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Raul G. Ordonez III (raul.ordonez@jhsmiami.org, linkedin.com/in/raul-g-ordonez-iii-03604557/) is Vice President & Chief Compliance Officer at Jackson Health System in Miami, FL.

Telehealth in a post-PHE world

by Raul G. Ordonez III

The COVID-19 pandemic ushered in a radical expansion of telehealth coverage seemingly overnight. Prior to the public health emergency (PHE), telehealth reimbursement was extremely limited; however, due to COVID-19, federal agencies removed various telehealth treatment and reimbursement restrictions. Throughout the pandemic, telehealth's prominence in a post-pandemic environment was unclear. Many proponents characterized telehealth's availability as the dawn of a new era in patient care delivery. Although some argued that there could be no going back to the pre-PHE days of limited telehealth coverage, many regulatory waivers that made telehealth services so available were designed to be temporary.[1] The uncertainty continued over three long years until the PHE finally concluded on May 11, 2023.

This article will discuss the present state of telehealth coverage and considerations for ensuring compliance in the new post-PHE era.

Telehealth Medicare reimbursement

By May 11, 2023, several important developments solidified telehealth coverage temporarily beyond the sunset of the PHE. First, through the passage of the Consolidated Appropriations Act (CAA) of 2023, Congress formally extended many of the telehealth flexibilities through December 31, 2024—an increase beyond the 151 days post-PHE originally allotted during the prior year's CAA.[2] One of the flexibilities relates to the geographic area where the patient must be located for the service to qualify for Medicare payment. The regulation requires that the patient must be present at an originating site that is either (1) a health professional shortage area that is outside a metropolitan statistical area (MSA) or within a rural census tract of an MSA or (2) a county not included in an MSA as of December 31 of the preceding year.[3]

The 2023 CAA extended the flexibility through December 31, 2024, guaranteeing coverage in all geographic areas during the increased timespan, and the Centers for Medicare & Medicaid Service (CMS) has agreed to confirm the regulatory change in its 2024 proposed rule.[4]

Similarly, another flexibility relates to the eligibility of the distant site practitioner (i.e., the clinician performing the telehealth service). The regulation limits Medicare reimbursement eligibility to services provided by the following providers: physician, nurse practitioner, physician assistant, nurse–midwife, clinical nurse specialist, certified registered nurse anesthetist, clinical psychologist, clinical social worker, or a registered dietitian or nutrition specialist.[5] However, the 2023 CAA also extended the flexibilities for services provided by federally qualified health centers (FQHCs), rural health centers, physical therapists, occupational therapists, speech-language pathologists, and audiologists through December 31, 2024.[6] Similarly, in the calendar year (CY)

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Medicare Physician Fee Schedule (MPFS) Proposed Rule, CMS implemented the regulatory changes regarding the continued eligibility of rural health centers and FQHCs through the end of 2024.[7]

Another flexibility relates to the "originating site" type, where the patient must receive services. To qualify for Medicare reimbursement, the patient must be present in one of the specific care locations—such as the office of a practitioner, hospital, rural healthcare clinic, or other qualifying locations. Meanwhile, the COVID-19 flexibility allowed for Medicare reimbursement when the patient receives telehealth services in any healthcare setting—including the patient's own home. Similarly, the 2023 CAA clarified that the flexibility would extend to December 31, 2024, as well, and CMS confirmed the regulatory change in the 2024 Physician Fee Schedule.[8]

The 2023 CAA also extended the flexibility related to the permitted means of communication. To qualify for Medicare reimbursement, the practitioners must typically provide the telehealth service using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.[9] However, with the current flexibility in place through December 31, 2024, providers can continue receiving payment for Medicare telehealth services despite not meeting the real-time audio and video standards, such as the use of an audio-only telephone call.[10]

