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Healthcare compliance in a post-pandemic world

by Larissa Morgan, Steve Lokensgard, and Jacob Hauschild

On January 31, 2020, pursuant to Section 319 of the Public Health Service Act, the secretary of the U.S. Department of Health & Human Services (HHS) determined that a public health emergency (PHE) exists due to the soaring number of COVID-19 cases in the United States. In March 2020, President Donald Trump issued a national emergency declaration according to Section 201 of the National Emergencies Act. Nobody knew at the time that the PHE would last 1,196 days, or the extent to which the pandemic would strain the country's healthcare system. Despite the best efforts of public health officials and healthcare providers, 102 million Americans would suffer from COVID-19, and 1.1 million would die. The pandemic was an event that happens once in a hundred years—an extreme situation requiring an extreme response.

The declaration of a national emergency and PHE gave the secretary of HHS, under Section 1135 of the Social Security Act, authority to waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements. A complete list of waivers was updated almost daily on the Centers for Medicare & Medicaid Services (CMS) website.[1] The flexibilities granted by CMS were designed to promote access to care and reduce the administrative burden on providers.

Both the national emergency and the PHE will cease at the end of the day on May 11, 2023. The fact that the pandemic lasted for over three years presents a special challenge for compliance officers. A report published in 2022 noted that in the previous five years, the average hospital turned over 100.5% of its workforce.[2] The average annual hospital turnover rate increased by 6.4% to 25.9%. The impact on hospitals is likely not a unique experience for other healthcare providers. This means that a significant percentage of the workforce can't just go back to business as usual because they were not around when the flexibilities were not in effect. Compliance officers will have a significant lift to educate their staff on changes required with the expiration of the PHE.

This article aims to identify key waivers that will continue or expire to assist compliance officers in adapting policies and procedures to the post-pandemic world. This article also focuses on certain types of providers and discusses only certain issues. CMS has published provider-specific fact sheets that identify flexibilities issued

during the pandemic and whether they will expire or continue, but these fact sheets are not comprehensive.[3] Other sources include the Consolidated Appropriations Act of 2023 (CAA)[4] and the 2023 Medicare Physician Fee Schedule (PFS).[5]

Physicians and other clinicians

CMS and other federal agencies have applied an array of waivers that have impacted how medical practices operate in nearly every setting. Many of these flexibilities will roll back immediately following the conclusion of the PHE; in contrast, others—namely, those related to telehealth—have been extended until at least the end of 2024.

Care in the traditional setting

Nonphysician practitioner diagnostic testing. During the PHE, CMS used the flexibility at 42 C.F.R. § 410.32(b) to allow nurse practitioners, clinical nurse specialists, certified nurse–midwives, and physician assistants to supervise diagnostic tests as authorized under state law.[6] Beginning at the end of the PHE, only physicians may supervise diagnostic X-ray tests, laboratory tests, and the other diagnostic tests contemplated by 42 C.F.R. § 410.32.

Locum Tenens 60-day limit. During the PHE, CMS modified the 60-day limit specified in section 1842(b)(6)(D)(iii) of the Social Security Act, allowing physicians or physical therapists to use the same substitute during the entire duration of their unavailability.[7] Beginning 61 days after the end of the PHE, the regular physician or physical therapist must use a different substitute or return to their practice for at least one day to reset the 60-day limit. This modified schedule applies to both reciprocal billing arrangements and fee-for-time compensation arrangements.

Licensing and provider enrollment. During the PHE, CMS made several temporary changes to licensing requirements, including: expediting enrollment for new and pending applications; allowing practitioners to cancel their opt-out status; permitting practitioners to render telehealth services from home without reporting their home address; and allowing licensed practitioners to bill Medicare for services provided outside of their state of enrollment. Immediately following the conclusion of the PHE, CMS will return to normal processing times for applications, opt-out statuses will only be cancellable within regulations, practitioners must resume reporting their home address on the Medicare enrollment, and regulations will continue to allow a deferral to state law for licensing. Compliance officers are advised to review updated state licensure requirements, as many states have made once-temporary flexibilities permanent.[8] For example, as of May 5, 2021, Arizona permanently allows healthcare providers licensed in another jurisdiction to practice telehealth with Arizona patients, assuming proper registration and compliance with other laws.

