MHA Member Guide to Federal Public Health Emergency Waiver Expirations

The federal COVID-19 Public Health Emergency (PHE) ends May 11, 2023. To help member hospitals and health systems navigate the expiration of waivers granted under the federal PHE, MHA compiled guidance from the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services, and other relevant federal and state agencies. For questions or more information, contact <u>mha@mhaonline.org</u>.

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Public Health Emergency Waivers Ending with Federal Public Health Emergency (May 11, 2023)

COVID-19 Vaccines, Testing, and Treatment

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Separate Medicare Payment for New COVID-19 Treatment - Hospital Outpatient Departments: Medicare has been paying for FDA-authorized or approved drugs and biologicals (including blood products) authorized or approved to treat COVID-19 (and for which the FDA authorization or approval does not limit use to the inpatient setting) separately.	Payment for these treatments will be packaged into the payment for a Comprehensive Ambulatory Payment Classification (C-APC) when these services are billed on the same outpatient claim.	CMS p
Price Transparency for COVID-19 Testing: CMS required providers of a diagnostic test for COVID-19 make public the cash price for tests on their websites. Providers without websites are required to provide price information in writing, within two business days upon request, and on a sign posted prominently at the location where the provider performs the COVID-19 diagnostic test if such location is accessible to the public.	Special price transparency requirement will terminate.1	- <u>CMS</u> , p. 15
HCPCS Code C9803 (Specimen Collection): Hospital outpatient departments can be paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) retroactive to March 1, 2020.	HCPCS code C9803 is a temporary code that was created to support increased testing during the COVID-19 PHE.	<u>CMS</u> , p. 16
Antibody (Serology) Tests: Medicare covered serology diagnostic tests for patients with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection.	Coverage is at the MAC's discretion.	
Orders for COVID-19 Tests: CMS has been allowing pharmacists, as well as other health care professionals who are authorized to order lab tests under the state scope of practice and other relevant laws, to order COVID-19 tests for Medicare beneficiaries.	Waiver is terminated.	<u>CMS</u> , p. 12

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¹ Price transparency requirements under other laws and regulations will continue to apply. Last Updated: May 10, 2023

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Lab Test Reporting: HHS has had the authority to require lab test reporting for COVID-19.	HHS will no longer have this express authority to require this data from labs. CDC has been working to sign voluntary Data Use Agreements (DUAs), encouraging states and jurisdictions to continue sharing vaccine administration data beyond the PHE. Additionally, hospital data reporting will continue as required by the CMS conditions of participation through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency.	<u>HHS</u>
<u>Staff Vaccination Requirement:</u> CMS required Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID-19 (i.e., obtain the primary vaccination series).	CMS will soon end the requirement that covered providers and suppliers establish policies and procedures for staff vaccination. CMS will share more details regarding ending this requirement at the anticipated end of the public health emergency.	<u>CMS</u> , p. 2
Routine Testing at Long-Term Care (LTC) Facilities: CMS required routine testing of residents and staff for COVID-19 infection.	Waiver is terminated.	<u>CMS</u> , p. 6

Alternate Care Sites / Care Model Flexibilities / Telehealth

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Temporary Expansion Sites: Use of temporary expansion sites (such as convention centers, vacant stores, tents or others allowed under the Hospital Without Walls program) and spaces within the hospital that do not conform to the conditions of participation requirements for patient rooms, such as conference rooms and surgical suites.	Hospitals required to provide services to patients within hospital departments pursuant to Conditions of Participation.	<u>CMS</u> , p. 4
Ambulatory Surgical Centers (ASCs): ASCs were allowed to temporarily re-enroll as hospitals and provide hospital services.	ASCs must decide either to meet certification standards for hospitals or return to ASC status.	<u>CMS</u> , p.
Off-Site Patient Screening: CMS partially waived EMTALA to allow hospitals to screen patients at location offsite from hospital's campus to prevent COVID-19 spread.	Waiver is terminated.	5
Written Policies/Procedures for Off-Campus Emergency Screening: CMS has been waiving certain requirements related to emergency services, with respect to the surge facility only, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities.	Waiver is terminated.	<u>CMS</u> , p. 21

