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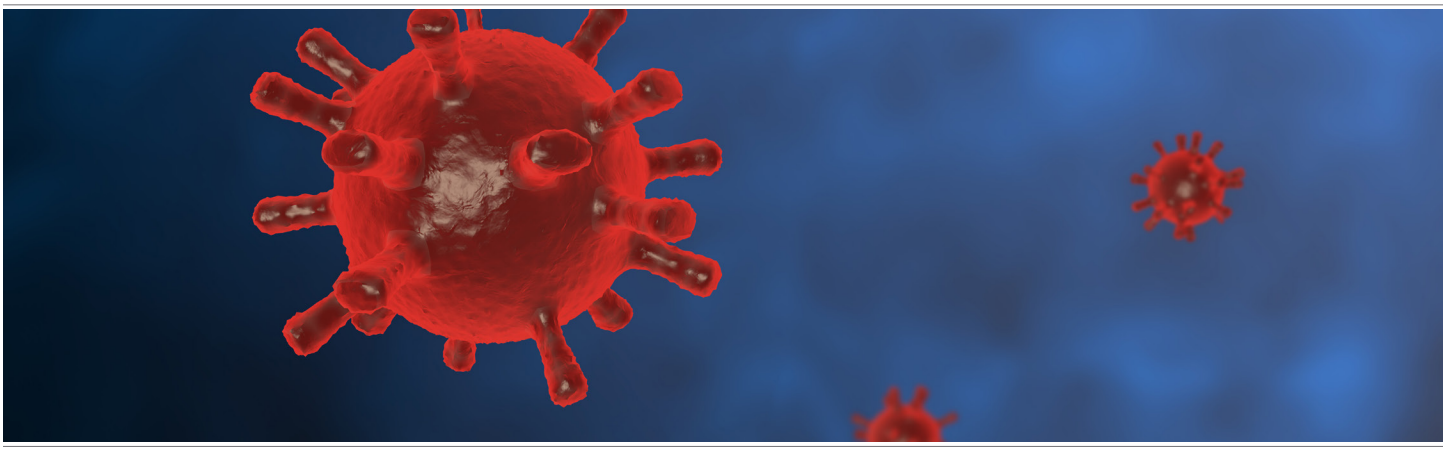

Tracking the Waivers: Implications of the Wind Down of the COVID-19 Public Health Emergency

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I. Introduction

The White House recently announced that the COVID-19 national emergency and public health emergency (PHE) declarations will end on May 11, 2023. These declarations have been in place since the beginning of the COVID-19 pandemic and provided the federal government with flexibility to waive or modify certain regulatory requirements applicable to the healthcare industry. The end of the PHE has significant implications, given that a relatively short and closing window remains for the industry to prepare for the reinstatement of waived requirements and to implement adjustments to internal operations. This article highlights the key changes that will occur upon the expiration of the PHE.

Emergency Declarations

In early 2020, the federal government issued several emergency declarations in response to the COVID-19 pandemic. Federal agencies including the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Drug Enforcement Agency (DEA) subsequently issued temporary waivers and new rules that resulted in the relaxation of certain regulations and provision of flexibilities to enable the healthcare industry to quickly and adequately respond to the COVID-19 pandemic.

HHS Waivers

Section 1135 of the Social Security Act (SSA) permits the Department of Health and Human Services (HHS) to temporarily waive various administrative requirements to increase access to medical services and make federal healthcare program reimbursement available in the event that providers cannot comply with certain requirements that would otherwise prohibit such reimbursement during a PHE. These waivers, commonly referred to as "1135 waivers", include both Medicare blanket waivers and provider/supplier individual waivers.

Medicare blanket waivers require specific waivers or modifications to be implemented on a "blanket" basis when a determination has been made that all similarly situated providers involved in the emergency require a waiver or modification. Once approved, these waivers apply automatically to all applicable providers and suppliers. In contrast, provider/supplier individual waivers can be issued for states, providers, or suppliers and need only be secured in the

event that a modification is required beyond the scope of an existing blanket waiver.

During the COVID-19 pandemic, HHS issued blanket waivers for hospitals and healthcare facilities and in the areas of provider licensing and enrollment, suspension of certain enforcement activities, telehealth, signature requirements, and financial relief for Medicare providers, among others. In addition, CMS approved a number of individual state waivers to provide flexibilities for Medicaid's program requirements.

Separate from the implementation of HHS waivers, Congress enacted certain legislation during the pandemic that provides additional flexibility for certain regulatory requirements applicable to the healthcare industry.

Waiver Implications

The PHE is set to come to an end, which will lead to the phasing out of most of the programs and waivers that were put in place during the COVID-19 pandemic. While a majority of these waivers will end on May 11, 2023, along with the emergency declarations, some waivers have been extended for a longer period of time.

To ensure continuity of care for Medicare beneficiaries and provide additional time for regulators to determine which flexibilities should be made permanent, President Biden signed into law the Consolidated Appropriations Act (CAA), which allocates more than $1.7 trillion in funding across a range of domestic initiatives and extends until December 31, 2024 certain flexibilities, such as Medicare coverage and payment for telehealth services and the acute hospital care at home program. This extension will enable healthcare providers to more easily adapt to a changing regulatory landscape. In addition, the Inflation Reduction Act of 2022 (IRA) made important changes to prescription drug coverage under Medicare Part B and D, which cement certain PHE flexibilities such as vaccine coverage for Part D beneficiaries.

It is crucial for the healthcare industry to be aware of the current status of applicable provisions, given the varying end dates for the wide range of PHE-related waivers, and prepare accordingly. Below please find a summary of the key changes and potential implications in the following areas:

*This list is limited to federal waivers and not intended to be exhaustive – for a complete list of the expiring federal waivers, please review the fact sheet and summaries prepared by CMS.

II. Coverage, Costs and Payments for COVID-19 Testing, Treatment and Vaccines

	COVID-19 Testing/Diagnosis		COVID-19 Treatment		COVID-19 Vaccines	
	During PHE	**After PHE Expiration**	**During PHE**	**After PHE Expiration**	**During PHE**	**After PHE Expiration**
Medicare	Covers without cost-sharing. Includes coverage for up to eight over-the counter COVID-19 tests per beneficiary per month. Covers one health practitioner-administered test without practitioner order, but order required for further tests. Covers antibody (serology) tests for patients with known or suspected current or prior infection.	Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted COVID-19 tests when ordered by a provider, but their current access to free over-the-counter (OTC) COVID-19 tests will end. Part C enrollees may have some cost-sharing when the PHE ends.	Monoclonal Antibodies: Covers beneficiaries without cost-sharing. No deductible when administered by provider. Oral Antivirals: Covers without cost-sharing or deductible. VEKLURYTM (remdesivir) in the Outpatient Setting: In most cases, beneficiary's yearly Part B deductible and 20% co-insurance apply.	Monoclonal Antibodies: No chvange. Oral Antivirals: Must be covered by Part D plans if meet statutory requirements for Part D coverage. VEKLURYTM (remdesivir) in the Outpatient Setting: No change.	Covers in-and out-patient setting without cost-sharing.	Covered under Part B without cost-sharing. Per the IRA, covered for Part D enrollees.
Medicaid and CHIP[1]	Covers full benefit enrollees without cost-sharing. Includes over-the-counter tests, but states may require a prescription or other conditions.	Terminates on September 30, 2024, after which coverage may vary by state.	Covers full benefit enrollees without cost-sharing.	Coverage without cost-sharing terminates on September 30, 2024, after which coverage may vary by state.	Covers all enrollees without cost-sharing.	Covered under IRA and American Rescue Plan Act (ARPA) without cost sharing.
Medicaid Optional COVID-19 Coverage	• During the PHE, states can file a Disaster Relief State Plan Amendment with CMS to provide COVID-19 testing, vaccination, and treatment to uninsured individuals, regardless of their income. o 18 states and U.S. territories have opted to provide Medicaid coverage to uninsured individuals for COVID-19 vaccinations, testing, and treatment o Limited beneficiary enrollees qualify for testing/diagnosis and treatment through this option. • This option terminates at PHE expiration.					

1 Medicaid provisions remain in place until the end of the first quarter that begins one year after PHE expiration, *i.e.*, until September 30, 2024. "CHIP" means the Children's Health Insurance Program.

	COVID-19 Testing/Diagnosis		COVID-19 Treatment		COVID-19 Vaccines	
Private Health Insurance	Covers without cost sharing or prior authorization even when provided by out-of-network providers. Includes coverage for up to eight over-the counter COVID-19 tests per beneficiary per month, without physician's order or prescription. Required minimum reimbursement for health plans of $12 per test.	Requirements terminate; Coverage will vary by state and insurer.	Regular cost-sharing policies apply.	Coverage will vary by state and insurer.	May cover with or without cost-sharing (coverage not required).	Most forms of private health insurance must continue to cover COVID-19 vaccines furnished by an in-network health care provider without cost sharing. People with private health insurance may need to pay part of the cost if an out-of-network provider vaccinates them.