Another extension relates to the in-person treatment requirements to qualify for Medicare payment for performing mental health services. Whereas the telehealth regulation already provided for the qualification of the patient's home as an eligible originating site for substance abuse services, it was not until the CAA of 2021 where other mental health services could qualify for telehealth payment when the patient receives treatment in their own home.[11] Notwithstanding, the regulation requires that in order for the home to qualify as an originating site, the treating practitioner must have treated the patient in-person within the six months prior to the initial telehealth visit and within 12 months of each subsequent telehealth visit unless the practitioner and patient agree that the risks of the in-person visit would outweigh the benefits.[12] The in-person requirements for mental health services would have begun on the 152nd day after the expiration of the PHE; however, the 2023 CAA postponed the implementation of the in-person requirement through December 31, 2024, and CMS has confirmed the regulatory change in its 2024 MPFS Proposed Rule.[13]

One flexibility that was not extended related to the ability for hospitals to receive originating site facility fees for telehealth services occurring in the patient's home or a temporary expansion site. Under the flexibilities, hospitals could receive facility fees when the patient's home or mobile stroke unit qualified as a provider-based department. However, the 2023 CAA stated that upon the expiration of the PHE, neither the patient's home nor a temporary expansion site can qualify for facility fee payment.[14]

Another notable flexibility relates to the "direct supervision" requirement whereby physicians can be "immediately available" during a procedure by having a virtual presence using two real-time audio and visual technologies. As of the end of the PHE, the flexibility was set to last through the last day of the year in which the PHE would end (December 23, 2023).[15] However, in the 2024 MPFS Proposed Rule, CMS proposes to extend the flexibility through the end of 2024.[16]

Similarly, another flexibility existed regarding the statutory requirement that the treating provider be licensed in the state where the patient receives the services; CMS had relaxed the requirement under its emergency authority.[17] When the PHE finally ended, however, the licensure requirements once again went into effect.

Another flexibility involves the requirement that teaching physicians be physically present to bill for services provided that involve residents. Since the CY 2021 Physician Fee Schedule Final Rule, teaching physicians have

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been able to bill for teaching services when they have been present for the key portions of the resident services through telehealth rather than through physical presence. In the CY 2024 MPFS Proposed Rule, CMS proposes to extend the flexibility through the end of 2024.[18]

Telehealth services list

As it pertains to the actual services eligible for reimbursement, i.e., those on the CMS "telehealth list," CMS stated in prior rulemaking that those services temporarily added to the telehealth list would remain eligible for reimbursement 151 days after the end of the PHE.[19] However, in the 2024 MPFS Proposed Rule, CMS proposes to extend coverage and payment through December 31, 2024, for the services temporarily added to the telehealth list during the PHE. Similarly, in the CY 2021 PFS Final Rule, CMS had created a new category of telehealth services that were under review for permanent addition to the telehealth list, i.e. the Category 3 services.[20] Category 3 telehealth services not added to the permanent categories on the telehealth list (Category 1 and Category 2) would remain reimbursable through the end of the CY in which the PHE ends, i.e. December 31, 2023.[21] However, in the CY 2024 Proposed Rule, CMS proposes to simplify the telehealth list approval process by doing away with the three categories altogether and replacing them with two categories: "permanent" and "provisional." Rather than expiring at the end of the year, CMS proposes to allow the provisional services (previously identified as Category 3) to be reimbursable until CMS makes a final determination regarding inclusion or exclusion from the permanent category.[22] Thus, CMS proposes to eliminate the current expiration date for reimbursement for Category 3 (December 31, 2023) and replace it with an indefinite one.

HIPAA flexibilities

In addition to the various CMS flexibilities, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) had issued a Notification of Enforcement Discretion stating that during the PHE, it would refrain from imposing penalties against providers engaged in "good faith" telehealth services despite possible utilization of noncompliant HIPAA technology.[23] OCR subsequently announced that enforcement discretion would lapse with the expiration of the PHE; however, it would continue not to impose penalties during a 90-calendar-day transition period lasting through August 9, 2023.[24] As such, the enforcement discretion era for noncompliant technology is over.