Supervision requirements. During the PHE, CMS modified the definition of direct supervision to allow for the "virtual presence" of the supervising clinician via synchronous audio and video technology to satisfy the "immediately available" requirement.[9] This modification of the definition will revert at the end of 2023.

Services provided by residents. Throughout the PHE, CMS waived existing regulations applicable to teaching physicians to permit such physicians to use audio/video real-time communication to supervise residents.[10] Following the PHE's expiration, teaching hospitals will only receive Medicare payment for services where a teaching physician is physically present for a main portion of services that involves residents, and where the physician is immediately available to provide care for the entire procedure, when necessary and applicable. Physicians teaching at residency training programs outside of a metropolitan statistical area—a "core area

containing a large population nucleus, together with adjacent communities that have a high degree of economic and social integration with that core"—would still be permitted to satisfy the physical presence requirement through audio/video real-time communications technology, except in certain high-risk, complex cases.[11]

In addition, during the PHE, physicians in primary care centers could supervise residents via telehealth and bill for all evaluation and management (E/M) services when residents provided the service. The flexibility will terminate upon the PHE's expiration, except for those teaching physicians at residency training sites outside of a metropolitan statistical area. The primary care exception will only allow a physician to bill for levels 1–3 E/M codes performed by a resident. To bill for levels 4–5, the physician must be physically present for the critical portion of the service performed by the resident.[12]

Telehealth

Throughout the PHE, clinicians could rely upon various regulatory flexibilities, allowing for expanded telehealth use across healthcare settings. While certain flexibilities will end this year, others will survive the PHE due to permanent changes that regulators have adopted, as well as temporary modifications made through the CAA.

Changes to occur in 2023

Remote patient monitoring (RPM). During the PHE, CMS waived the requirement for RPM services to be limited to "established patients." After the PHE, however, RPM services will be limited to established patients, and a physician must conduct a new patient evaluation before ordering RPM for a new patient. RPM services may be provided to patients with acute or chronic conditions.

Additionally, during the PHE, Medicare allowed clinicians to bill for certain RPM services (described by Current Procedural Terminology (CPT) codes 99453 and 99454) after as few as two days of data collection if the patient was diagnosed with or suspected of having COVID-19. When the PHE ends, the waiver of CPT coding guidance also terminates, meaning that such RPM services must collect at least 16 days of data before clinicians may bill for these services.

Frequency limitations. Throughout the PHE, Medicare waived frequency limitations for certain telehealth services. Such frequency limitations will be reinstated following the end of the PHE. This change means that subsequent inpatient visits may only be furnished via telehealth once every three days, subsequent skilled nursing facility (SNF) visits may only be provided via telehealth once every 14 days, and critical care consult codes may only be furnished by telehealth to a Medicare beneficiary once per day.

Opioid treatment programs. During the PHE, periodic assessments furnished as part of an opioid treatment program (OTP) were permitted to be delivered by telephone when the beneficiary did not have access to synchronous, interactive audio–video technology.[13] Immediately following the PHE, such flexibility will end, and all OTP patient counseling and therapy services must be delivered in person or via two-way interactive audio-video technology.

Prescription of controlled substances. Throughout the PHE, the Drug Enforcement Agency (DEA) relaxed its requirements for prescribing controlled substances by waiving the in-person exam rule of the Ryan Haight Act, allowing for telemedicine prescriptions for both established and new patients. When the PHE ends, the in-person exam requirement will again apply, and telemedicine prescriptions for certain controlled substances will no longer be allowed. This means patients who received prescriptions based solely on virtual visits during the PHE should be seen in person for a new prescription. On February 24, 2023, DEA issued two proposed rules that would introduce limitations to the prescribing of controlled substances through telehealth and allow for the use

of telehealth prescribing under certain conditions.[14] Compliance officers should stay apprised of these proposed rules and how they impact prescribing of controlled substance post-PHE if they are finalized.