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Provider-Based Departments (PBDs): CMS waived certain requirements to allow hospitals to expand capacity by creating new, or relocating existing, provider-based departments. Hospitals could relocate PBDs to patient's home and continue to receive full OPPS payment amount under extraordinary circumstances relocation exception policy.	Temporary extraordinary circumstances relocation policy ends. Hospitals may seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated, but these hospitals would need to follow the standard extraordinary circumstances application process. ²	<u>CMS</u> , p. 7-9
Remote Outpatient Therapy and Education Services: Hospitals could provide behavioral health and education services furnished by hospital-employed counselors or other professionals who cannot bill Medicare directly for their professional services, including partial hospitalization services. These services could be furnished to a beneficiary in their home when the beneficiary is registered as an outpatient of the hospital and the hospital considers the beneficiary's home to be a provider-based department of the hospital.	These services will no longer be able to be paid when provided in the patient's home. ³	<u>CMS</u> , p. 10
Housing Acute Care Patients in Excluded Distinct Part Units: CMS has been waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatients.	Acute care hospitals under the IPPS cannot bill for acute care inpatients housed in excluded distinct part units.	
Excluded Inpatient Psychiatric Units in Acute Care Unit: CMS has been waiving requirements to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit.	Inpatients receiving psychiatric services paid under the IPF PPS and furnished by the excluded distinct part psychiatric unit of an acute care hospital cannot be housed in an acute care bed and unit.	<u>CMS</u> , p. 13
Excluded Inpatient Rehabilitation Unit Patients in Acute Care Unit: CMS has been waiving requirements to allow acute care hospitals with excluded distinct part inpatient rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit.	Inpatients receiving rehabilitation services, paid under the IRF PPS and furnished by the excluded distinct part rehabilitation unit of an acute care hospital, cannot be housed in an acute care bed and unit.	
Inpatient Rehabilitation Facilities re: 60% Rule: CMS has been allowing IRFs to exclude patients from the freestanding hospitals, or excluded distinct part unit's, inpatient population for purposes of calculating the applicable thresholds associated	All inpatients will again be included in the freestanding hospitals, or excluded distinct part unit's, inpatient population for purposes of	<u>CMS</u> , p. 14

² If temporarily relocated off-campus PBDs do not go back to their original location, they will be considered to be non-excepted PBDs and paid the PFS-equivalent rate. ³ In the CY 2023 OPPS/ASC Final Rule, CMS finalized OPPS payment after the PHE ends for behavioral health services furnished remotely by clinical staff of hospital outpatient departments.

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
with the requirements to receive payment as an IRF (commonly referred to as the 60%	calculating the applicable thresholds	
rule), if an IRF admits a patient solely to respond to the emergency and the patient's	associated with the requirements to receive	
medical record properly identifies the patient as such.	payment as an IRF (the 60% rule).	
 <u>Telemedicine from Off-Site Hospital:</u> CMS has been waiving the provisions related to telemedicine for hospitals, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. These telemedicine requirements are specific to the credentialing and privileging processes (and their supporting written agreements) used by hospitals for the credentialing and privileging of distant-site telemedicine practitioners providing services to patients in the hospital. <u>Hospital-Only Clinical Staff In-Person Services:</u> CMS considered the beneficiary's 	Waiver is terminated.	
home to be a provider-based department of hospital for purposes of receiving outpatient services (such as infusions and wound care) and the beneficiary would be registered as a hospital outpatient.		
Remote Physiologic Monitoring (RPM) - Generally: CMS has permitted clinicians to	Clinicians must once again have an	
bill for remote physiologic monitoring (RPM) services furnished to both new and established patients, and to patients with both acute and chronic conditions.	established relationship with the patient prior to providing RPM services. ⁴	
Remote Physiologic Monitoring (RPM) - Data: CMS allowed clinicians to bill CPT codes 99453 and 99454 when as few as two days of data were collected if the patient was diagnosed with, or was suspected of having, COVID-19 and if all other billing requirements of the codes were met.	Clinicians must only bill for these services when at least 16 days of data have been collected.	<u>CMS</u> , p. 9
Frequency Limitations on Telehealth Services: CMS waived frequency limitations on subsequent inpatient visits, skilled nursing facility visits, and/or critical care consult codes.	Waiver is terminated.	
<u>Virtual Check-Ins</u> : CMS allowed annual beneficiary consent for virtual check-ins may be obtained at the same time as the services are furnished for both new and established patients.	Virtual check-ins may only be furnished to established patients.	<u>CMS</u> , p. 10
Emergency Preparedness Policies/Procedures: CMS has been waiving requirements for the hospital to develop and implement emergency preparedness policies and procedures, and that the emergency preparedness communication plans for hospitals contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals to have specific contact	Waiver is terminated.	<u>CMS</u> , p. 21

⁴ Medicare will allow RPM services to continue being furnished to patients with both acute and chronic conditions. However, clinicians must only bill for RPM services when at least 16 days of data have been collected.