During the PHE, Medicare, Medicaid/CHIP, and private health insurance coverage were broadly extended to cover COVID-19 testing/diagnosis, treatments, and vaccines for both insured and uninsured individuals to maximize accessibility and limit the spread and impact of COVID-19. After the expiration of the PHE, coverage will be highly varied – while COVID-19 testing and treatment will ultimately be reduced in 2025 and beyond, coverage for COVID-19 vaccines under Medicare, Medicaid and CHIP will continue. Coverage by private health insurance will vary greatly depending on state and insurer, as federal requirements to ensure access to COVID-19 testing and vaccines will terminate with the expiration of the PHE.

III. Medicaid and CHIP Eligibility

Before the pandemic, state Medicaid agencies conducted yearly eligibility reviews of Medicaid enrollees and were permitted to disenroll ineligible individuals. During the PHE, the Families First Coronavirus Response Act ("FFCRA") paused this eligibility review process and prohibited state Medicaid agencies from involuntarily disenrolling beneficiaries or transferring enrollees to a different coverage group that provides a more restrictive benefit package. After the PHE expires in May 2023, and although the Biden administration has granted states an extra 14 months after the termination of the PHE to resume disenrollment processes, state Medicaid agencies are permitted to begin disenrollment activities immediately.

As a result, Urban Institute and HHS estimate that 15-18 million Americans will lose Medicaid coverage over the course of the fourteen months after the termination of the PHE. The Urban Institute further estimates that, of those that lose Medicaid coverage, approximately 17% will be children that will transition to CHIP coverage, 21% will become uninsured, 53% will become exclusively reliant on employer-sponsored private insurance, and 5% will enroll in the nongroup market.

The Medicaid.gov website contains many guidance documents that include information on Medicaid continuous

enrollment condition changes, conditions for receiving federal medical assistance under the FFCRA, changes to reporting requirements, and enforcement provisions in the CAA.

IV. Impact to Medicare Shared Savings Program, Medicare Advantage (MA), and Part D

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Shared Savings Program[2]		
Extreme and Uncontrollable Circumstances Policy on Calculation of Shared Losses[3]	CMS mitigated shared losses for all ACOs participating in a performance-based risk track, including: the ENHANCED track, BASIC track, levels C through E.	Standard calculations will resume under 42 CFR § 425.512 and CMS rulemaking.
Extreme and Uncontrollable Circumstances Policy on Quality Reporting	CMS allowed ACOs that are unable to report quality data via the Alternative Payment Model Performance Pathway to have their ACO quality performance score set equal to the 30th percentile Merit-based Incentive Payment System (MIPS) quality performance category score.	Standard quality reporting will resume under 42 CFR § 425.512 and CMS rulemaking.
Participation in the Shared Savings Program	For PY 2023, CMS allowed BASIC track ACOs participating in the glide path that elected to forgo their first automatic advancement along the glide path's increasing levels of risk and potential reward in PY 2021 and PY 2022, to be automatically advanced to the level at which they would have otherwise participated under automatic advancement.	Flexibility terminates. ACOs will be able to elect to operate under the automatic advancement track only as specified by 42 CFR § 425.600 and CMS rulemaking.
Financial Methodology	CMS removed all Parts A and B payment amounts for episodes of care for treatment of COVID-19 from the determination of benchmark year and performance year expenditures.	Part A and Part B payment amounts for COVID-19 treatment will be included in the determination of benchmark year and performance year expenditures.
Medicare Advantage[4]		
Expanded Benefits	CMS allowed Medicare Advantage plans to expand telehealth services and other mid-year benefit enhancements, beyond those included in their approved 2020, 2021, and 2022 bids describing covered benefits, when such mid-year benefit enhancements are provided in connection with the COVID-19 outbreak, are beneficial to enrollees, and are provided uniformly to all similarly situated enrollees.	Flexibility terminates. Prohibition on mid-year benefit enhancements will resume and MAOs must terminate the practice of offering COVID-19-related services as mid-year benefit enhancements.
Audit Reviews	CMS temporarily reprioritized audit activity in 2020 under its oversight discretion, returned to normal oversight activities in 2021, and continued providing flexibility to audited organizations when needed.	Under its oversight discretion, CMS will continue to provide flexibility to audited organizations when CMS determines that this flexibility is necessary.

2 Medicare Shared Savings Program: CMS Flexibilities to Fight COVID-19

3 The Secretary's declaration of the PHE for COVID-19 in January 2020 triggered the Medicare Shared Savings Program's Extreme and Uncontrollable Circumstances Policy under 42 CFR § 425.512.

4 Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Appeals: Timeline to File an Appeal[5]	CMS extended the timeframe for filing a request for appeal if there was good cause for the late filing.	Flexibility will continue to apply, so long as there is good cause for the late filing as consistent with regulatory requirements.
Appeals: Requests for Additional Information to Adjudicate Appeals	CMS waived requirements for timeliness for requests for additional information to adjudicate appeals.	Flexibility will continue to apply, so long as requests for appeals meet existing regulatory requirements.
Appeals: Appointment of Representation Form	CMS allowed the processing of an appeal even with incomplete Appointment of Representation forms (any communication was sent only to the beneficiary).	Flexibility terminates. Beneficiaries will need to ensure that Appointment of Representation forms are complete before plans may process appeals.
Appeals: Requests for Appeal	CMS allowed plans to process requests for appeal that do not meet the required elements, but instead use information that is available.	Flexibility terminates. Plans will only be able to process requests for appeal that meet all of the required elements, and will not be able to use externally available information to process the appeal.
Part D Plans[6]		
Prior Authorization of Part D Drugs	Part D Sponsors may waive or relax prior authorization requirements at any time for formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers.	Flexibility terminates. Part D Sponsors will not be able to waive or relax prior authorization requirements for formulary drugs.
Part D "Refill-Too-Soon" Edits and Maximum Day Supply	Consistent with section 3714 of the CARES Act, CMS required Part D sponsors to permit enrollees to obtain the total supply prescribed for a covered Part D drug up to a 90-day supply in one fill or refill, if requested by the enrollee, prior authorization or step therapy requirements. Additionally, Part D plan sponsors were required to relax their "refill-too-soon" edits. Part D sponsors continued to have operational discretion as to how these edits are relaxed, as long as access to Part D drugs is provided at the point of sale.	Requirement terminates. Part D Sponsors will no longer be required to permit enrollees to obtain the total supply prescribed in one fill or refill. Part D Sponsors will no longer be required to relax "refill-too-soon" edits, and will continue to have operational discretion as to if and how such edits are relaxed.
Home or Mail Delivery of Part D Drugs	CMS allowed Part D Sponsors to voluntarily relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery, for retail pharmacies that choose to offer these delivery services in such instances.	Flexibility terminates. Part D Sponsors will still be allowed to voluntarily relax plan-imposed policies that discourage certain methods of delivery for retail pharmacies in situations when a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy.
Audit Reviews	CMS temporarily reprioritized audit activity in 2020 under its oversight discretion, returned to normal oversight activities in 2021, and continued providing flexibility to audited organizations when needed.	Under its oversight discretion, CMS will continue to provide flexibility to audited organizations when CMS determines that this flexibility is necessary.

5 Per Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19, CMS flexibilities pertaining to the appeals process were also applied to Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the Fee For Service program (42 CFR 405.942 and 42 CFR 405.962).

6 Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Appeals: Timeline to File an Appeal	CMS extended the timeframe for filing a request for appeal if there was good cause for the late filing.	Flexibility will continue to apply, so long as there is good cause for the late filing as consistent with regulatory requirements.
Appeals: Requests for Additional Information to Adjudicate Appeals	CMS waived requirements for timeliness for requests for additional information to adjudicate appeals.	Flexibility will continue to apply, so long as requests for appeals meet existing regulatory requirements.
Appeals: Appointment of Representation Form	CMS allowed the processing of an appeal even with incomplete Appointment of Representation forms (any communication was sent only to the beneficiary).	Flexibility terminates. Beneficiaries will need to ensure that Appointment of Representation forms are complete before plans may process appeals.
Appeals: Requests for Appeal	CMS allowed plans to process requests for appeal that don't meet the required elements, but instead use information that is available.	Flexibility terminates. Plans will only be able to process requests for appeal that meet all of the required elements, and will not be able to use externally available information to process the appeal.

During the PHE, HHS temporarily modified and waived certain MSSP, MA, and Part D requirements to allow providers to rapidly respond to people impacted by COVID-19 so as to ensure continued access to the health care they needed. The majority of these waivers are currently active, but are set to terminate at the conclusion of the PHE. In preparation for a return to pre-PHE requirements, health plans and providers should:

- Conduct an analysis of the organization's current operational policies and procedures to ensure compliance with post-pandemic Medicare regulatory requirements, updating them if necessary; and
- Ensure that processes are in place to train staff accordingly.

