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Memo

Date:	May 11, 2023
TO:	James Balda, President & CEO, Argentum
FR:	Thomas Barker, Partner Alexander Somodevilla, Associate Regina DeSantis, Associate
RE:	Implications of COVID-19 PHE Expiration

On January 31, 2020, then 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 (and final) extension ending May 11, 2023.[2]

This memo lays out the current state of various policy matters relevant to Argentum that pertain to the legal status of the COVID-19 emergency—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.[3]
- *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

[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 (February 9, 2023), https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.

[3] Many flexibilities under the Medicare and Medicaid programs also relied on the President's declaration of a national emergency. On April 10, 2023, President Biden signed H.J.Res. 7 into law, which officially ended this national emergency declaration.

[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).

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.

Pursuant to a January 30, 2023, Statement of Administration Policy, the Biden Administration will allow Section 319 PHE to expire on May 11, 2023.[7] The other two key federal emergency policies—under the PREP Act and Section 564 of the FDA—are unaffected by the lapse of the PHE.

Emergency policies can also be affected by states' own emergency declarations. As of May 3, 2023, six states had emergency declarations in place,[8] although this may change following the end of the federal PHE.

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

The first COVID-19 PREP Act declaration was issued in March 2020 and 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."

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[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] 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.

[8] States' COVID-19 Public Health Emergency Declarations, Nat'l Academy for State Health Policy (NASHP) (updated May 3, 2023), https://nashp.org/states-covid-19-public-health-emergency-declarations/.

[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).

- 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: In 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 EUAs, 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 (OGC) 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, OGC 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 PREP 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 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

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

[11] Letter from Robert Charrow to Thomas 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. Circuit for cases beyond willful misconduct, *see Cannon v. Watermark Ret. Cmtys., Inc*., 45 F.4th 137 (D.C. Circ. 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).

Congress failed to demonstrate intent to preempt state law.[16] Argentum 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] More recently, the Second Circuit in *Solomon v. St. Joseph Hospital* found that the PREP Act did not completely preempt the plaintiff's state-law claims for malpractice, negligence, or gross negligence.[19]

It should be noted that that 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,[20] but on November 21, 2022, the Supreme Court declined to consider the case.[21] 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 passed liability legislation related to COVID-19 in 2020 alone.[22]

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." The governor most recently renewed Texas' declaration on April 15, 2023, which is currently set to expire May 15, 2023.[23]

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[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] *Solomon v. St. Joseph Hosp.*, 62 F.4th 54 (2nd Cir. 2023).

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

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

[22] Nat'l Conference of State Legislatures, COVID-19 Liability Legislation (updated Feb. 1, 2021), https://www.ncsl.org/fiscal/covid-19-liability-legislation.

[23] Governor Abbott Renews COVID-19 Disaster Declaration In April 2023 (Apr. 15, 2023), https://gov.texas.gov/es/news/post/governor-abbott-renews-covid-19-disaster-declaration-in-april-2023.

- *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,[24] 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.[25]

- *Illinois*: While Illinois has not passed legislation to provide COVID-19-related liability protections, the governor issued an executive order in April 2020[26] citing existing Illinois statutes to provide certain emergency liability protections "for the duration of the Gubernatorial Disaster Proclamations" related to the virus (which also ends on May 11, 2023[27]).

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)[28] and does not narrow its eligibility criteria[29] 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 and recommends that states prioritize redeterminations by likelihood of current ineligibility. States have two months following the 12 month period to complete redeterminations,

[24] S.B. 359 (2020), https://www.legis.ga.gov/legislation/57192.

[25] H.B. 112 (2021), https://gov.georgia.gov/document/2021-signed-legislation/hb-112/download.

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

[27] Executive Order 2023-07 (Apr. 28, 2023), https://www.illinois.gov/government/executive-orders/executive-order.executive-order-number-07.2023.html.

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

[29] FFCRA Sec. 6008(b)(2).

and generally are encouraged by CMS to "mitigate churn for eligible beneficiaries and smoothly transition individuals between coverage programs."[30] A March 2022 survey found that, of 48 states that began planning for the redetermination process, 41 expected to initiate the process for enrollees within 9 to 12 months, while the remaining states were expected to do so more quickly.[31] 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.[32] 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.[33]

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.[34] One of the risk-based approaches proposed by CMS for redetermining eligibility would deprioritize populations like the aged "whose eligibility tends to be stable."[35]

In the Consolidated Appropriations Act, 2023 (CAA, 2023),[36] Congress created a new statutory framework for the unwinding of the enhanced FMAP and continuous coverage requirements, thereby allowing states to begin redeterminations on April 1, 2023.[37] Throughout 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:

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[30] 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.