Cost sharing. HHS Office of Inspector General announced that during the PHE, it would not penalize providers under the federal Anti-Kickback Statute for reducing or eliminating cost-sharing amounts for telehealth or RPM services.[15] Once the PHE ends, physicians will no longer be able to routinely waive cost-sharing amounts for these services.

HIPAA. The HHS Office for Civil Rights announced that it would exercise its enforcement discretion not to impose penalties for HIPAA violations against covered entities in connection with their good faith provision of telehealth using communication technologies that were not HIPAA-compliant.[16] This policy will end with the culmination of the PHE.

Changes to occur in 2024

The CAA extended certain telehealth flexibilities created during the PHE through December 31, 2024. For example, prior to the PHE, a telehealth visit had to take place via a synchronous, interactive audio–video system; the patient had to be in a specific location (i.e., hospital/clinic) and in a certain geographic area (i.e., outside of a metropolitan statistical area); and the patient could only receive specific identified services. The CAA extended all these flexibilities such that, through December 31, 2024, a patient can have a valid telehealth visit in their home —regardless of where they live—for an expanded list of services.

Flexibilities that were extended until the end of 2024 include:

- Reimbursement for particular audio-only evaluation and management services, as well as behavioral health counseling and educational services
- An expanded list of providers eligible to deliver telehealth services from a distant site
- An expanded list of services that may be delivered by telehealth[17]
- Reimbursement for nonphysician practitioner remote evaluation of patient videos and images and other virtual services that are conducted via online patient portals (often referred to as "e-visits") to both new and established patients
- Allowance for end-stage renal disease monthly visits to be furnished by telehealth
- Allowance for practitioners to perform visits to nursing home residents by telehealth
- Allowance for patient consent for virtual check-ins at the same time as the services are furnished for both new and established patients through the end of 2024

Hospitals

Conditions of payment flexibilities

The following essential flexibilities will end upon the PHE's expiration, resulting in hospital reimbursement and payment changes.

Hospital originating site facility fee for professional services furnished via telehealth. Telehealth became a critical tool for hospitals to deliver care to patients during the COVID-19 pandemic. To facilitate hospitals' use of

telehealth during the PHE, CMS permitted practitioners to bill services provided through telehealth to patients in their homes as hospital outpatient services. CMS established this flexibility since the service would have been provided in an outpatient setting at the hospital but for the PHE. Under this flexibility, CMS paid for providers' services under the PFS at the facility rate, which excludes payment for resources traditionally supplied in a hospital outpatient unit, such as supplies and clinical staff. Instead, the hospital may bill for these associated costs as an originating site facility fee under the Outpatient Prospective Payment System (OPPS). After the PHE expires, hospitals may no longer bill for telehealth services rendered while a patient is at home as if these services were performed in a hospital outpatient department.[18]

The Calendar Year 2023 OPPS/Ambulatory Surgical Center Payment Systems final rule permits payment for behavioral health services furnished through telehealth by practitioners of hospital outpatient departments to patients at their homes.[19] In general, providers are allowed to bill these services as covered outpatient department services payable under the OPPS.[20] However, after December 31, 2024, CMS requires an in-person visit within six months before the start of telehealth services and every 12 months thereafter, with exceptions based on specific beneficiary circumstances.[21]

Hospitals Without Walls. In late March 2020, CMS established Hospitals Without Walls, an initiative that expanded the delivery of patient care in nontraditional settings through virtual hospital services.[22] This initiative allowed hospitals and critical access hospitals (CAHs) to set up "expansion sites" to provide care in other facilities, including in ambulatory surgical centers (ASCs), hotels, and dorms, among other community-based facilities.[23] As part of this initiative, CMS permitted ASCs and independent, freestanding emergency departments to enroll in Medicare as hospitals, enabling these entities to provide hospital services outside the scope for which Medicare traditionally reimburses them. In November 2020, CMS expanded the Hospitals Without Walls initiative through another initiative—"Acute Hospital Care at Home"—which permitted hospitals to provide at-home care and services to patients with acute conditions traditionally treated in inpatient settings.[24] These waivers will end with the expiration of the PHE.