V. Telehealth

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Medicare Waivers & Flexibilities		
Clinician Services	CMS added 200+ codes to the Medicare Telehealth Services List (List), which afforded eligibility for reimbursement.	Some codes have been added permanently to the List. All codes on the List for CY 2023 are available through 2023, with revisions anticipated for CY 2024.
Communication Technology-Based Service/Remote Evaluation Services	CMS allowed clinicians to provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients.	Waiver terminates. Medicare will no longer reimburse remote evaluations of patient video/images and virtual check-in services for new patients.
Expansion of Practitioners Who May Bill For E-Visits	CMS allowed licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists to provide e-visits (HCPCS codes G2250- G2251).	Waiver terminates. Medicare will no longer reimburse e-visits provided by LCSWs, clinical psychologists, PTs, OT, and SLPs.
Payment for Telephone E/M Visits	CMS allowed payment for telephone E/M visits (CPT codes 99441-99443) to be equivalent to the Medicare payment for office/outpatient visits with established patients.	Waiver terminates 151 days after end of PHE. Medicare will no longer allow payment for telephone E/M visits to be equivalent to the Medicare payment for office/outpatient visits.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Use of Telephone E/M Codes for Audio-Only Technology	CMS allowed clinicians to bill for E/M services furnished using audio-only technology.	Waiver terminates 151 days after end of PHE. Clinicians will not be able to bill for E/M services furnished using audio-only technology.
RPM for New Patients	CMS permitted clinicians to bill for RPM services furnished to new patients.	Waiver terminates. Clinicians will not be able to bill for RPM services furnished to new patients, but rather will need to have an established relationship with the patient before billing for RPM services.
Billing for RPM Services With <16 Days of Data	CMS allowed clinicians to bill codes 99453 and 99454 with less than 16 days of collected physiologic data, if patient diagnosed with, or suspected of having, COVID-19.	Waiver terminates. Clinicians will only be able to bill for RPM services with at least 16 days of collected data.
Removal of Frequency Limitation of Subsequent Inpatient Visit	CMS removed the limitation that inpatient telehealth visits be no more frequent than once every three days (CPT codes 99231-99233).	Waiver terminates. Subsequent inpatient visits may only be furnished via telehealth once every three days
Removal of Frequency Limitation of Subsequent SNF Visit	CMS removed the limitation that telehealth visits with SNF residents be no more frequent than once every fourteen days (CPT codes 99307- 99310).	Waiver terminates. Skilled nursing facility visits may only be furnished via telehealth once every fourteen days
Removal of Frequency Limitation of Critical Care Consult Codes	CMS removed the limitation that critical care consult codes be billed no more than once per day (CPT codes G0508-G0509).	Waiver terminates. Critical care consults may only be furnished via telehealth once per day
Home Dialysis Monthly ESRD-Related Visits	CMS allowed these visits to be furnished via telehealth.	Waiver terminates. Medicare will no longer reimburse home dialysis monthly ESRD-related visits if furnished via telehealth.
Face-To-Face, In-Person Visits For Evaluations and Assessments	CMS removed NCD or LCD requirements for evaluations and assessments to be provided face-to-face or in-person.	Waiver terminates. Prior requirements for face-to-face or in-person visits will be reinstated.
Annual Beneficiary Consent For Virtual Check-Ins	CMS allowed consent for virtual check-ins to be obtained at the time of service.	Flexibility will continue indefinitely.
Physician Visits For Nursing Home Residents	CMS allowed physicians to conduct visits with nursing home residents via telehealth.	Waiver terminates. Medicare will no longer reimburse physicians for telehealth visits with nursing home residents.
Opioid Treatment Program Periodic Assessments	CMS waived the requirement to furnish periodic opioid program treatment assessments in-person or via two-way A/V technology.	Waiver terminates. Periodic opioid program treatment assessments must be furnished in-person or via two-way A/V technology.
Hospital Originating Site Facility Fee For Professional Services Furnished Via Telehealth	CMS allowed hospitals to bill for the originating site facility fee when a practitioner who typically furnishes services in the outpatient department furnished telehealth services to the patient's home as a "distant site" practitioner.	Waiver terminates. CMS will no longer permit hospitals to bill for the originating site facility fee when a practitioner furnishes services to the patient's home as a "distant site" practitioner.
Hospital-Only Remote Outpatient Therapy and Education Services	CMS allowed hospital-only remote outpatient therapy and education services to be furnished to a beneficiary in their home via telehealth.	Waiver terminates. CMS will no longer permit hospital-only remote outpatient therapy and education services to be furnished to a beneficiary via telehealth.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Agreement With Distant Site Hospitals	CMS waived certain Conditions of Participations for Hospitals and Critical Access Hospitals related to agreements with offsite hospitals.	Waiver terminates. CMS will reinstate Conditions of Participations for Hospitals and Critical Access Hospitals for agreements with offsite hospitals.
Reporting Home Address	CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.	Waiver terminates. Practitioners will no longer be permitted to render telehealth services from their home unless they report their home address on their Medicare enrollment.
CMHC Provision of Partial Hospitalization Services In Patient Home	CMS waived the prohibition against CMHCs providing partial hospitalization and other CMHC services in an individual's home.	Waiver terminates. CMHCs will be unable to provide partial hospitalization services in the patient's home.
CMHC Partial Hospitalization Services	CMS allowed CMHCs to furnish and bill for individual psychotherapy, patient education, and group psychotherapy delivered in temporary expansion locations, including patient homes, via telehealth.	Waiver terminates. CMS will no longer allow CMHCs to furnish and bill individual psychotherapy, patient education, and group psychotherapy delivered in temporary expansion locations via telehealth.
Teaching Physician Services	CMS allowed teaching physicians to use audio/video real time communications technology to interact with the resident physician, for certain services.	Waiver terminates. CMS will no longer permit teaching physicians to use A/V technology to interact with resident physicians.
In-Patient Rehab Facility Face-To-Face Visit	CMS allowed physicians to use telehealth to complete the required inpatient rehab facility visit at least three days a week for the duration of a Medicare Part A fee-for-service patient's stay in an inpatient rehabilitation facility.	Waiver terminates. Physicians will need to complete inpatient rehabilitation facility visits face-to-face.
Federal Cost-Sharing Waivers	OIG will not impose administrative sanctions for practitioners who reduce or waive cost-sharing obligations that a beneficiary may owe for telehealth services.	Waiver terminates, after which practitioners may face OIG administrative sanctions for reducing or waiving cost-sharing obligations that a beneficiary owes for telehealth services.
FQHC/RHC Provision of Telehealth Services	CMS authorized FQHCs/RHCs to serve as a distant site provider for behavioral/mental telehealth services.	HHS states that this is a permanent Medicare change.[7]
FQHC/RHC Provision of Telehealth Services	CMS authorized FQHC/RHCs to serve as a distant site provider for non-behavioral/mental telehealth services.	Waiver extended until December 31, 2024. On and after January 1, 2025, FQHC/RHCs will not be able to serve as a distant site provider for non-behavioral/mental telehealth services unless rules or legislation extend this waiver again.
Physician Supervision of NPs in FQHCs/RHCs	CMS authorized physicians to provide medical direction of NPs in FQHCs and RHCs via telehealth and other remote communications.	Waiver terminates. Physicians will be required to provide in-person supervision of nurse practitioners in FQHCs and RHCs.
Supervision of Health Care Providers	CMS allowed health care providers to supervise services through A/V communication, instead of only in-person.	Waiver terminates December 31, 2023. On and after January 1, 2024, CMS will no longer permit providers to use A/V technology to supervise health care services.

7 Telehealth policy changes after the COVID-19 public health emergency | Telehealth.HHS.gov

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Licensure Requirement	CMS waived the requirement that a physician or non-physician practitioner be licensed in the state in which they are practicing if, among other requirements, they are furnishing services via telehealth in a state in which the emergency is occurring.	Waiver terminates. Physicians and practitioners will need to be licensed in the state in which they are practicing.
Types of Eligible Providers	CMS allowed any provider who is eligible to bill Medicare to bill for the same services, if provided via telehealth.	Waiver terminates. Only eligible providers, as determined by the CAA and CMS rulemaking, will be eligible to bill for services provided via telehealth.
Out-Of-State Telehealth Services	HHS approved health care providers to deliver care via telehealth across state lines.	Waiver terminates. As a general matter, health care providers will not be able to provide telehealth services across state lines.
Diagnosis, Evaluation and Treatment of Mental Health Disorder	With respect to services associated with mental health disorders, CMS removed originating site geographic restrictions and added an individual's home as a permissible originating site.	Flexibility will continue indefinitely.
In-Person Visit Requirement for Telehealth Mental Health Services	CMS waived the requirement for physicians and practitioners to conduct in-person exams within six months before an initial telehealth service for purposes of diagnosis, evaluation, or treatment of a mental health disorder.	Waiver extended until January 1, 2025. On and after January 2, 2025, an in-person exam will be required within six months prior to an initial telehealth mental health service.
Audio-Only Telehealth for Behavioral/Mental Health Care	CMS allowed audio-only telehealth for behavioral/mental health care if the patient does not have A/V technology.	Flexibility will continue indefinitely.
Definition of "Originating Site"	CMS allowed any site in the United States to serve as an originating site, including the patient's home.	Waiver extended until December 31, 2024. On and after January 1, 2025, the patient's home will not be included in the definition of originating site.
Definition of "Practitioner"	CMS expanded the definition of "practitioner" to include a qualified occupational therapist, qualified physical therapist, a qualified speech-language pathologist, and a qualified audiologist.	Waiver extended until December 31, 2024. On and after January 1, 2025, the definition of practitioner will not include these service providers.
Audio-Only Telehealth	CMS allowed telehealth services furnished using audio-only telecommunications technology to be covered and reimbursable.	Waiver extended until December 31, 2024. On and after January 1, 2025, audio-only telehealth services will not be covered and reimbursable (with certain exceptions).
Recertification of Eligibility For Hospice Care	CMS permitted the use of telehealth for conducting face-to-face encounters prior to recertification of eligibility for hospice care.	Waiver extended until December 31, 2024. On and after January 1, 2025, recertification of eligibility for hospice care will need to be conducted in person.
DEA Waivers		
Prescription of Controlled Substances – Ryan Haight Act	DEA waived the requirement for an in-person visit to predicate the prescription of controlled substances via telehealth.	Waiver has been extended an additional 180 days. After this, the Ryan Haight Act's in-person requirement will again be enforced by DEA unless DEA proposed rule is finalized.[8]