[31] 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/.

[32] Medicaid and the Public Health Emergency, MACPAC, July 2022 (presentation available at: https://www.macpac.gov/publication/medicaid-and-the-public-health-emergency/).

[33] 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.

[34] 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/.

[35] State Health Officer Letter 22-001.

[36] H.R. 2617 (2022), Pub. L. No: 117-328.

[37] CAA, 2023, Sec. 5131.

- 6.2%: through 3/31/2023
- 5%: 4/1/2023 – 6/30/2023
- 2.5%: 7/1/2023 – 9/30/2023
- 1.5%: 10/1/2023 – 12/31/2023

On February 24, 2023, CMS released a list of anticipated state timelines for initiating the unwinding process; eight states began preliminarily processing their Medicaid renewals in February 2023, and five of these states—Arizona, Arkansas, Idaho, New Hampshire, and South Dakota—scheduled to begin terminations in April 2023.[38] The other three states—Iowa, Ohio, and West Virginia—scheduled to begin in May 2023.[39] The remaining states were scheduled to initiate unwinding processes in March and April, with terminations beginning in May, June, and July, except for Oregon, which has an October 2023 start date for terminations.[40]

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.[41] 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.[42] All 50 states have now submitted spending plans to CMS and received permission to claim the full additional increase in HCBS matching funds.[43] 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.[44] However, the Inflation Reduction Act (IRA), which passed in August 2022 using the budget reconciliation process, did

[38] Anticipated 2023 State Timelines for Initiating Unwinding-Related Renewals As of February 24, 2023, CMS (Feb. 24, 2023), https://www.medicaid.gov/resources-for-states/downloads/ant-2023-time-init-unwin-reltd-ren-02242023.pdf; *see also* Dorothy Mills-Gregg, Five States Scheduled To Begin Medicaid Disenrollments In April, Inside Health Policy (Mar. 2, 2023), https://insidehealthpolicy.com/daily-news/five-states-scheduled-begin-medicaid-disenrollments-april?destination=node/133794.

[39] Anticipated 2023 State Timelines for Initiating Unwinding-Related Renewals As of February 24, 2023, CMS (Feb. 24, 2023), https://www.medicaid.gov/resources-for-states/downloads/ant-2023-time-init-unwin-reltd-ren-02242023.pdf.

[40] Anticipated 2023 State Timelines for Initiating Unwinding-Related Renewals As of February 24, 2023, CMS (Feb. 24, 2023), https://www.medicaid.gov/resources-for-states/downloads/ant-2023-time-init-unwin-reltd-ren-02242023.pdf; *see also* Dorothy Mills-Gregg, Five States Scheduled To Begin Medicaid Disenrollments In April, Inside Health Policy (Mar. 2, 2023), https://insidehealthpolicy.com/daily-news/five-states-scheduled-begin-medicaid-disenrollments-april?destination=node/133794.

[41] American Rescue Plan, Sec. 9817 (P.L. 117–2).

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

[43] 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.

[44] H.R. 5376 (2021), Secs. 30711–30715.

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 provided significant flexibilities for CMS and states to expand coverage of services, such as those 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 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."[45]

In the CAA, 2023,[46] Congress extended 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, through December 31, 2024.

The HHS Office for Civil Rights (OCR) 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."[47] In an October 2021 letter to OCR, the American Medical Association asked HHS to create a post-PHE "glide path" for enforcement.[48] On April 13, 2023, OCR issued a rule announcing that its enforcement discretion will terminate with the end of the PHE, but providers will be given a 90-day transition period, meaning providers

[45] Consolidated Appropriations Act, 2022, Sec. 301 (P.L. 117–203).

[46] CAA, 2023, Sec. 4113.

[47] 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.