Controlled substances

Lastly, during the PHE, the U.S. Drug Enforcement Administration (DEA) provided its own waivers regarding the Controlled Substances Act requirements. The requirements included the obligation to conduct at least one in-person medical evaluation before prescribing a controlled substance through telehealth unless a specific narrow telemedicine exception applies.[25] The waivers allowed providers to prescribe Schedule II–V controlled medications via telehealth and Schedule III–V narcotic controlled medications for opioid use disorder treatment via audio-only technology without having provided a prior in-person encounter.[26] Similarly, another requirement from the Controlled Substances Act mandates that in order to prescribe controlled substances, providers must have a DEA registration on file with each state where the patients is located.[27] However, since the onset of the PHE, the DEA had temporarily waived the requirement so long as the provider would be permitted to prescribe without the DEA registration by both the state where the provider is registered and the state where the drug is dispensed.[28] On the eve of the PHE's expiration, the DEA announced that it was extending the PHE waivers through November 11, 2023, and furthermore, if the provider and patient engage in a telemedicine relationship by that date, the waiver will continue to apply through November 11, 2024.[29] Subsequently, in response to feedback provided during two Telehealth Listening Sessions hosted by the DEA, the

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agency further extended the Covid-19 telemedicine flexibilities through December 31, 2024.[30]

In addition to extending the current waivers, earlier in the year, the DEA published a proposed rule to add additional flexibility permanently for ordering controlled substances through telehealth without meeting the in-person exception.[31] The rule offers an additional telehealth exception to the prior in-person requirement for when:

> the 'practice of telemedicine' . . . [is] 'being conducted under any other circumstances that the Attorney General and the Secretary [of Health and Human Services] have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.[32]

However, under the proposed option the provider is limited to prescribing a nonnarcotic Schedules III, IV, or V controlled substance (or buprenorphine for treatment of opioid use disorder) without having provided a prior in-person examination. In addition, the provider can only prescribe a 30-day supply, after which any additional prescribing will require an in-person exam. Alternatively, if a provider receives a "qualified telemedicine referral," whereby the provider obtains a referral from another provider who treated the patient in-person, the receiving provider could prescribe Schedule II–V narcotic-controlled substances after conducting a telemedicine exam.[33] .

Conclusion

The rules relating to telehealth practice have continually evolved throughout the PHE and its aftermath. At this time, several of the PHE-related flexibilities will be extended through various dates while others have expired or are set to expire in the not-too-distant future. Compliance programs should track the various expiration dates and ensure their organizations are prepared to respond accordingly. Preparation should include educating necessary stakeholders regarding the various expiration dates and considering whether policies and procedures should be updated in accordance with the permitted practices. Given the aforementioned proposed rules published by CMS and the DEA earlier this year, compliance programs should also pay special attention to the respective final rules to confirm whether the proposals are implemented and understand their ultimate impact on telehealth practice moving forward.

Although this article focused on specific federal telehealth rules, compliance programs should also consider their state laws and Medicaid policies to ensure compliance in those areas. Lastly, compliance programs should include telehealth within their auditing and monitoring programs, considering the enforcement and attention given to telehealth services by various government enforcement agencies.

Takeaways

- Despite the end of the public health emergency on May 11, 2023, various telehealth flexibilities remain temporarily available.
- Congress and the Centers for Medicare & Medicaid Services (CMS) have each extended various flexibilities governing Medicare payment for telehealth services through December 31, 2024.
- The U.S. Drug Enforcement Agency (DEA) has extended the flexibility to order controlled substances through telehealth without having performed an in-person visit through November 11, 2023, and through November 11, 2024, when a telemedicine relationship is established by the earlier date.

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- CMS and DEA are currently considering substantive changes that will affect telehealth reimbursement and practice on a go-forward basis through the rulemaking process.
- Compliance programs should continue to monitor the telehealth regulatory landscape to inform organizational stakeholders for policy development and its auditing program.

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