8 2023-04248.pdf (govinfo.gov)

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Prescription of Buprenorphine	DEA authorized practitioners to prescribe buprenorphine to new and existing patients with opioid use disorder via telephone.	Waiver terminates. Practitioners will not be able to prescribe buprenorphine to new and existing patients with opioid use disorder via telephone unless DEA proposed rule is finalized.[9]

Given the sheer number of telehealth-related waivers, and the inconsistency in termination status at the end of the PHE, including various dates of termination and extension, practitioners and providers relying on such waivers should carefully monitor the status of telehealth flexibilities. The termination of telehealth-related waivers heralds substantial operational and billing changes for the healthcare industry, including:

- Discontinuation of reimbursement for many visits, services, and clinical supervision currently performed with the aid of remote technology;
- Resumption of in-person evaluation requirements, which may cause significant clinical workflow changes for patients and practitioners alike, as well as the many facilities that host them;
- Reinstatement of state licensure requirements and restrictions;
- Loss of a hospital's ability to receive an originating site facility fee in certain circumstances; and
- Reinstatement of requirement that at least 16 days' of data have been collected in order to bill certain RPM services provided to patients diagnosed with or suspected of having COVID-19.

The status of these flexibilities is subject to continued change as federal legislation has been proposed and industry groups have called for permanent extension of certain flexibilities. The submission of claims for services provided via telehealth is subject to heightened regulatory scrutiny and has been designated as an area of enforcement focus. As the PHE draws to a close, entities utilizing telehealth should evaluate their operational and billing policies, procedures, and practices to ensure compliance with federal and state law, *e.g., to ensure that claims for payment do not represent services as furnished in-person, if they continue to be furnished (or supervised) with the assistance of remote technology.*

VI. HIPAA Enforcement

On April 21, 2020, the HHS Office for Civil Rights (OCR) published guidance stating that it would not impose penalties for noncompliance with HIPAA regulatory requirements applicable to covered health care providers in connection with the good faith provision of telehealth services during the PHE. This discretion will end with the termination of the PHE, meaning that OCR will again enforce penalties for noncompliance with HIPAA provisions. As a result, covered health care providers should consider:

- Prohibiting or appropriately restricting patient-facing communications on popular videotelephony applications that do not meet HIPAA standards, many of which were frequently utilized during the COVID-19 pandemic;
- Communicating with staff that use of such platforms may need to cease after the expiration of the PHE;
- Making arrangements to secure the use of HIPAA-compliant videotelephony applications and ensure that communications with patients occur solely on those platforms;

9 2023-04248.pdf (govinfo.gov)

- Entering into Business Associate Agreements with HIPAA-compliant technology vendors for telecommunications; and
- Reviewing OCR's guidance and FAQs on permitted remote communications.

VII. Workforce

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Medicare Physician Supervision Requirements	CMS modified direct supervision requirements to permit the supervising provider to be "immediately available," to include "virtual presence" via real-time audio and video technology.	Flexibility terminates on December 31, 2023. On and after January 1, 2024, virtual presence will not constitute being "immediately available", and thus will not comply with direct supervision requirements.
Medicare Nonphysician Practitioners	CMS created the flexibility at 42 CFR § 410.32(b), on an interim basis during the PHE, to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and physician assistants (PAs) to supervise diagnostic tests as authorized under state law and licensure.	CMS made this provision permanent via its rulemaking authority at 85 Fed. Reg. 84590 at 84592 (Dec. 28, 2020).
Supervision Requirements for Non-Surgical Extended Duration Therapeutic Services	CMS waived the requirement for direct supervision at the initiation of non-surgical extended duration therapeutic services in hospital outpatient departments and critical access hospitals (and therefore general supervision sufficed).	CMS made this provision permanent via its rulemaking authority at 85 Fed. Reg. 85866 (Dec. 29, 2020).
Pharmacists	CMS permitted pharmacists (and other health care professionals authorized to order lab tests) to order COVID-19 tests for Medicare beneficiaries during the PHE (so that Medicare would pay for those tests).	Flexibility terminates. Medicare will no longer cover COVID-19 tests ordered by pharmacists and certain other professionals.
Public Readiness and Emergency Preparedness (PREP) Act	The PREP Act provides immunity from liability to certain licensed healthcare professionals and others who administer COVID-19 countermeasures.	According to HHS, immunity from liability under the PREP Act for providers furnishing COVID-19 countermeasure activities for the federal government will not be affected by the end of the PHE. However, PREP Act liability protections for countermeasure activities unrelated to the federal government will end unless another federal, state, or local emergency declaration is in place. HHS is currently reviewing whether to continue to provide this coverage going forward.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Teaching Physicians	During the PHE, flexibility is granted for a teaching physician to: (i) bill Medicare for services when the teaching physician is present virtually during the key portion of the service, (ii) oversee primary care services furnished by up to four residents via telehealth, and (iii) oversee and bill for an expanded scope of care furnished by up to four residents at a time in certain primary care centers.	After the PHE, only teaching physicians in residency training sites located outside of a metropolitan statistical area may: (i) meet the presence for the key portion requirement through telehealth, and (ii) direct, manage, and review resident care via telehealth. After the PHE, teaching physicians can bill levels 4-5 of an office/outpatient evaluation and management visit provided by residents in primary care centers, so long as the teaching physician is physically present for the key portion of the service.
Counting of Resident Time at Alternate Locations	During the PHE, a hospital that was paying the resident's salary and fringe benefits for the time that the resident is at home or in a patient's home, but performing duties within the scope of the approved residency program and meeting appropriate physician supervision requirements, was allowed to claim that resident for purposes of direct graduate medical education (DGME) payments or indirect medical education (IME) payments. This allowed medical residents to perform their duties in alternative locations, including their own home or a patient's home, as long as such activities meet appropriate physician supervision requirements.	Flexibility terminates. A hospital will not be able to count a resident for purposes of Medicare DGME payments or IME payments if the resident is performing activities within the scope of his/her approved program in his/her own home, or a patient's home.
Graduate Medical Education (GME) Residents' Training in Other Hospitals	During the PHE, a teaching hospital that sent residents to other hospitals was able to continue to claim those residents in the teaching hospital's IME and DGME Full Time Employee (FTE) resident counts, if certain requirements were met: 1) the teaching hospital sent the resident to the other hospital in response to COVID-19; 2) the time spent by the resident training at the other hospital was in lieu of time that would have been spent training at the sending hospital; and 3) the time that the resident spent training immediately prior to and/or subsequent to the time frame that the PHE has been in effect was included in the FTE count for the sending hospital.	Flexibility terminates. Teaching hospitals that send residents to other hospitals will not be able to claim those residents for its IME and DGME FTE resident counts. In addition, the presence of residents in non-teaching hospitals will trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals (and for DGME, it will trigger establishment of PRAs at those non-teaching hospitals).
National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) – Providers	Prior to the PHE, NCDs and LCDs determined what practitioner type or physician specialty may furnish or supervise a service. During the PHE, the Chief Medical Officer or equivalent of a hospital/facility was granted the authority to make staffing decisions as to what provider type may furnish or supervise a covered service.	Flexibility will terminate. After the PHE, and for coverage purposes, only NCDs and LCDs will determine what practitioner type or physician specialty may furnish or supervise a service.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
NCDs and LCDs – Therapeutic Continuous Glucose Monitors	During the PHE, CMS did not enforce the current clinical indications in LCDs for therapeutic continuous glucose monitors.	Waiver terminates. After the PHE, CMS will again enforce the current clinical indications in LCDs for coverage of therapeutic continuous glucose monitors.
Locum Tenens Modification	CMS modified the 60-day limit to allow a physician or physical therapist to use the same substitute the entire time the physician/physical therapist is unavailable to furnish services during the PHE, plus an additional period of no more than 60 continuous days after the PHE expires.	Waivers terminate. On the 61st day after the PHE ends (or earlier if desired), the regular physician or physical therapist must use a different substitute or return to work in his or her practice for at least one day in order to reset the 60-day clock.
Provider Enrollment Hotlines and Flexibilities	CMS established toll-free hotlines for certain providers/suppliers who established and receive temporary Medicare billing privileges.	Hotlines will shut down.
Expedited Enrollment	CMS expedited enrollment of providers/suppliers.	Normal enrollment processing times resume.
Opt-Out Enrollment	CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients. CMS also allowed MACs to accept opt-out cancellation requests via email, fax, or phone call to the hotline. Providers were not required to submit a written notification to cancel their opt-out status.	When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than as permitted under 42 CFR 405.445.
Reporting Home Address	CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.	Waiver terminates. Practitioners rendering telehealth services from their home will be required to report their home address on the Medicare enrollment.
State Licensure	CMS specifically allowed providers to bill Medicare for services provided outside of their state of enrollment, irrespective of whether state law restricted such cross-state billing.	When the PHE ends, CMS will defer to state law as to whether a Medicare provider must be licensed in its state of enrollment in Medicare. CMS's permissive cross-state license/billing waiver will no longer apply.
Stark Law	CMS issued blanket waivers of certain provisions of the Stark Law which applied to financial relationships and referrals that are related to the PHE. The remuneration and referrals described in the blanket waivers must be solely related to PHE purposes, as defined in the blanket waiver document and the explanatory guidance.	Waivers terminate, even with respect to existing arrangements. Therefore, arrangements which relied upon the blanket waivers may need to be revisited and modified to comply with existing Stark Law exceptions as of May 12, 2023.