[48] 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.

will have until August 9, 2023 to "come into compliance with the HIPAA Rules with respect to their provision of telehealth using non-public facing remote communication technologies."[49]

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.[50] State plans for the future of these flexibilities vary: California, for instance, extended COVID-19-related Medicaid telehealth flexibilities through the end of the PHE and has been updating its provider manual for permanent policies,[51] while New York State announced in February 2023 that it will "continue to cover services delivered via audio-visual telehealth, when appropriate," and audio-only services when certain criteria are met.[52]

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.[53] Some states took steps to make these flexibilities permanent by replacing the temporary flexibilities that were dependent on the state of emergency; on June 5, 2021, Arizona enacted a law permitting health providers licensed in another jurisdiction, who are in good standing, to practice telemedicine in Arizona.[54] Other states extended flexibilities temporarily; in New Jersey, out-of-state providers can practice telemedicine in New Jersey for 60 days after the PHE ends.[55]

2. Other Provisions

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[49] Notice of Expiration of Certain Notifications of Enforcement Discretion Issued in Response to the COVID-19 Nationwide Public Health Emergency, 88 Fed. Reg. 22380 (Apr. 13, 2023).

[50] State Medicaid & CHIP Telehealth Toolkit, CMS (2020), https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf; State Medicaid & CHIP Telehealth Toolkit Supplement #1, CMS (2021), https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf.

[51] 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; Medi-Cal & Telehealth, Calif. Dep't of Health Care Servs. (revised Mar. 17, 2023), https://www.dhcs.ca.gov/provgovpart/Pages/Telehealth.aspx.

[52] New York State Medicaid Update - February 2023 Comprehensive Guidance Regarding Use of Telehealth including Telephonic Services After the Coronavirus Disease 2019 Public Health Emergency Special Edition Volume 39 - Number 3, N.Y. Dep't of Pub. Health (revised Mar. 2023), https://www.health.ny.gov/health_care/medicaid/program/update/2023/no03_2023-02_speced.htm.

[53] U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Fed. Of State Med. Bds. (updated Apr. 12, 2023), https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf.

[54] Executive Order 2021-13, https://azgovernor.gov/file/37583/download?token=1o65XbrM; *see also* U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Federation of State Medical Boards (updated Apr. 12, 2023), https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf.

[55] S. 4139, https://legiscan.com/NJ/text/S4139/2020; *see also* U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19, Federation of State Medical Boards (updated Apr. 12, 2023), https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf.

Medicare. 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.[56] For example, CMS used its authority to under Section 1812(f) of the Social Security Act to temporarily waive the requirement for a three-day hospitalization period for coverage of a stay in a skilled nursing facility (SNF); in addition to providing temporary coverage for a SNF stay, the waiver authorizes a one-time renewal for SNF coverage without a 60-day "wellness period" (defined as a 60-day period of non-inpatient status, which is normally required to end before restarting SNF benefits).[57] According to a cohort study recently published in *JAMA Internal Medicine*, this policy led to a significant increase in waiver episodes without preceding acute care (e.g., the three-day hospital stay) since the declaration of the PHE.

CMS has also created individual waiver programs for particular providers to apply for expanded flexibilities, such as Acute Hospital Care At Home waivers.[58] 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.[59] 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."[60] In the CAA, 2023, Congress enabled the HHS Secretary to grant waivers under the Hospital Care At Home program through December 31, 2024.[61]

Medicaid HCBS. In Medicaid, CMS granted states a range of emergency waivers to modify their Medicaid programs, particularly with respect to their HCBS programs. In order to modify existing waivers that states have under Section 1915(c) that apply to their HCBS programs, states could file a request for emergency modifications using an appendix to their Section 1915(c) waivers (Appendix K). All 50 states have used this Appendix K process to make multiple changes to the operation of their HCBS programs,[62] with numerous states expanding services such as home-

[56] 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.

[57] Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19, CMS (Feb. 24, 2023), https://www.cms.gov/files/document/long-term-care-facilities-cms-flexibilities-fight-covid-19.pdf.

[58] 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.

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

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

[61] CAA, 2023, Sec. 4140.

