴⁸ U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Fed. Of State Med. Bds. (Jan. 24, 2023), <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>.

⁴⁹ Executive Order 2021-13, <https://azgovernor.gov/file/37583/download?token=1o65XbrM>.

these flexibilities permanent, replacing the temporary flexibilities that were dependent on the state of emergency. Other states, such as New Jersey,⁵⁰ have extended the flexibilities for some time beyond the state’s public health emergency declaration.

2. Other Provisions

In Medicare, CMS has implemented a variety of blanket waivers for health care providers to increase access to care for beneficiaries by reducing various regulatory provisions, such as staffing, documentation, and quality reporting requirements.⁵¹ CMS has also created individual waiver programs for particular providers to apply for expanded flexibilities, such as Acute Hospital Care At Home waivers.⁵² More than 200 hospitals have received waivers under this program, which gives hospitals flexibility from Medicare conditions of participation in order to receive payment for care provided for acute conditions in a patient’s home.⁵³ CMS has noted that “[ma]ny existing Acute Hospital Care at Home programs provide [at-home hospital level of] care in assisted living but this waiver is not intended to be used by nursing home facilities. If care is provided in these facilities by a hospital, the hospital must work with the facility to ensure that there are not duplicate state or federal payments to facilities while a hospital is being paid for inpatient level care.”⁵⁴

These Medicare flexibilities are made possible by the Section 319 PHE and will end with its expiration. In April 2022, however, CMS issued a memorandum terminating some of the blanket waivers for particular sets of providers, including skilled nursing facilities, with some flexibilities ending 30 days from the issuance of the memorandum and some within 60 days.⁵⁵ In August 2022, CMS updated the memorandum with respect to nurse aide certification waivers specifically.⁵⁶ Such waivers can also be extended by legislation: In the CAA, 2023, Congress enabled the HHS Secretary to grant waivers under the Hospital Care At Home program through December 31, 2024.⁵⁷

In Medicaid, CMS has granted states a range of emergency waivers to modify their Medicaid programs. In order to modify existing waivers that states have under Section 1915(c) that apply to their HCBS programs, states can file a request for emergency modifications using an appendix to the Section 1915(c) waivers, Appendix K. All 50 states have used this Appendix K process to

⁵⁰ S. 4139, <https://legiscan.com/NJ/text/S4139/2020>.

⁵¹ COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers, CMS (Apr. 7, 2022), <https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf>.

⁵² CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge, CMS (Nov. 25, 2020), <https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge>.

⁵³ Approved Facilities/Systems for Acute Hospital Care at Home, CMS (May 26, 2022), <https://qualitynet.cms.gov/acute-hospital-care-at-home/resources>.

⁵⁴ Acute Hospital Care At Home Frequently Asked Questions, CMS, <https://qualitynet.cms.gov/acute-hospital-care-at-home/resources#tab2>.

⁵⁵ Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers, CMS (Apr. 7, 2022), <https://www.cms.gov/files/document/qso-22-15-nh-nltc-lsc.pdf>.

⁵⁶ Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers, CMS (Aug. 29, 2022), available at: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/update-covid-19-emergency-declaration-blanket-waivers-specific-providers-revised>.

⁵⁷ CAA, 2023, Sec. 4140.

make multiple changes to the operation of their HCBS programs,⁵⁸ with numerous states expanding services such as home-delivered meals or delivery of case management services via telemedicine.⁵⁹ States have also made technical changes to enrollment, with California, for instance, permitting some enrollment visits to occur via telemedicine⁶⁰ and providing accelerated intake for HCBS services for applicants in COVID-19 “hot spots.”⁶¹ Some Appendix K provisions have end dates prior to the end of the PHE, and CMS has stated that end dates for approved waivers will be no later than six months following the conclusion of the PHE.⁶²

III. EMERGENCY USE AUTHORIZATIONS

As discussed above, Section 564 of the Food, Drug, and Cosmetic Act provides for the HHS Secretary to make a declaration that authorizes the FDA to issue emergency use authorizations for countermeasures, which requires a different standard of approval than FDA would provide for products it regulates. Most of the countermeasures being used against COVID-19, including oral antivirals, monoclonal antibodies, and many testing tools, have received EUAs from the FDA.

A Section 564 declaration remains in effect until the Secretary makes a declaration that the threat no longer exists, or a particular EUA is revoked, at which point products under EUAs would need to receive the traditional approval, license, or clearance from FDA in order to remain on the market. Some EUA products have received the relevant approvals already, including certain diagnostics⁶³ and the initial dosing regimen of Pfizer⁶⁴ and Moderna vaccines⁶⁵ (but not the booster regimens or new bivalent boosters, which remain under EUA).