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
information for staff, entities providing services under arrangement, patients' physicians, other hospitals, and volunteers.		
Physician Services: CMS has been waiving requirements that Medicare patients be under the care of a physician.		
Anesthesia Services: CMS has been waiving the requirements that a certified registered nurse anesthetist (CRNA) be under the supervision of a physician. ⁵	Waiver is terminated.	<u>CMS</u> , p. 26
<u>Respiratory Care Services:</u> CMS has been waiving the requirement that hospitals designate, in writing, the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to conduct specific		26
procedures. End-Stage Renal Disease (ESRD) Patients: Medicare patients with end-stage renal disease (ESRD) who are on home dialysis could receive a telehealth visit at least monthly in the case of the initial three months of home dialysis and at least once every three consecutive months after the initial three months.	Monthly visit must be face-to-face, without the use of telehealth.	<u>CMS</u> , p. 9-10
Inpatient Rehabilitation Facilities: CMS allowed telehealth to be used to fulfill requirement for physicians to conduct the required face-to-face visits 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.	Rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) will be required to visit IRF patients face-to-face at least 3 times per week.	<u>CMS</u> , p. 3

Post-Acute Care, Discharge Planning, and Long-Term Care

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
SNF 3-Day Prior Hospitalization: 3-day inpatient hospital stay was not required prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met. CMS granted certain beneficiaries who exhausted their SNF benefits a one-time renewal of SNF Part A coverage, beginning a new benefit period, without first having the typical 60-day wellness period that must typically occur before a beneficiary to obtain a new benefit period.	All new SNF stays beginning on or after May 12th will require a qualifying hospital stay before Medicare coverage. Additionally, for any new benefit period that begins on or after May 12th, the beneficiary will need to have completed a 60-day wellness period. ⁶	<u>CMS</u> , p. 5
Swing Beds: CMS allowed hospitals to establish SNF swing beds, payable under the SNF prospective payment system (PPS), to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF.	Waiver is terminated.	<u>CMS</u> , p. 11

⁵ Exemption from requirement is available but must be requested via a letter from the state's Governor.

⁶ Providers may continue SNF 3-day rule waiver if they are participants in certain types of accountable care organizations. Last Updated: May 10, 2023

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Limited Discharge Planning Information: CMS has been waiving certain detailed regulatory requirements to provide information regarding discharge planning, such as using quality measures and data to select a nursing home or home health agency. Modified Discharge Planning: CMS has been waiving certain, more detailed, requirements related to hospital discharge planning for post-acute care services, including certain requirements for those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services.	Waiver is terminated.	<u>CMS</u> , p. 18
<u>Nursing Aides</u> : In cases where barriers to certification for nursing aides existed due to workforce shortages, CMS granted individual, time-limited waivers to help facilities retain staff while continuing to seek training and certification.	Facilities will have four months (i.e., until September 10, 2023) to have all nurse aides who are hired prior to the end of the PHE complete a state-approved Nurse Aide Training and Competency Evaluation Program (NATCEP) or Competency Evaluation Program (CEP). Nurse aides hired after the end of the PHE will have up to four months from their date of hire to complete a state approved NATCEP/CEP.	<u>CMS</u> , p. 5-6
Preadmission Screening and Annual Resident Review (PASRR): CMS allowed allowing nursing homes to admit new residents who have not received Level I or Level II Preadmission Screening.	Waiver is terminated.	<u>CMS</u> , p. 3
Resident Roommates and Grouping: CMS waived certain requirements solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID-19 and separating them from residents who are asymptomatic or tested negative for COVID-19.	Waiver is terminated. ⁷	
Resident Transfer and Discharge: CMS waived various requirements for a facility to provide advance notification of options relating to the transfer/discharge to another facility and for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice was to be provided as soon as practicable (with some exceptions); to allow a long-term care facility to transfer or discharge residents to another LTC facility solely for cohorting purposes.	Waiver is terminated. ⁸	<u>CMS</u> , p. 4

 ⁷ The waiver for the requirement for written notice of a room change ended in May 2021.
 ⁸ The waiver for the requirement of reasonable accommodation of resident needs and preferences ended in May 2021. Last Updated: May 10, 2023

Fraud and Abuse Laws (Federal Physician Self-Referral Law)

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Remuneration from an entity to a physician (or an immediate family member of a physician) that is above or below the fair market value for services personally		
performed by the physician (or the immediate family member of the physician) to the		
entity.		
Rental charges paid by an entity to a physician (or an immediate family member of a physician) that are below fair market value for the entity's lease of office space from		
the physician (or the immediate family member of the physician).		
Rental charges paid by an entity to a physician (or an immediate family member of a		
physician) that are below fair market value for the entity's lease of equipment from the		
physician (or the immediate family member of the physician).		
Remuneration from an entity to a physician (or an immediate family member of a		
physician) that is below fair market value for items or services purchased by the entity		
from the physician (or the immediate family member of the physician).		
Rental charges paid by a physician (or an immediate family member of a physician) to		
an entity that are below fair market value for the physician's (or immediate family		
member's) lease of office space from the entity.		
Rental charges paid by a physician (or an immediate family member of a physician) to	Waivers terminate and entities must	<u>HHS</u> , p
an entity that are below fair market value for the physician's (or immediate family	immediately comply with all provisions of the	3-5
member's) lease of equipment from the entity.	federal physician self-referral law.	
Remuneration from a physician (or an immediate family member of a physician) to an		
entity that is below fair market value for the use of the entity's premises or for items or		
services purchased by the physician (or the immediate family member of the		
physician) from the entity.		
Remuneration from a hospital to a physician in the form of medical staff incidental		
benefits that exceeds the limit set of low value (that is, less than \$25) with respect to		
each occurrence of the benefit. The \$25 limit is adjusted each calendar year to the		
nearest whole dollar by the increase in the Consumer Price Index-Urban All Items for		
the 12-month period ending the preceding September 30.		
Remuneration from an entity to a physician (or the immediate family member of a		
physician) in the form of nonmonetary compensation that exceeds the limit of		
compensation from an entity in the form of items or services (not including cash or		
cash equivalents) that does not exceed an aggregate of \$300 per calendar year, as		
adjusted for inflation each calendar year to the nearest whole dollar by the increase in		
the Consumer Price Index-Urban All Items for the 12-month period ending the		
preceding September 30, and if certain conditions are satisfied. ast Updated: May 10, 2023		