[62] 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

delivered meals or delivery of case management services via telemedicine.[63] States have also made technical changes to enrollment, with California, for instance, permitting some enrollment visits to occur via telemedicine[64] and providing accelerated intake for HCBS services for applicants in COVID-19 "hot spots."[65] 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.[66]

3. Coverage of COVID-19 Vaccinations, Testing, and Treatment

Section 3713 of the CARES Act requires Medicare to cover the COVID-19 vaccine and boosters without cost-sharing.[67] In subsequent rulemaking, CMS required Medicare to cover COVID-19 vaccines granted EUA, but not yet approved by the FDA, at no cost.[68] Medicare will still cover COVID-19 vaccines at no cost to beneficiaries after the PHE ends. Additionally, traditional (fee-for-service) Medicare will continue to cover COVID-19 antigen and PCR tests without cost-sharing, if ordered by a physician or health practitioner and performed in a laboratory, after the PHE ends; cost-sharing for Medicare Advantage (MA) enrollees might change after the PHE ends, but MA plans may continue to cover over the counter tests as a supplemental benefit.[69] According to CMS, the end of the PHE will not change Medicare coverage for COVID-19 treatments (additionally, cases where cost-sharing or deductibles currently apply will not change).[70]

As required by the ARP, after the PHE ends, Medicaid will continue to cover COVID-19 vaccines, testing, and treatment, without copayments or cost-sharing, through September 30, 2024, after which Medicaid will continue to cover Advisory Committee on Immunization Practices (ACIP)-

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[63] 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/.

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

[65] 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.

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

[67] Jennifer Kates et al., Commercialization of COVID-19 Vaccines, Treatments, and Tests: Implications for Access and Coverage, Kaiser Family Foundation (Feb. 13, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/commercialization-of-covid-19-vaccines-treatments-and-tests-implications-for-access-and-coverage/#footnote-567083-1.

[68] Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 71142, 71146 (Nov. 6, 2020) ("…even though section 3713 of the CARES Act refers to a COVID-19 vaccine 'licensed under section 351 of the PHS Act,' CMS could consider any vaccine for which FDA issued an EUA during the PHE, when furnished consistent with terms of the EUA, to be eligible for Medicare coverage and payment.").

[69] CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

[70] CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

recommended vaccines for most beneficiaries.[71] However, when the requirements under the ARP expire, Medicaid and CHIP coverage for treatment and testing for COVID-19 will vary by state.[72] According to CMS, 18 states and U.S. territories opted to extend Medicaid coverage for COVID-19 vaccinations, testing, and treatment to uninsured individuals during the PHE, therefore, this coverage ends on May 11, 2023.[73]

Most individuals with private health insurance will generally continue to have access without cost-sharing to COVID-19 vaccines with a formal recommendation by ACIP.[74] However, mandatory coverage for over the counter and laboratory-based COVID-19 tests will end with the PHE, after which coverage will vary by plan (e.g., there may be cost-sharing).[75] When the PHE ends, private insurance plans are not expected to change their current coverage policies for COVID-19 treatment.[76]

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 EUAs 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

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[71] Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, HHS (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html; CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

[72] Jennifer Kates et al., Commercialization of COVID-19 Vaccines, Treatments, and Tests: Implications for Access and Coverage, Kaiser Family Foundation (Feb. 13, 2023), https://www.kff.org/coronavirus-covid-19/issue-brief/commercialization-of-covid-19-vaccines-treatments-and-tests-implications-for-access-and-coverage/#footnote-567083-1; CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency; State Health Officer Letter 21-006, CMS (Oct. 22, 2021), https://www.medicaid.gov/federal-policy-guidance/downloads/sho102221.pdf.

[73] CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

[74] Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, HHS (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

[75] CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

[76] CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency, CMS (Feb. 27, 2023), https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency.

diagnostics[77] and the initial dosing regimen of Pfizer[78] and Moderna vaccines[79] (but not the booster regimens or new bivalent boosters, which remain under EUA).

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 tests[80]) and Zika (issued in 2016 to allow for diagnostic EUAs[81]) remain in effect. However, FDA has revoked certain broad, non-product-specific EUAs, such as certain non-approved respirators.[82] The agency also issued a draft guidance in December 2021 (finalized in March 2023) laying out the process for regularizing the status of products when an EUA is terminated.[83] 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 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 EUAs are subject to separate timeframes. Stakeholders 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.

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[77] 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.

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

[79] 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.

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

[81] 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).

[82] 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.

[83] Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff, FDA (Mar. 27, 2023), https://www.fda.gov/media/155039/download.