Hospital-only clinical staff in-person services. During the PHE, CMS permitted health professionals to furnish certain outpatient services, including wound care, drug administration, and infusions, at a beneficiary's home under the order and supervision of a physician or qualified nurse practitioner. Under this flexibility, CMS considered a beneficiary's home a provider-based department (PBD). Accordingly, hospitals may bill such services as hospital outpatient services. Hospitals may receive payment for these services under the OPPS—which reimburses at a higher rate than PFS-equivalent services—so long as the "PBD is an on-campus or excepted off-campus PBD that relocated to the patient's home, applied, and was approved for an extraordinary circumstances relocation exception."[25] These flexibilities will stop upon the PHE's expiration, meaning that hospitals may no longer bill services provided at beneficiaries' homes as outpatient hospital services under OPPS.[26]

Distinct part units. CMS permitted hospitals to relocate inpatients to certain units to accommodate capacity issues amid the surge in hospitalizations during the pandemic. CMS allowed hospitals to house acute care inpatients in excluded distinct part units (i.e., inpatient psychiatric facilities and inpatient rehabilitation facilities) so long as the beds in the unit are appropriate for acute care inpatients. Under the Inpatient Prospective Payment System (IPPS), the hospital may then bill for care provided to these patients and note that the patient was housed in an excluded unit due to overcapacity. When the PHE expires, hospitals will no longer be able to bill under the IPPS for acute care patients in beds in excluded distinct part units.[27]

In addition, CMS also permitted hospitals to transfer patients in inpatient psychiatric units and inpatient

rehabilitation units to other appropriate acute care beds and units during the PHE. Hospitals may continue to bill for these services under the IPPS while noting in the medical record that the hospital relocated the patient in response to capacity issues or outstanding circumstances due to COVID-19. These waivers will expire when the PHE ends.[28]

Finally, inpatient rehabilitation facilities (IRFs) were allowed to exclude certain patients from the freestanding hospital or distinct part units' inpatient population count applicable to the thresholds for requirements to receive payment as an IRF. This flexibility applies to patients an IRF admits in response to the PHE, and the hospital must note this in the patient's medical record upon billing. When the PHE ends, IRFs must include all patients in this population count.[29]

SNF 3-day rule billing. During the PHE, CMS waived the requirement that a number of Medicare beneficiaries must have a medically necessary three-day inpatient hospital stay to qualify for SNF extended care services coverage under Medicare.[30] This coverage extends a patient's care after the patient is discharged from a hospital or swing bed.[31] SNFs could apply for the waiver so that they could furnish Medicare Part A services and bill for such services without the three-day hospitalization prerequisite so long as they met certain conditions.[32] Once the PHE ends, the three-day billing rule will apply, and stakeholders must meet the requirements at 42 C.F.R. § 409.30.

Stark Law blanket waivers

CMS waived particular requirements applicable to hospitals under the Stark Law.[33] Specifically, these waivers apply to referrals or remuneration solely for COVID-19 purposes.[34] These blanket waivers include:

- **Fair market value.** Hospitals were permitted to pay for the personal services of a physician valued above or below fair market value (FMV). Hospitals were also permitted to pay or charge below FMV for renting or purchasing equipment, items, or services. For example, to address workforce shortages, hospitals could provide a physician with space at no charge to treat hospital patients who are not eligible for emergency department or inpatient care.
- **Financial support.** Physician owners of a hospital were permitted to make interest-free, personal loans to their hospital to aid in critical operations, such as the administration of payroll to staff and payments to vendors.
- **Hospital staff benefits.** Hospitals were permitted to offer benefits to their physician staff, including daily meals, laundry services, and childcare services during the physician's shift and when a physician was involved in activities that benefited the hospital and patients.
- **COVID-19 items and services.** Hospitals were allowed to offer items and services solely related to COVID-19 purposes beyond the annual nonmonetary compensation cap. For example, hospitals could provide isolation shelter to families of physicians exposed to COVID-19 while working in the emergency department.
- **Licensed beds.** Physician-owned hospitals were permitted to increase or convert the number of licensed beds, operating rooms, and procedure rooms to address the influx of patients during the PHE.