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
 Waiver Summary (What Was Permitted) Remuneration from an entity to a physician (or the immediate family member of a physician) resulting from a loan to the physician (or the immediate family member of the physician): (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician (or the immediate family member of a physician) to an entity resulting from a loan to the entity: (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician (or the immediate family member of the physician). The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect on December 31, 2010 (or, in the case of a hospital that did not have a provider agreement in effect and approval of the expansion of facility capacity as required under federal expansion limitations. Referrals by a physician owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital that converted from a physician owned ambulatory surgical center to a hospital during the COVID-19 federal PHE; (iii) the hospital enrolled in Medicare as a hospital during the COVID-19 federal PHE; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the COVID-19 federal PHE; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the COVID-19 federal PHE; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the COVID-19 fe	Next Steps (After PHE Ends) Waivers terminate and entities must immediately comply with all provisions of the federal physician self-referral law.	HHS, p. 3-5

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes. The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.	Waivers terminate and entities must immediately comply with all provisions of the federal physician self-referral law.	<u>HHS</u> , p. 3-5
Referrals by a physician to an entity with whom the physician (or an immediate family member of the physician) has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies each other requirement of the applicable exception unless such requirement is waived under one or more of the other COVID-19 blanket waivers.		

Utilization Review / Administration

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
Paperwork Requirements: CMS waived certain paperwork requirements for hospitals located in states that have widespread confirmed COVID-19 cases, such as timeframes in providing medical record copies, patient visitation policies, and seclusion.	Waiver is terminated.	<u>CMS</u> , p. 5-6
Alcohol-Based Hand Rub (ABHR) Dispensers: CMS waived requirements for placement of ABHR dispensers and bulk containers for use by staff and others.	Waiver is terminated.	<u>CMS</u> , p. 6-7
Sole Community Hospitals (SCHs) ONLY: CMS waived certain eligibility requirements and "market share" and bed requirements for eligibility to be classified as SCH.	tals (SCHs) ONLY: CMS waived certain eligibility Medicare Administrative Contractors (MACs)	
<u>Verbal Orders:</u> CMS allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours.	Waiver is terminated.	<u>CMS</u> , p. 17
Reporting Requirements re: Restrained Patients: CMS has been waiving reporting requirements for hospitals to report patients in an intensive care unit whose death is caused by their disease process, but who required soft wrist restraints to prevent pulling tubes/IVs, may be reported later than close of business next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits.	Waiver is terminated.	<u>CMS</u> , p. 18
Completion of Medical Records: CMS has been waiving certain requirements that cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention	Waiver is terminated.	<u>CMS</u> , p. 19

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
requirements. CMS has also allowed flexibility in completion of medical records within		
30 days following discharge.		
Advance Directives: CMS has been waiving the requirements for hospitals to provide		
information about its advance directive policies to patients.		
Utilization Review (UR) Plans: CMS has been waiving requirements for hospitals to		
have utilization review plans that meet specified requirements. CMS has also waived		
requirement that a hospital must have a utilization review (UR) plan with a UR		
committee that provides for review of services furnished to Medicare and Medicaid		
beneficiaries to evaluate the medical necessity of the admission, duration of stay, and		
services provided.		
Quality Assessment and Performance Improvement (QAPI) Program: CMS has		
been waiving requirements to provide details on the scope of the program, the	Waiver is terminated.	<u>CMS</u> , p. 20
incorporation, and setting priorities for the program's performance improvement		20
activities, and integrated QAPI programs (for hospitals that are a part of a hospital		
system).		
Nursing Services: CMS has been waiving requirements that nursing staff to develop		
and keep current a nursing care plan for each patient, and the provision that requires		
the hospital to have policies and procedures in place establishing which outpatient		
departments are not required to have a registered nurse present.		
Food and Dietetic Services: CMS has been waiving the requirement to have a current		
therapeutic diet manual approved by the dietitian and medical staff readily available to	Waiver is terminated.	
all medical, nursing, and food service personnel. Such manuals would not need to be		
maintained at surge capacity sites.		<u>CMS</u> , p.
Signature Requirements for Drugs and Durable Medical Equipment (DMEs): CMS		21
is not enforcing signature and proof of delivery requirements for Part B drugs and	Signature and proof of delivery requirements	
Durable Medical Equipment when a signature cannot be obtained because of COVID-	reinstated.	
19.		
Provider Enrollment Hotline: CMS established toll-free hotlines for physicians, non-		
physician practitioners, and Part A certified providers and suppliers who have	Hotline is shut down.	<u>CMS</u> , p.
established isolation facilities to enroll and receive temporary Medicare billing		22
privileges.		
Expedited Provider Enrollment: CMS expedited any pending or new applications		<u>CMS</u> , p.
from providers and suppliers, including physicians and non-physician practitioners	Normal processing times resume.	23
received on or after March 1, 2020.		20