During the PHE, various workforce-related flexibilities and waivers were granted in order to reduce compliance burdens, increase access to care, and limit the spread of COVID-19. A majority of these waivers will terminate at the conclusion of the PHE. Providers should start planning for the end of the PHE by reviewing and revising compliance obligations to ensure that operational policies and procedures adhere to obligations applicable post-PHE, to include, without limitation, billing standards, supervision standards, and licensure requirements. DHS entities maintaining a financial relationship with a referring physician should review and ensure that, if the financial relationship implicates the Stark Law and was reliant upon a Stark Law waiver, the relationship either is restructured to satisfy a Stark Law exception by May 12, 2023, or terminated.

VIII. Hospitals

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements[10]	Status at PHE Termination
Emergency Medical Treatment and Active Labor Act (EMTALA) Enforcement	In place of the requirement that a hospital with an emergency department must provide an appropriate on-site medical screening when requested on behalf of an individual,[11] CMS permitted hospitals, including psychiatric hospitals and critical access hospitals (CAHs), to screen patients offsite from their campuses to prevent the spread of COVID-19.	Waiver terminates. A hospital with an emergency department must provide an appropriate on-site medical screening when requested on behalf of an individual.
Verbal Orders	To facilitate more efficient treatment during surges, CMS waived requirements related to verbal orders to allow authentication to occur later than 48 hours after. The following requirements were waived: • If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently. • All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient. • Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders.	Waiver terminates. Verbal order requirements will be reinstated.
Reporting Requirements	CMS waived the requirement that when a patient dies in an intensive care unit, either while in soft wrist restraints or within 24 hours after being removed from restraints, the hospital must report the information to CMS no later than the close of the next business day.	Waivers terminate. When a patient dies in an intensive care unit while in soft restraints or within 24 hours of being removed from restraints, the information must be reported to CMS no later than the close of the next business day.
Medical Staff Credentialing	In response to workforce concerns caused by COVID-19, CMS waived several details of the processes for credentialing and granting privileges to medical staff at hospitals. CMS allowed physicians to continue practicing if their privileges would have expired and allowed new physicians to practice in hospitals before their privileges were reviewed and approved by the full medical staff or governing body.	Waiver terminates. Physicians seeking privileges will need to apply or reapply and be approved by the full medical staff or governing body before practicing in a hospital.

10 Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19

11 Social Security Act Section 1867(a), Social Security Act §1867 (ssa.gov).

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements[10]	Status at PHE Termination
Medical Records	CMS authorized flexibility in the requirement that medical records must be finalized within 30 days of discharge, or promptly for CAHs. CMS also waived the requirements governing the organization and staffing of the medical records department, the form and content of the medical record, and the retention of records.	Flexibility terminates. CMS will reinstate requirement that medical records must be finalized within 30 days of discharge or promptly for CAHs. Requirements governing medical records will be reinstated.
Advance Directives	CMS waived the requirement that hospitals and CAHs provide patients information about their advance directive policies.	Waiver terminates. Hospitals and CAHs will need to ensure that they provide patients information about their advance directive policies.
Utilization Review	CMS waived the utilization review plan requirements imposed on Medicare and Medicaid hospitals. CMS waived the Utilization Review CoP that requires hospitals to have a utilization review plan and committee to evaluate the medical necessity of an admission, the duration of stay, and the services provided.	Waivers terminate. Utilization review requirements will be reinstated.
Critical Access Hospitals – Personnel Qualifications	Although Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants still have to meet state specifications for licensure and scope of practice, CMS waived the minimum personnel qualifications and provided that no federal requirements could exceed state requirements.	Waiver terminates. Minimum personnel qualifications requirement will be reinstated.
Critical Access Hospitals – Staff Licensure	CMS deferred to state law for staff licensure, certification, and registration requirements to create flexibility where the federal requirements are more strict.	Flexibility terminates. Federal requirements will be reinstated and preempt state requirements.
Critical Access Hospitals – Status and Location	CMS created flexibility in the establishment of surge cite locations by waiving the requirement that a CAH be located in a rural area, and similar off-campus and co-location requirements.	Waiver terminates. Requirements at 42 CFR § 485.620 will be reinstated.
Critical Access Hospitals – Length of Stay	CMS waived the 96 hour limit on length of stay under the conditions of participation for Medicare.	Waiver terminates. 96 hour limit will be reinstated for length of stay at CAHs.
Critical Access Hospitals – Responsibilities of Physicians	To allow remote performance of responsibilities when appropriate, CMS waived the prerequisite that physicians be physically present to provide medical direction, consultation, and supervision of services in CAHs.[12]	Flexibility terminates. Physicians will again be required to be physically present to provide medical direction, consultation, and supervision of services in CAHs.
IME Payments Held Harmless for Temporary Increase in Beds	CMS held teaching hospitals harmless from a reduction in IME payments due to beds temporarily added during the PHE, by not considering such beds when determining IME payments	Flexibility terminates. Any added beds will be considered in determining the hospital's IME payments.

12 CMS maintained the requirement that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral." 42 C.F.R. § 485.631(b)(2).

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements[10]	Status at PHE Termination
Inpatient Psychiatric Facilities (IPFs) and Inpatient Rehabilitation Facilities (IRFs) Teaching Status Adjustment Payments	CMS froze the IPFs' and IRFs' teaching status adjustment payments at their values prior to the PHE, in order to help alleviate bed capacity issues. Thus, for the duration of the PHE, a teaching IPF's and a teaching IRF's teaching status adjustment payments have been the same as they were on the day before the COVID-19 PHE was declared.	Flexibility terminates. Any change to a teaching IPF's or a teaching IRF's average daily census will be considered in determining its teaching status adjustment payments.

CMS provided many waivers to enable hospitals to focus on bedside care, efficiently handle increased care demands during hospital surges, and decrease the spread of COVID-19. All of these flexibilities and waivers will terminate. Hospitals must have systems in place to resume on-site screenings, comply with reporting requirements and medical record form, content, and maintenance requirements, ensure that clinical staff are properly and timely qualified and credentialed, and provide required information to patients, such as policies on advanced directives.

IX. Hospice Care

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Medicare Telehealth for Hospices – Routine Home Care	Hospice providers were permitted to provide services to a Medicare patient receiving routine home care through telecommunications technology.	Flexibility terminates. Hospice providers will not be permitted to provide routine home care services to Medicare patients through telecommunications technology.
Medicare Telehealth for Hospices – Patient Recertification	Face-to-face encounters for purposes of patient recertification for the Medicare hospice benefit may be conducted via telehealth.	Flexibility expires on December 31, 2024, after which in-person face-to-face encounters will be required for recertification of the Medicare hospice benefit.
Training and Assessment of Aides	CMS waived the requirement for a registered nurse to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the hospice.	Waiver terminates. Annual onsite supervisory visits will be required, and all postponed onsite assessments must be completed by no later than July 10, 2023.
Annual Training	CMS modified the requirement for hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required by postponing the deadline for completing this requirement until the end of the first full quarter after the declaration of the PHE concludes.	Waiver terminates. Hospices will be required to conduct annual assessments and provide necessary in-service training and education programs by no later than September 30, 2023.
Quality Assurance and Performance Improvement (QAPI)	CMS modified the requirement to develop, implement, evaluate, and maintain an effective, ongoing, hospice-wide, data-driven QAPI program by narrowing the scope of the QAPI program to concentrate on infection control issues.	Flexibility terminates. Hospices will be required to resume the development, implementation, evaluation, and maintenance of a comprehensive QAPI program.
Use of Volunteers	CMS waived the requirement for hospices to use volunteers (including at least 5% of patient care hours).	Waiver terminates. Hospices will be required to utilize volunteers to provide day-to-day administrative and/or direct patient care services for at least 5% of the total patient care hours of all paid hospice employees and contract staff.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Comprehensive Assessments	CMS extended the timeframe to update comprehensive assessments of patients from 15 to 21 days.	Flexibility terminates. Hospices will be required to perform assessment updates no less frequently than every 15 days.
Non-Core Services	CMS waived the requirement for hospices to provide certain non-core hospice services (including physical therapy, occupational therapy, and speech language pathology).	Waiver terminates. Hospices will be required to provide certain non-core hospice services such as physical therapy, occupational therapy, and speech language pathology.
Specific Life Safety Code (LSC) for Hospice and CAHs	CMS waived or modified the below requirements for inpatient hospice: • *Alcohol-based Hand-Rub (ABHR) Dispensers* – waived prescriptive requirements for the placement of ABHR dispensers for use by staff and others; • *Fire Drills* – modified requirement for quarterly fire drills to instead permit a documented orientation training program; and • *Temporary Construction* – waived requirements that would otherwise not permit temporary walls and barriers between patients.	Waivers terminate. Inpatient hospices will be required to comply with the LSC including requirements for the placement of ABHR dispensers, performance of quarterly fire drills, and absence of temporary walls and barriers between patients.