Once the PHE expires, these blanket waivers will end.[35] Given the severity of Stark Law penalties and sanctions, hospital compliance officers should attempt to identify any transactions with physicians that will continue past the PHE's expiration and ensure that they meet an applicable Stark exception.

Conditions of participation flexibilities

CMS also provided flexibilities for hospital conditions of participation to further relieve hospitals of administrative burdens related to staffing and hospital operations.[36]

Medical staff requirements. CMS allowed physicians whose privileges expired to continue to practice at their hospitals during the PHE. New physicians were also allowed to practice at their hospitals before the governing body reviewed and approved their privileges. These flexibilities will end upon PHE's expiration, and hospitals will need to ensure that all physicians are practicing according to 42 C.F.R. § 482.22(a)(1)-(4).

CAH personnel qualifications and licensure. CMS waived the federal minimum personnel qualifications for clinical nurse specialists, nurse practitioners, and physician assistants. CMS deferred to state law regarding staff licensure, certification, and registration requirements. Upon PHE's expiration, hospitals must ensure that all affected practitioners comply with applicable federal requirements.[37]

Hospital services. CMS temporarily lifted the requirements outlined in 42 C.F.R. § 482.12(c)(1)-(2) and (4), which previously required that physicians care for Medicare patients in the hospital. This waiver expires after the PHE, meaning physician assistants and nurse practitioners may no longer care for Medicare beneficiaries without physician supervision.

Discharge planning for hospitals and CAHs. CMS waived regulatory requirements for providing certain detailed information on discharge planning to allow hospitals and CAHs to attend to increased hospitalizations. Hospitals were required to ensure that patients were discharged to appropriate settings but did not need to assist patients in selecting a post-acute care provider that met patients' needs. After the PHE, hospitals and CAHs will be required to assist patients using quality measures to choose an appropriate provider upon discharge. Hospitals will want to ensure that they are meeting the requirements outlined in 42 C.F.R. § 482.43(a), 482.61(e), and § 485.642(a)(8).

Life safety code requirements for hospitals and CAHs. CMS waived certain life safety code standards, specifically for the placement and storage of alcohol-based, hand-rub dispensers, the practice of fire drills, the use of temporary walls and barriers between patients, and the use of PBD as temporary expansion sites. For example, CMS permitted hospitals and CAHs to create new or relocate existing PBDs to expand patient capacity. These flexibilities will stop upon PHE's expiration.

Home health

CMS provided significant flexibilities to both payment and conditions of participation related to home health agencies, some of which will expire on May 11, while others have been extended or made permanent.

Allowed practitioners. At the outset of the PHE, CMS allowed nurse practitioners, clinical nurse specialists, and physician assistants to order home health services, establish a plan of care, and certify and recertify eligibility for home health services. This flexibility was made permanent via the Coronavirus Aid, Relief, and Economic Security Act and federal regulation.[38]

Certification and recertification. A physician or allowed practitioner must certify that the patient is homebound and needs skilled nursing care to cover home health services. This certification requires the provider to conduct a face-to-face encounter with the patient no more than 90 days before or within 30 days after starting home healthcare. During the PHE, this face-to-face encounter could occur via telehealth (i.e., two-way, audio–video telecommunications technology that allows for real-time interaction between the provider and the patient). The ability to use telehealth is permanent, but the ability for the patient to be at home during the encounter at this

point only extends through December 31, 2024.

Homebound. During the PHE, CMS clarified that a patient was considered "homebound" when their physician advised them not to leave home because of a confirmed or suspected COVID-19 diagnosis or if the patient has a condition that makes them more susceptible to contracting COVID-19. This interpretation will not change at the expiration of the PHE.