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
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. CMS allowed a provider to apply (an 855-I or 855-R for example) to cancel their opt-out.	Opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulations allow.	
<u>Medical Staff Requirements:</u> CMS has been waiving the Medical Staff requirements to allow for physicians, whose privileges would have expired, to continue practicing at the hospital and for new physicians to be able to practice in the hospital before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS has also been waiving certain details of the credentialing and privileging process.		
Quality Assessment and Performance Improvement (QAPI) for CommunityMental Health Centers (CMHCs):CMS waived certain specific detailed requirementsfor the QAPI program's organization and content.Provision of Services at CMHCs:Provision of Services at CMHCs:CMS has been waiving the specific requirementthat prohibits CMHCs from providing partial hospitalization services and other CMHCservices in an individual's home so that clients can safely shelter in place during thePHE while continuing to receive needed care and services from the CMHC.	Waiver is terminated.	<u>CMS</u> , p. 28
<u>CMHC 40% Rule</u> : CMS has been waiving the requirement that a CMHC provides at least 40% of its items and services to individuals who are not eligible for Medicare benefits.	Waiver is terminated.	<u>CMS</u> , p. 29
National and Local Coverage Determinations (NCDs, LCDs) - Staffing Requirement: To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish or supervise a service, the Chief Medical Officer or equivalent of a hospital or facility has had the authority to make those staffing decisions.	Waiver is terminated.	<u>CMS</u> , p. 13
Local Coverage Determinations (LCDs) for Glucose Monitors: CMS has exercised enforcement discretion and has not enforced the current clinical indications in LCDs for therapeutic continuous glucose monitors during this public health emergency.	Discretion expires.	
National and Local Coverage Determinations (NCDs, LCDs) - Certain Devices: CMS has not enforced clinical restrictions in certain NCDs and LCDs that otherwise would have restricted coverage of respiratory-related devices, home infusion pumps, and home anticoagulation therapy for COVID-19 patients.	Discretion expires.	<u>CMS</u> , p. 18
National Coverage Determination (NCDs) - Certain Cardiac Devices: CMS has not enforced the procedural volume requirements contained in these percutaneous left atrial appendage closure, transcatheter aortic valve replacement, transcatheter mitral	Discretion expires.	<u>CMS</u> , p. 19

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
valve replacement, and ventricular assist devices for facilities and providers that, prior		
to the public health emergency for COVID-19, met the volume requirements.		
Maryland Nursing "Emergency Situation" Exception: An "emergency situation" exists such that registered nurses (RNs) or licensed practical nurses (LPNs) who hold a current active RN or LPN license in any other state or jurisdiction may render nursing care in Maryland.	Exception expires.	MBON
Inspection, Testing, and Maintenance (ITM) Requirements: CMS modified ITM requirements, including ITM required by the Life Safety Code (LSC) and Health Care Facilities Code (with specified exceptions) to permit facilities to adjust ITM frequencies and activities as necessary to reduce disruption of patient care and potential exposure/transmission of COVID-19.		
Fire Drills: CMS waived fire drills required by the LSC due to the inadvisability of drills that move and mass staff together. Instead, CMS permitted a documented orientation training program related to the current fire plan, which considered current facility conditions.	Waiver is terminated.	<u>CMS</u> , p. 15
<u>Temporary Walls/Barriers Between Patients:</u> CMS waived LSC requirements that would not permit temporary walls and barriers between patients.		
Outside Window/Door in Sleeping Room: CMS waived the requirement to have an outside window or outside door in every sleeping room. This permitted spaces not normally used for patient care to be utilized for patient care and quarantine.		