Hospices should plan for the end of the PHE by:

- Ensuring processes are in place to: (i) perform previously postponed onsite assessments by no later than July 10, 2023; and (ii) complete all requisite assessments and trainings of hospice staff by no later than September 30, 2023;
- Reviewing current processes and procedures to ensure consistent updates to the comprehensive assessment of patients at least every 15 calendar days. For some hospice providers, this may require examination of current staffing models to ensure that the interdisciplinary team is able to meet within the required 15-day timeline to review and update the comprehensive assessment;
- Reviewing current processes, procedures, and recruitment strategies related to volunteer services;
- For hospices that utilized the QAPI waiver, reevaluating current QAPI programs and preparing to develop, implement, evaluate, and maintain an effective, ongoing QAPI program in accordance with 42 CFR §418.58; and
- Preparing to resume non-core hospice services (including physical therapy, occupational therapy, and speech language pathology), which may result in the need for additional staff or contracted personnel to ensure these services can be rendered.

X. Home Health Agencies

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Medicare Telehealth and Telecommunications Technology	CMS allowed for home health agencies to provide home health services to Medicare beneficiaries through the use of telecommunications technology.	Home health services may be conducted via telecommunications technology if it is included in the patient's plan of care; however, services furnished through telehealth must be denoted and included on home health claims beginning on July 1, 2023.
Medicare Telehealth and Telecommunications Technology	CMS permitted face-to-face encounters between practitioners and patients to be performed via telecommunications technology.	Flexibility continues through December 31, 2024, after which in-person face-to-face encounters will be required.
Detailed Information Sharing for Discharge Planning	CMS waived the requirement to provide detailed information about post-acute care providers (including the use and sharing of data related to quality and resource use measures) in connection with the discharge planning process in order to expedite the discharge and movement of residents among care settings.	Waiver terminates. HHAs will be required to utilize and share data about post-acute care providers (as applicable) with patients and their caregivers and representatives in connection with the discharge planning process under 42 CFR §484.58(a).
Plans of Care and Certifying/Recertifying Patient Eligibility	In addition to physicians, CMS permitted nurse practitioners, clinical nurse specialists, and physician assistants to order home health services, establish and review plans of care, and certify/recertify patient eligibility for Medicare-eligible home health patients.	This change has been made permanent as set forth under 42 CFR §409.43.
Clinical Records	CMS extended the deadline for HHAs to provide a patient with a copy of their medical record, at no cost, upon request at the earlier of the next home visit or within ten business days (*i.e.*, rather than four business days).	Waiver terminates. Under 42 CFR §484.110, HHAs will be required to provide a patient with a copy of their medical record, at no cost, upon request at the earlier of the next home visit or within four business days.
Training and Assessment of Aides	CMS waived the requirement for a registered nurse or other appropriate skilled professional to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the HHA.	Waiver terminates. All postponed onsite supervisory visits must be completed by no later July 10, 2023.
12-Hour Annual In-Service Training for Home Health Aides	CMS modified the requirement that HHAs must ensure that each home health aide receives 12 hours of in-service training during in a 12-month period.	Waiver terminates. Any training that was not completed (to meet the 12-hour annual requirement) during the PHE must be completed by no later than September 30, 2023. Beginning January 1, 2024, HHAs will be required to ensure that each home health aide receives at least 12 hours of in-service training during a 12-month period.
Quality Assurance and Performance Improvement (QAPI)	CMS modified the requirement to develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program by narrowing the scope of the QAPI program to concentrate on infection control issues.	Flexibility terminates. HHAs will be required to resume the development, implementation, evaluation, and maintenance of a comprehensive QAPI program.
OASIS Data Transmission	CMS extended the five-day completion requirement for the comprehensive assessment to 30 days and waived the 30-day OASIS submission requirement.	Waiver terminates. HHAs will be required to complete comprehensive assessments of home health patients within 5 days and submit OASIS data within 30 days.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Allow Rehabilitation Professionals to Perform Initial and Comprehensive Assessment for All Patients	CMS waived the requirement that rehabilitation professionals may only perform the initial and comprehensive assessment if therapy services are ordered, which permitted rehabilitation professionals to perform these assessments for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law.	Waiver terminates. Rehabilitation professionals may only perform the initial and comprehensive assessment if therapy services are ordered.

While many of the flexibilities granted during the PHE will remain, other administrative and clinical workflow flexibilities will terminate and HHAs should prepare by:

- For HHAs that utilized the discharge planning waiver, reinstating the utilization and sharing of data about post-acute care providers with patients and their caregivers and representatives;
- Ensuring processes are in place to complete any outstanding onsite supervisory visits of home health aides by no later than July 10, 2023, and/or the 12-hour annual in-service training requirement by no later than September 30, 2023;
- For HHAs that utilized the QAPI waiver, reevaluate current QAPI programs and prepare to develop, implement, evaluate, and maintain an effective, ongoing QAPI program;
- Preparing to resume the completion of initial and comprehensive assessments by physicians if therapy services are not ordered, which may result in the need for additional staff and/or contracted personnel; and
- Ensuring processes are in place to complete comprehensive assessments of home health patients within 5 days and to submit OASIS data within 30 days.

XI. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Mental Health Visits Furnished Using Telehealth	RHCs and FQHCs were allowed to report and receive reimbursement for mental health visits furnished via real-time telecommunication technology in the same way in-person visits are reported and reimbursed, including audio-only visits when the beneficiary is not capable of, or does not consent to, the use of video technology.	Waiver has been made permanent. As a result, RHCs and FQHS may report and receive payment for mental health visits furnished through telehealth technology after the PHE Termination (*i.e.*, in the same manner as in-person mental health visits).

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Virtual Communication Services	• Virtual communication services were expanded to include online digital evaluation and management services, which are non-face-to-face, patient-initiated, digital communications using a secure patient portal. • All virtual communication services were also available to new patients that had not been seen in the RHC or FQHC within the previous 12 months. • In situations where obtaining prior beneficiary consent would interfere with the timely provision of services (or monthly care management services), consent could be obtained at the time services were furnished instead of *prior to* the provision of services; however, consent was required to be obtained *before* services were billed. • CMS allowed patient consent to be obtained by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication and monthly care management codes (i.e., direct supervision was not required).	Waivers terminate. Upon termination of the PHE: • Medicare payment for virtual communication services (G0071) will no longer include online digital evaluation and management services; • Payment for online digital evaluation and management services may only be provided to established patients under existing CPT codes (e.g., 99421, 99422, and 99423); and • Patient consent for virtual communication and monthly management services must be obtained by staff under the direct supervision of the RHC/FQHC practitioner.
Home Nursing Visits	RHCs and FQHCs were permitted to provide visiting nurse services to a beneficiary's home with fewer requirements. Specifically, during the PHE: • Any area typically served by the RHC, or included in the FQHC's service area, was determined to have a shortage of home health agencies for which a formal request for determination of such shortage was not required; • Any home visit that was made solely to obtain a nasal or throat culture *was not* considered a "nursing service"; and • The definition of "homebound" was broadened to include situations in which a physician had determined that it was medically necessary for the Medicare patient to remain home in certain circumstances, which expanded the ability of RHCs/FQHCs to provide visiting nursing services to these patients.	Waivers terminate. • Any RHC/FQHC located in an area that has not been formally determined to have a current home health agency shortage (and seeks to provide visiting nurse services) will be required to make a written request along with justification that the area it serves meets the required conditions; • Any RHC/FQHC visiting nurse service that is limited to the provision of a nasal or throat culture *will* be considered a "nursing service"; and • The definition of "homebound" will not apply to patients who receive visiting nurse services from RHCs/FQHCs.
Staffing Requirements	CMS waived the requirement that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50% of the time the RHC operates.	Waiver terminates. A nurse practitioner, physician assistant, or certified nurse-midwife must be available to furnish patient care services at least 50% of the time that the RHC operates.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Temporary Expansion Locations	CMS waived the requirement that approval be obtained in the event that RHC/FQHC services are furnished at multiple permanent locations.	Waiver terminates. RHCs/FQHCs must obtain approval for services directly furnished outside of one permanent location.
Bed Count for Provider-Based RHCs and RHC Payment Limit	During the PHE, CMS permitted RHCs that are operated as an essential part of a hospital with fewer than 50 beds to continue to receive payment that they would otherwise have received in the absence of the PHE. Specifically, CMS permitted recognition of the pre-PHE hospital bed count as the official bed count to determine the RHC's exemption from the national payment limit. This change was intended to ensure that hospitals were not discouraged from increasing bed capacity, if needed, during the pandemic.	Waiver terminates. RHCs associated with provider-based hospitals that have 50 or more beds will no longer be exempt from the national RHC payment limit.