Conditions of participation. CMS waived several conditions of participation during the PHE, which will end at the PHE's conclusion. These conditions include the annual requirement for a registered nurse to directly observe each aide who provides home health services,[39] the requirement that each home health aide receives 12 hours of in-service training per year,[40] and particular quality assurance and performance improvement (QAPI) reporting requirements.[41] In addition, the requirement for a nurse to conduct an on-site visit every two weeks to ensure aides are providing care consistent with the care plan was waived during the PHE. After the PHE expires, an amendment to the rule allows these visits to occur via telehealth infrequently and not more than once every 60 days for skilled nursing services.[42] For patients receiving non-skilled care, there must be an in-person visit every 60 days.[43]

Durable medical equipment

Local coverage determinations (LCDs) and national coverage determinations (NCDs). Throughout the PHE, CMS waived the clinical indications for coverage required for respiratory devices, home anticoagulation management, and infusion pumps. This essentially voided the medical necessity requirements contained in specific NCDs and LCDs.[44] The waiver applied to a number of items of durable medical equipment (DME), including those related to home oxygen, ventilators for home use, continuous positive airway pressure for obstructive sleep apnea, and infusion pumps. These waivers will expire at the conclusion of the PHE. It remains unclear whether DME subject to a rental period and billed with a catastrophe/disaster related-modifier will continue to be covered through the end of the rental period when the medical necessity requirements are not met. Staff will need to be reeducated on these NCDs and LCDs and the process used by the company to ensure compliance with these coverage requirements.

Written order. During the PHE, CMS allowed DME to be provided based on a verbal order, except for power mobility devices. The DME supplier had to obtain a written order from the physician before submitting a claim to Medicare. Upon PHE's expiration, a similar process can be followed except for power mobility devices and other DME, prosthetics, orthotics, and supplies items identified by CMS that require a written order prior to delivery.[45]

Face-to-face encounter. For power mobility devices and certain other DME items, a physician or other qualified practitioner must have had a face-to-face encounter with the patient no more than six months before issuing the DME order. This encounter can occur via telemedicine,[46] and through December 31, 2024, the patient can be at home.

Proof of delivery. DME suppliers have particular requirements to obtain and maintain proof that a beneficiary has received a DME item or supply.[47] During the PHE, CMS waived the signature and proof of delivery requirements for DME when a signature could not be obtained because of the inability to collect signatures for the duration of the PHE. This waiver will expire at the end of the PHE.[48]

Ambulances

Allowable destinations. CMS had expanded the list of destination sites to include any destination equipped to treat the patient's condition in a manner consistent with state and local emergency medical services protocols where the services will be furnished. These locations could include any location determined to be part of a hospital, critical access hospital, SNF, physician office, urgent care facility, and the beneficiary's home. This waiver will expire at the conclusion of the PHE.

Treat in place. Ambulance suppliers were allowed to bill Medicare for treating a patient in their home or at the scene of an incident or accident without transporting them to a hospital or other allowable destination. The waiver applies when a patient—but for community-wide emergency medical services protocols related to the PHE—would have been transported to a Medicare-covered destination. This waiver will discontinue with the end of the PHE.

Orders to transport. CMS indicated that it would not review transport orders signed during the PHE by a physician or certain nonphysician personnel—absent indications of potential fraud and abuse. CMS recommended that ambulance suppliers document in the medical record that a signature is not able to be obtained because of COVID-19. Upon expiration of the PHE, ambulance suppliers should ensure that all orders for transport are signed.

Takeaways

- The shift in post-public health emergency (PHE) requirements presents increased challenges for compliance professionals, who must equip staff to adjust again to a new—but once familiar—normal.
- Flexibilities terminating at the expiration of the PHE include conditions of payment, such as a waiver of local coverage determination requirements for certain items and services, as well as conditions of participation.
- Flexibilities that improved provider capabilities to meet demand in traditional healthcare settings are largely set to revert to pre-pandemic rules immediately following the end of the PHE.
- Key flexibilities—such as the Hospitals Without Walls initiative—will end upon PHE's expiration, changing Medicare's scope of reimbursable services and items.
- The Consolidated Appropriations Act of 2023 extended many telehealth flexibilities through the end of 2024, but certain flexibilities such as the waiver of frequency limitations and the U.S. Department of Health & Human Services Office for Civil Rights' HIPAA enforcement discretion will end with the PHE.

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