Miscellaneous

Waiver Summary (What Was Permitted) Next Steps (After PHE Ends)		Agency
Sterile Compounding: CMS has been waiving hospital sterile compounding requirements to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only.	Waiver is terminated.	<u>CMS</u> , p. 25
Teaching Physicians: CMS allowed services furnished by a resident in a teaching setting to be billed by a teaching physician who is present during the key portion of the service. If the training setting is located outside of a metropolitan statistical area, the teaching physician could have a virtual presence through audio/video real-time technology. This virtual presence of the teaching physician was allowed for all teaching settings. A teaching physician could bill for certain services when they direct and review the care furnished by up to four residents at a time. For all teaching settings during the	Teaching physicians only in residency training sites located outside of a metropolitan statistical area may direct, manage, and review care furnished by residents through audio/video real-time communications technology. This policy does not apply in the case of surgical, high risk, interventional, or	<u>CMS</u> , p. 12

Waiver Summary (What Was Permitted)	Next Steps (After PHE Ends)	Agency
PHE, teaching physicians may direct care and review services each resident provides during or at once after each visit virtually.	other complex procedures, services performed through an endoscope, and anesthesia services.	
 FDA Guidance Documents: FDA has found that certain guidance documents will no longer be in effect, including: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act 	Guidance no longer in effect.	<u>FDA</u>
FEMA Incident Period: FEMA provided Public Assistance funding for certain eligible costs under its incident period disaster declarations. ⁹	Incident period ends. ¹⁰	<u>FEMA</u>
PREP Act Liability Immunity – Routine Childhood Vaccinations: Pharmacists, pharmacy interns, and pharmacy technicians have PREP Act coverage for all routine childhood vaccinations.	Coverage ends.	HHS
Emergency Preparedness – Training and Testing Program: During or after an actual emergency, the emergency preparedness regulations allow for a one-year exemption from the requirement that the provider/supplier perform testing exercises. The exemption only applies to the next required full-scale exercise (not the exercise of choice), based on the 12-month exercise cycle. The cycle is determined by the provider/supplier (e.g., calendar, fiscal or another 12-month timeframe). The exemption only applies when a provider/supplier activates its emergency preparedness program for an emergency event.	Providers/suppliers are expected to return to normal operating status and comply with the regulatory requirements for emergency preparedness with the conclusion of the PHE.	<u>CMS</u> , p. 2
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs): CMS waived the requirements for clients to be able to participate in social, religious, and community group activities.	Waiver is terminated.	<u>CMS</u> , p. 19
<u>Certain Mandatory Training Requirements:</u> CMS waived, in part, the requirements related to routine staff training programs unrelated to the public health emergency.	Waiver is terminated.	<u>CMS</u> , p. 20

⁹ HHS has announced a new "<u>HHS Bridge Access Program for COVID-19 Vaccines and Treatments</u>" program to maintain access to COVID-19 care for uninsured individuals. ¹⁰ Although costs incurred for work related to COVID-19 after May 11, 2023 will not be eligible for Public Assistance funding, FEMA is providing a limited 90-day extension to August 9, 2023, to complete demobilization, disposition, and disposal activities. Last Updated: May 10, 2023

Public Health Emergency Waivers Ending at Other Times

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Category	Waiver Summary	Agency	Date Waiver Ends
COVID-19 Vaccinations, Testing, and Treatments	Enhanced Payments for New COVID-19 Treatments - Hospital Inpatient Stays: Medicare program has provided an enhanced payment for eligible inpatient cases that involve use of certain new products authorized or approved to treat COVID-19.	<u>CMS</u> , p. 15	End of the fiscal year that COVID-19 PHE ends
COVID-19 Vaccinations, Testing, and Treatments	Monoclonal Antibodies: CMS will pay for monoclonal antibodies used for the treatment or for post-exposure prophylaxis of COVID-19 as CMS pays for biological products and through the applicable payment system, using the appropriate coding and payment rates, similar to the way we pay for administering other complex biological products. Monoclonal antibodies that are used for pre-exposure prophylaxis prevention of COVID-19 will continue to be paid under the Part B preventive vaccine benefit if they meet applicable coverage requirements.	<u>CMS</u> , p. 3	Effective January 1 of the year following the year in which Secretary ends EUA declaration for COVID-19 drugs and biologicals
COVID-19 Vaccinations, Testing, and Treatments	<u>Medicaid and CHIP Coverage</u> : States must provide Medicaid and CHIP coverage without cost sharing for COVID-19 vaccinations, testing, and treatments through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE.	<u>CMS</u> , p. 2	September 30, 2024
COVID-19 Vaccinations, Testing, and Treatments	Long-Term Care Facilities (LTC) Infection Reporting: CMS required all LTC facilities report COVID-19 information using CDC National Healthcare Safety Network. Additionally, facilities are required to inform the residents, their representatives and families following the occurrence of either a single confirmed infection of COVID-19 or three or more residents or staff with newonset of symptoms.	<u>CMS</u> , p. 5	December 31, 2024
COVID-19 Vaccinations, Testing, and Treatments	<u>LTC Vaccination Reporting</u> : CMS required facilities to report COVID-19 vaccination status of residents and staff through CDC National Healthcare Safety Network.	<u>CMS</u> , p. 5	Permanent unless regulatory action taken
COVID-19 Vaccinations, Testing, and Treatments	LTC Education and Offering of COVID-19 Vaccine: CMS required all LTC facilities to educate residents and staff on the COVID-19 vaccine (including any additional doses) and offer to help them get vaccinated.	<u>CMS</u> , p. 6	May 21, 2024, unless regulatory action taken
Alternate Care Sites	Acute Hospital Care at Home: CMS created flexibility to allow hospitals to expand their capacity to provide inpatient care in an individual's home.	<u>CMS</u> , p. 5	December 31, 2024 ¹¹