RHCs and FQHCs should start planning for the end of the PHE by:

- Reviewing billing/coding procedures to ensure that virtual communication services are appropriately billed, including the provision of online digital evaluation and management services to established patients only;
- Implementing policies and procedures to ensure that patient consent for virtual communication and monthly management services is obtained by staff under the *direct supervision* of the RHC/FQHC practitioner;
- Submitting a formal request for determination for any RHC/FQHC located in an area that has not been formally determined to have a current home health agency shortage and seeks to provide visiting nurse services;
- Reviewing policies and procedures to ensure that visiting nursing services comply with applicable billing requirements;
- For RHCs, ensuring that a nurse practitioner, physician assistant, or other healthcare provider is available to furnish services for at least 50% of the time in which the RHC operates;
- Submitting request(s) for approval to furnish services to Medicare patients at multiple permanent locations; and
- For provider-based RHCs that are operated as an essential part of a hospital with 50 or more beds *after* the expiration of the PHE, making adjustments to budgets and/or operations in light of the reinstatement of the national RHC payment limit.

XII. Long Term Care (LTC) Facilities

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
3-day Prior Hospitalization	CMS temporarily waived the requirement of a 3-day prior hospitalization for coverage of a Skilled Nurse Facility (SNF) stay, thus providing temporary emergency coverage of SNF services without a qualifying hospital stay. In addition, for certain beneficiaries who exhausted their SNF benefits, CMS authorized a one-time renewal of SNF coverage without first having to start and complete a 60-day "wellness period."	Waivers terminate. A 3-day prior hospitalization will be required for coverage of a SNF stay and the one-time extension of SNF coverage for certain beneficiaries who have exhausted their SNF benefits will no longer be available.
Waive Pre-Admission Screening and Annual Resident Review (PASRR)	CMS allowed states and nursing homes to suspend Level 1 and Level II assessments of new residents for 30 days. After the initial 30-day grace period, new patients admitted to nursing homes with a mental illness or intellectual disability should receive the assessment as soon as resources become available.	Waiver terminates. Level 1 and Level II PASRR assessments will be required to be performed prior to admission (subject to limited exceptions).
Resident Roommates and Grouping	CMS waived certain requirements including the right of residents to share a room with a roommate of their choice, when practicable, and to refuse a transfer to another room within the facility. The waiver of these requirements enabled LTC facilities to isolate residents with respiratory illness symptoms and/or confirmed diagnosis of COVID-19 from residents who are asymptomatic or tested negative for COVID-19 during the pandemic.	Waiver terminates. LTC facilities will be required to provide residents with the right to share a room with their roommate of choice, when practicable, and to refuse to transfer to another room in the facility under certain circumstances.
Required Facility Reporting	During the PHE, LTC facilities were required to report COVID-19 cases to the CDC National Health Safety Network (NHSN) on a weekly basis. Failure to make the required reports were subject to the imposition of a civil money penalty for each occurrence: $1,000 for the first occurrence, followed by $500 added to the previously imposed civil money penalty for each subsequent occurrence, not to exceed a maximum amount. LTC facilities were also required to notify residents and their representatives and families of the status of COVID-19 in the facility.	The 2022 CY Home Health PPS Rule extended this mandatory COVID-19 reporting requirement beyond the current PHE until December 31, 2024. As such, LTC facilities will continue to be required to report COVID-19 cases on a weekly basis to the NHSN and notify residents and their representatives/families of the status of COVID-19 in the facility, including any new cases of COVID-19 (once identified).
Alcohol-based Hand-Rub (ABHR) Dispensers	During the PHE, CMS waived certain conditions of the Life Safety Code including specific requirements for the placement of alcohol-based hand rub (ABHR) dispensers for use by staff and others due to the need for the increased use of ABHR in infection control. Due to the increased fire risk, containers (i.e., over five gallons) continued to be required to be stored in a protected hazardous materials area.	Waiver terminates. LTC facilities will be required to comply with requirements related to placement of ABHR dispensers.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Established new requirements for LTC Facility to conduct SARS-CoV-2 testing for Staff and Residents	CMS required LTC facilities to test residents and staff (including individuals providing services under arrangement and volunteers) for COVID-19.	Requirement terminates. COVID-19 testing will no longer be mandated by federal law.

LTC facilities should plan for the end of the PHE by:

- Helping patients understand the impact of the reinstatement of the 3-day prior hospitalization rule on Medicare coverage for SNF services;
- Coordinating with community partners to ensure they will be performing pre-admission screening to minimize potential delays in the admission process;
  and
- Reestablishing policies and procedures that provide residents with the right to share a room with their roommate of choice, when practicable, and to refuse to transfer to another room within the facility under certain circumstances.

XIII. End-Stage Renal Dialysis Facilities

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Periodic Audits	CMS waived the requirement for on-time periodic audits for operators of the water/dialysate equipment.	Waiver terminates. Periodic audits will be required to demonstrate that water and equipment used for dialysis meets the requirements for water and dialysate standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation publication.
Emergency Preparedness	CMS waived the requirement for maintenance of CPR certification due to the limited availability of CPR classes.	Waiver terminates. ESRD facilities will be required to demonstrate that their patient care staff maintains current CPR certification.
Ability to Delay Some Patient Assessments	CMS waived requirements for 1) an initial comprehensive assessment for all new dialysis patients within the latter of 30 calendar days or 13 outpatient hemodialysis sessions, and 2) a follow up comprehensive reassessment within three months.	Waivers terminate. ESRD facilities will be required to complete initial assessments for new patients and follow up reassessments within required time frames.
Home dialysis machine designation — clarification	CMS provided guidance that the ESRD Conditions for Coverage do not explicitly require that each home dialysis patient have their own designated home dialysis machine. Dialysis facilities are required to follow FDA labeling and manufacturer's directions and properly clean and disinfect dialysis machines to minimize the risk of infection in the event used to treat multiple patients.	42 CFR § 494.30 and subsequent rulemaking may provide further guidance. Dialysis facilities will need to continue to follow FDA labeling and manufacturer's directions and properly clean machines and equipment.
Provider Enrollment Hotlines	CMS established toll-free hotlines for physicians, non-physician practitioners, and Part A certified providers and suppliers who established isolation facilities to enroll and receive temporary Medicare billing privileges.	At the end of the PHE, the hotlines will shut down.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Medicare Care Planning for ESRD	CMS provided flexibilities related to care planning: • CMS modified the requirement that the dialysis facilities implement the initial plan of care within the later of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. • This modification also applied to the requirement for monthly or annual updates to the plan of care within 15 days of the completion of the additional patient assessments. • CMS waived the requirement for monthly in-person physician visits if the patient was stable.	Waivers terminate. Thereafter, the requirements for care planning and monthly in-person physician visits will be reinstated.
Dialysis home visits to assess adaptation and home dialysis machine designation	CMS waived the requirement for periodic monitoring of the patient's home adaptation, including home visits by facility personnel.	Waiver terminates. The requirement for periodic monitoring of the patient's home adaptation (including home visits by facility personnel) will be reinstated.
Special Purpose Renal Dialysis Facilities (SPRDF) designation expanded	CMS authorized the establishment of SPRDFs to address access to dialysis care due to the COVID-19 pandemic and the need to mitigate transmission among vulnerable populations without the required determination of the existence of a lack of access to care as that standard was automatically satisfied during the nationwide PHE.	Flexibility terminates. SPRDFs will be required to obtain formal approval to operate and undergo a federal survey *prior to* providing services.
Furnishing dialysis services on the main premises	CMS waived the requirement that dialysis facilities must provide services directly on its main premises, to allow dialysis facilities to provide service to patients in nursing homes, long-term care facilities, assisted living facilities and similar types of facilities. These facilities were advised to bill using the full care unit billing code.[13]	Waiver terminates. Full care unit billing code will no longer be available to be used for this purpose, and dialysis facilities will be required to provide services on its main premises or on other premises that are contiguous with the main premises.
Dialysis Patient Care Technician certification	CMS allowed patient care technicians to continue working even if they had not achieved certification within 18 months or met on-time renewals.	Flexibility terminates. Dialysis patient care technicians will be required to demonstrate successful achievement of initial certification or certification renewal.
Transferability of physician credentialing	CMS allowed physicians who are appropriately credentialed at a certified dialysis facility to provide care at designated isolation locations without separate credentialing at that facility.	Flexibility terminates. Physicians will be required to be appropriately credentialed at each dialysis facility location.

Facilities that provide dialysis should begin planning for the end of the PHE by:

• Ensuring processes are in place to perform previously required audits, certifications, assessments, and home visits;

13 Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility).