In November 2022, CMS finalized a proposal to extend certain payment levels for COVID-19 vaccinations beyond the Section 319 Public Health Emergency, as had been planned, through the end of the EUA declaration.⁶⁶ In August 2022, HHS published an analysis of coverage considerations around COVID-19 products and therapeutics that envisioned the EUA declaration continuing for some substantial period of time following the end of the Section 319 Public Health

⁵⁸ Emergency Preparedness and Response for Home and Community Based (HCBS) 1915(c) Waivers, CMS, <https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/home-community-based-services-public-health-emergencies/emergency-preparedness-and-response-for-home-and-community-based-hcbs-1915c-waivers/index.html>

⁵⁹ States Race to Secure Home- and Community-Based Services during COVID-19, NASHP (May 7, 2020), <https://www.nashp.org/states-race-to-secure-home-and-community-based-services-during-covid-19/>.

⁶⁰ Appendix K: CA.0141, CMS (Mar. 14, 2020), <https://www.medicaid.gov/state-resource-center/downloads/ca-0141-appendix-k-appvl.pdf>.

⁶¹ Appendix K: CA.0139, 0431 Combined, CMS (Sept. 17, 2020), <https://www.medicaid.gov/state-resource-center/downloads/ca-combined-5-appendix-k-appvl.pdf>.

⁶² State Health Officer Letter 20-004, CMS (Dec. 22, 2020), <https://www.medicaid.gov/federal-policy-guidance/downloads/sho20004.pdf>.

⁶³ FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process, Food & Drug Admin (FDA) (Mar. 17, 2021), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process>.

⁶⁴ FDA Approves First COVID-19 Vaccine, FDA (Aug. 23, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

⁶⁵ FDA Takes Key Action by Approving Second COVID-19 Vaccine, FDA (Jan. 31, 2022), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

⁶⁶ CY 2023 Final Physician Fee Schedule, 87 Fed. Reg. 69,404 (Nov. 18, 2022).

Emergency.⁶⁷ In the same month, HHS convened a gathering of stakeholders to discuss potential plans for transitioning medical countermeasures from federal purchases to “commercialization,” which in some cases will require adjustments to EUAs given to products. Taken together, it seems likely that the EUA declaration will remain in effect for some period of time following the end of the Section 319 declaration.

Section 564 declarations allowing for the issuance of EUAs for products have remained in effect for very long periods of time. For example, the Section 564 declarations regarding Ebola (issued in 2014 to allow EUAs for diagnostic tests⁶⁸) and Zika (issued in 2016 to allow for diagnostic EUAs⁶⁹) remain in effect. However, FDA has revoked certain broad, non-product-specific EUAs, such as certain non-approved respirators.⁷⁰ The agency also issued a draft guidance in December 2021 laying out the process for regularizing the status of products when a given EUA is terminated.⁷¹ Thus, although the Secretary’s Section 564 declaration regarding COVID-19 is likely to remain in effect for the foreseeable future, the agency does appear to envision that some products marketed under EUAs will see those authorizations terminated over time.

IV. CONCLUSION

The May 11, 2023, expiration of the federal COVID-19 PHE declaration will bring significant changes to federal health care programs and their participants, with various regulatory flexibilities expiring either immediately upon the end of the PHE or within a short period of time. However, many policy interventions to combat COVID-19 will continue after the formal end of the PHE: Stakeholders will continue pushing to make permanent flexibilities like broader Medicare coverage of telehealth, while liability protections under the PREP Act and the marketing of countermeasures under FDA Emergency Use Authorizations are subject to separate timeframes. Numerous states also have flexibility to continue state-level flexibilities, such as emergency orders that broaden telehealth access. Stakeholders that are making use of COVID-19 flexibilities should pay close attention to further communications from both federal agencies and state authorities, which can be expected to continue developing their plans for transitioning from an emergency footing.

⁶⁷ Understanding Coverage Considerations for COVID-19 Vaccines and Treatments, HHS ASPE (Aug. 31, 2022), <https://aspe.hhs.gov/reports/covid-19-vaccines-treatments>.

⁶⁸ Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus, HHS, 79 Fed. Reg. 47,141 (Aug. 12, 2014).

⁶⁹ Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection, HHS, 81 Fed. Reg. 10,878 (Mar. 2, 2016).

⁷⁰ FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators, FDA (June 30, 2021), <https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators>.

⁷¹ Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Draft Guidance for Industry and Food and Drug Administration Staff, FDA (Dec. 2021), <https://www.fda.gov/media/155039/download>.