¹¹ Explicit criteria and data collection requirements were established as part of this extension in the Consolidated Appropriations Act, 2023. Last Updated: May 10, 2023

Category	Waiver Summary	Agency	Date Waiver Ends
Alternate Care Sites	Emergency Certificates of Need (E-CONs): MHCC automatically extended the validity of 21 emergency CONs granted between March 2020 and January 2021. However, if a hospital with a valid E-CON does not intend to close the bed capacity approved in its E-CON by the April 30, 2023 termination date, it must notify MHCC of its intent to file a formal CON application (or request other action by MHCC to allow continued operation of the bed capacity approved in its E-CON) on or before March 30, 2023. The formal CON application would be due June 2, 2023.	MHCC	April 30, 2023
Telehealth	Telehealth Flexibilities: Waivers including geographic and originating site restrictions so that Medicare patients can continue to use telehealth services from their home and allowing certain audio-only telehealth services.	<u>HHS</u>	December 31, 2024
Telehealth	Eligible Providers: CMS has waived requirements that specify the types of practitioners who may bill for their services when furnished as Medicare telehealth services from a distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services.	<u>CMS</u> , p. 5	December 31, 2024
Telehealth	Medicare Telehealth Payment Parity: CMS allows physicians and practitioners to continue to bill with the place of service (POS) indicator that would have been reported had the service been furnished in-person. These claims will require the modifier "95" to identify them as services furnished as telehealth services. Claims can continue to be billed with the place of service code that would be used if the telehealth service had been furnished in-person.	<u>CMS</u>	Later of the end of CY 2023 or end of the year in which PHE ends
Telehealth	Behavioral Health Telehealth: In-person visit requirements before a patient may be eligible for telebehavioral health care services waived.	HHS	December 31, 2024
Telehealth	Medicare Telehealth Services List: CMS finalized that certain services added to the Medicare telehealth services list will remain on the list through December 31, 2023, allowing additional time for us to evaluate whether the services should be permanently added to the Medicare telehealth services list. CMS also extended inclusion of certain cardiac and intensive cardiac rehabilitation codes.	<u>CMS</u>	December 31, 2023
Telehealth	Reporting Home Address for Telehealth: 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.	<u>CMS</u> , p. 15	December 31, 2023
Telehealth	Physician Supervision Requirements: CMS has temporarily modified the regulatory definition of direct supervision, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include "virtual presence" of the supervising clinician through real-time audio and video technology.	<u>CMS</u> , p. 11	End of calendar year that COVID-19 PHE ends
Telehealth	HSCRC Telehealth Regulations: HSCRC extended the effective date of COMAR 10.37.10.07- 1 (telehealth regulations) to the end of the extension of the federal telehealth flexibilities.	HSCRC	December 31, 2024

Category	Waiver Summary	Agency	Date Waiver Ends
Telehealth	Telemedicine Flexibilities for Prescription of Controlled Medications: DEA extended current flexibilities for telemedicine prescription of controlled medications.	DEA	November 11, 2023 ¹²
HIPAA	 HIPAA – Enforcement Discretion: OCR published four Notifications of Enforcement Discretion in the Federal Register regarding how the Privacy, Security, Breach Notification, and Enforcement Rules ("HIPAA Rules") would be applied to certain violations during the COVID-19 nationwide public health emergency. Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites Enforcement Discretion for Telehealth Remote Communications Enforcement Discretion Under HIPAA to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID-19 Vaccination 	<u>OCR</u>	90-calendar day transition period for covered health care providers to come into compliance with the HIPAA Rules with respect to their provision of telehealth. ¹³
PREP Act Liability Protections	Liability for Federal Agreements: Liability immunity to manufacturers, distributors, public and private organizations conducting countermeasure programs, and providers for COVID-19 countermeasure activities related to an agreement with the federal government (e.g., manufacturing, distribution, or administration of the countermeasures subject to a federal contract, provider agreement, or memorandum of understanding).	<u>HHS</u>	December 31, 2024
PREP Act Liability Protections	Pharmacy Administration of Vaccines and Tests: PREP Act immunity from liability exists for pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests.	<u>HHS</u>	December 31, 2024

¹² Additionally, for any practitioner-patient telemedicine relationships that have been or will be established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID–19 PHE will continue to be permitted via a one-year grace period through November 11, 2024.