- Confirming that new and existing providers and technicians are properly certified, licensed and credentialed; and
- Implementing protocols that again require dialysis to be conducted at the main facility rather than at nursing homes and long-term care facilities, and to make adjustments to staffing (as necessary) to accommodate the number of patients who will no longer be able to receive dialysis treatments in their homes or facilities.

XIV. FDA Waivers

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
Emergency Use Authorization (EUA) may be declared by HHS (EUA declaration)[14], per 21 U.S.C. § 360bbb-3 upon declaration by HHS that a public health emergency exists. 42 USC 247d	EUA declarations authorize FDA to issue EUAs for (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Emergency Use Authorization Declaration March 27, 2020.	Termination of EUAs that FDA issued based on the HHS Secretary EUA declaration is not linked to the end of the PHE. The HHS Secretary issued four EUA declarations for 1. IVD devices; 2. Personal respiratory protective services; 3. Medical devices; 4. Drugs and biological products. If the HHS Secretary terminates any of the four EUA declarations above, then the EUAs issued under such declarations will also terminate and FDA may no longer issue EUAs covered under that declaration.[15] FDA's Center for Devices and Radiological Health (CDRH) issued EUAs in nine categories, *listed below*, related to COVID-19.
EUA for Blood Purification Devices	Four EUAs were issued for the use of specific blood purification devices during the PHE. Blood Purification Devices EUAs	Will continue.
EUA for Continuous Renal Replacement Therapy and Hemodialysis Devices	Three EUAs were issued for the use of specific CRRT and hemodialysis devices during the PHE. Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs	Will continue.
EUA for In Vitro Diagnostics	A number of EUAs were issued for the use of IVDs (tests performed on samples taken from human body, e.g. swabs from nose or throat; blood from a vein or fingerstick) to detect diseases or other conditions. In Vitro Diagnostics EUAs	Will continue.
EUA for Infusion Pumps	One EUA was issued to increase infusion pumps and related accessories integral to treatment of patients. Infusion Pump EUAs	Will continue.

14 EUA declarations enable FDA to issue EUAs. EUA declarations are issued by the HHS Secretary pursuant to §564 of the FD&C Act and declare that circumstances exist to justify the authorization of FDA to issue EUAs. FDA has authority to issue EUAs pursuant to §564, §564A, and §564B of the Federal Food, Drug, and Cosmetic Act (FD&CA). If the HHS Secretary terminates an EUA declaration, then any EUAs issued based on that EUA declaration will cease to be in effect and FDA may not issue EUAs for products covered by that declaration.

15 Upon termination of a EUA declaration by the HHS Secretary, notice of termination will be published in the Federal Register providing advanced notice to the public and initiating the transition period.

Description of Current Waivers	Scope of PHE Waiver(s) of Requirements	Status at PHE Termination
EUA for PPE	A number of EUAs were issued for the use of certain PPE products for use. Personal Protective Equipment EUAs	Will continue.
EUA for Remote or Wearable Patient Monitoring Devices	Six EUAs were issued for remote or wearable patient monitoring devices to aid in the monitoring and treatment of patients and reduction of HCP exposure. Remote or Wearable Patient Monitoring Devices EUAs	Will continue.
EUA for Respiratory Assist Devices	Six EUAs were issued for respiratory assist devices for the treatment of patients. Respiratory Assist Devices EUAs	Will continue.
EUA for Ventilators and Ventilator Accessories	An umbrella EUA was issued for ventilators and related accessories to authorize the emergency use of certain ventilators, anesthesia gas machines modified for use as ventilators, positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and ventilator accessories that the FDA determines meet specified criteria for safety, performance, and labeling. The devices that are eligible for inclusion under the EUA are those that are not currently marketed in the U.S., or those that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to the FDA, as discussed in the agency's Ventilator Enforcement Policy. Ventilators and Ventilator Accessories EUAs.	Will continue.
EUAs for Other Medical Devices	Eight EUAs were issued for medical devices that are approved for use, but do not otherwise fall into the prior categories. Other Medical Device EUAs	Will continue.

In 2020, the HHS Secretary issued EUA declarations for IVD devices, Personal respiratory protective services, Medical devices, and Drugs and biological products, which enabled FDA to issue EUAs. During the PHE, FDA issued EUAs authorizing the emergency use of certain medical products prior to full approval from FDA in order to facilitate the availability of certain key medical devices for patients.

As the EUA declarations are not dependent on declaration of a PHE, the end of the PHE does not necessarily entail the termination of EUAs. However, if the HHS Secretary determines that the circumstances leading to a EUA declaration no longer exist, the Secretary may decide to terminate an EUA declaration. If a EUA declaration is terminated, then any EUAs issued based on that EUA declaration will cease to be in effect and FDA may not issue EUAs for products covered by that declaration.

Upon termination of an EUA declaration by the HHS Secretary, notice of termination will be published in the Federal Register 180 days prior to the termination of the EUA declaration, providing advanced notice to the public and time for manufacturers to determine appropriate next steps. In 2021, FDA published guidance related to the transition period for terminations of EUAs issued during the PHE, subject to a comment period and finalization. Any manufacturers of drugs or devices that received FDA EUAs can start planning for the end of EUAs by considering:

- post-EUA or post-PHE regulatory and disposition strategies;

- submitting a marketing submission to FDA along with a transition implementation plan, if a manufacturer seeks to continue marketing and distributing devices post-EUA;
- the discontinuance of distribution of any EUA devices, if a manufacturer does not intend to continue distribution post-termination, with the exception of the following:
  - Single use, non-life supporting / non-life-sustaining devices (*e.g.*, facemasks);
  - Reusable, non-life supporting / non-life-sustaining devices (*e.g.*, remote patient monitoring devices), if restored to FDA-cleared or approved versions;
  - Reusable life-supporting devices (*e.g.*, ventilators), if restored to FDA-cleared or approved versions; and
  - In vitro diagnostic devices, if used or expired within two years.

FDA also issued draft guidance for devices that fell within Enforcement Policies issued during the PHE. The guidance provides a 3-phase transition plan under a similar 180-day transition period after which manufacturers will be expected to comply with all statutory and regulatory requirements applicable to their devices with the exception of any pre-market authorization exceptions.

FDA will also adopt a "risk-based approach" for certain life-supporting and life-sustaining devices, such as ventilators and portable oxygen generators. Manufacturers of such devices should submit a notice of intent to the CDRH Document Control Center to inform FDA as to the manufacturer's intent to continue distribution of their device and should include a proposed termination plan.

For unique compliance situations unaddressed in the draft documents, FDA encourages manufacturers to request an exemption or variance through the Q-Submission program within 90 days of publication of the advance notice of termination of the EUA declaration to formulate alternative solutions.

XV. Conclusion

We have sought to identify and summarize most, but not all, of the waivers, flexibilities, and associated payment, administrative, operational, and clinical workflow changes that are implicated by the end of the PHE. Given the sheer number of waivers and flexibilities that were issued during the PHE, as well as the inconsistencies between those that will terminate and those that will continue, all affected entities should review carefully CMS guidance on the winddown of the PHE, the IRA, and the CAA to ensure compliance with post-pandemic requirements. Entities should also consider how to manage increases in administrative and in-person clinical work as many waivers terminate.

For example, across the board, healthcare providers will need to resume and/or accommodate previously required in-person clinical visits, ensure that staff are properly credentialed, qualified, and licensed, furnish services in designated sites, and verify compliance with billing requirements. In addition, providers should consider providing detailed guidance and communications to staff, leadership, facility and practitioner stakeholders, and patients on changes to how care will be provided and paid for after the PHE has ended. They should also consult with their legal teams on the status of Medicaid and CHIP state program waivers, flexibilities, and eligibility determinations, and how they are impacted by the PHE. Entities that provide telehealth services should track the telehealth waivers that were extended in the CAA, ensure that controlled substances are only prescribed after an in-person visit, contract with HIPAA-compliant technology vendors, and prohibit use of noncompliant communication platforms.

For health plans, it will be particularly important to monitor state regulations and requirements, in addition to the changes in the federal legislation and guidance summarized above before making any coverage-related policy changes. Health plans will also need to ensure that any changes to coverage for COVID-19 testing, vaccine, and

treatment comply with new requirements in the CAA, IRA, and ARPA. State Medicaid agencies will be permitted, but not required, to resume eligibility reviews of Medicaid enrollees and involuntary disenrollment of ineligible individuals within the 14-month period following the end of the PHE, after which the reinstatement of these disenrollment processes will be mandatory. Additionally, participants in the MSSP, MA and Part D programs should analyze their current policies and procedures and make any necessary changes to reflect the end of pandemic-related waivers and ensure compliance with post -PHE regulatory requirements. They should also ensure that staff are trained to handle the changes effectively.

Lastly, manufacturers should track EUA guidance and start preparing for the potential termination of EUAs by reading the draft guidance by FDA, preparing transition implementation plans or proposed termination plans if necessary, and requesting exemptions or variances where applicable.

If you have any questions about the approaching expiration of the PHE and its impact on the regulatory requirements applicable to you or your organization, please contact a member of the Sheppard Mullin Healthcare Team.

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