¹³ The transition period will be in effect beginning on May 12, 2023 and will expire at 11:59 p.m. on August 9, 2023. OCR will continue to exercise its enforcement discretion and will not impose penalties on covered health care providers for noncompliance with the HIPAA Rules that occurs in connection with the good faith provision of telehealth during the 90-calendar day transition period.

Category	Waiver Summary	Agency	Date Waiver Ends
FDA Enforcement Policies	FDA Guidance Documents: FDA is revising guidance regarding the enforcement policy for the following devices:• Remote digital pathology devices• Imaging systems• Non-invasive fetal and maternal monitoring devices used to support patient monitoring• Telethermographic systems• Digital health devices for treating psychiatric disorders• Extracorporeal membrane oxygenation and cardiopulmonary bypass devices• Ophthalmic assessment and monitoring devices• Infusion pumps and accessories• Face shields, surgical masks, and respirators• Gowns, other apparel, and gloves• Sterilizers, disinfectant devices, and air purifiers• Ventilators and accessories and other respiratory devices• FDA-cleared molecular influenza and RSV tests• Coagulation systems for measurement of viscoelastic properties• Viral transport media	<u>FDA</u> , p. 5-6	180 days after the federal PHE expires (November 7, 2023)
FDA Emergency Use Authorizations (EUAs)	FDA Transition Document: FDA is assessing how to transition medical devices issued EUAs related to COVID-19, including ventilators, oxygen delivery devices, and related accessories.	<u>FDA</u>	Upon termination of each device's EUA declaration
Medicare Chronic Care Management	Beneficiary Consent for Chronic Care Management (CCM): CMS allowed informed consent to receive services furnished by auxiliary personnel, including for example CCM services, must have been obtained prior to the start of the service. Consent has not had to be obtained at the required initiating visit for CCM that must be performed by the billing practitioner, but it could have been obtained at that time. Further, there need not be an employment relationship between the person obtaining the consent and the billing practitioner.	<u>CMS</u> , p. 11	End of calendar year that COVID-19 PHE ends
Care Waivers	ICF/IIDs Continuous Active Treatment Program: CMS waived the requirement that each client must receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services. CMS waived those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only. In accordance with §483.440(c)(1), any	<u>CMS</u> , p. 21	60 days after federal PHE expires

Category	Waiver Summary	Agency	Date Waiver Ends
	modification to a client's Individual Program Plan (IPP) in response to treatment changes		
	requires the approval of the interdisciplinary team.		
Care Waivers	ICF/IIDs Staffing Flexibilities: CMS waived the requirements for the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. DSS perform activities such as cleaning of the facility, cooking, and laundry services.	<u>CMS</u> , p. 22	End of calendar year that COVID-19 PHE ends

Appendix: Acronyms

Acronym	Name
ABHR	Alcohol-Based Hand Rub
ASC	Ambulatory Surgical Center
C-APC	Comprehensive Ambulatory Payment Classification
CCM	Chronic Care Management
CDC	Center for Disease Control
CEP	Competency Evaluation Program
CHIP	Children's Health Insurance Program
CMHC	Community Mental Health Center
CMS	Centers for Medicare and Medicaid Services
COMAR	Code of Maryland Regulations
CRNA	Certified Registered Nurse Anesthetist
DCS	Direct Care Staff
DEA	Drug Enforcement Administration
DME	Durable Medical Equipment
DUA	Data Use Agreement
DSS	Direct Support Staff
E-CON	Emergency Certificate of Need
EMTALA	Emergency Medical Treatment and Labor Act
ESRD	End-Stage Renal Disease
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HCPCS	Healthcare Common Procedure Coding System
HHA	Home Health Agency
HHS	Health and Human Services
HIPAA	Health Information Portability and Accountability Act
HSCRC	Health Services Cost Review Commission
ICF/IID	Intermediate Care Facility for Individuals with
	Intellectual Disabilities

IPF PPS	Inpatient Psychiatric Facility Prospective Payment System
IPPS	Inpatient Prospective Payment System
IRF	Inpatient Rehabilitation Facility
ITM	Inspection, Testing, and Maintenance
LCD	Local Coverage Determination
LPN	Licensed Practical Nurse
LTC	Long-Term Care
LTCH	Long-Term Care Hospital
LSC	Life Safety Code
MAC	Medicare Administrative Contractor
MHCC	Maryland Health Care Commission
NATCEP	Nurse Aide Training and Competency Evaluation
	Program
NCD	National Coverage Determination
OCR	Office for Civil Rights
OPPS	Outpatient Prospective Payment System
PASRR	Preadmission Screening and Annual Resident Review
PBD	Provider-Based Departments
PHE	Public Health Emergency (also referred to as section
POS	319 federal public health emergency) Place of Service
PREP Act	
	Public Readiness and Emergency Preparedness Act
RN	Quality Assessment and Performance Improvement Registered Nurse
RPM	
SCH	Remote Physiologic Monitoring
SNF	Sole Community Hospital
	Skilled Nursing Facility Utilization Review
UK	