The End of the PHE

Health Law Webinar

March 8, 2023

Fredrikson

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Agenda

- The Basics of the Ending
- Telehealth
- Status of Other CMS Waivers
- Coverage and Payment for COVID-19 Vaccines, Testing and Treatment
- PREP Act
- HIPAA Enforcement & Guidance
- State Law Implications

The End of the PHE

- What's happening?
- Why do we care?
- What's not happening?

Telehealth

Medicare Telehealth Before the PHE

- Largely a statutory creature.
- Limited “originating sites” (i.e., patient location):
  - *Designated rural areas.*
  - *Specific facility locations (patient home was NOT an originating site).*
  - *Some demonstration projects.*
- Limited modalities: “telecommunication system” – CMS regulations require two-way audio and video.
- Limited eligible professionals and providers (did not include FQHCs and RHCs).
- Limited CMS list of telehealth codes.

Medicare Telehealth During the PHE

- Patient location: telehealth was available to patients located in their homes and outside of designated rural areas.
- Types of telehealth services: significantly expanded list of telehealth codes/services that can be provided during the PHE.
- Technology: some E&M services can be audio-only; i.e., visits can be conducted using a phone.
- Providers/licensure: any provider eligible to bill Medicare for professional services can bill for telehealth, even across state lines (subject to state laws).

Medicare Telehealth After the PHE

- Permanent changes and temporary changes.
- The HHS Telehealth webpage is pretty good:

  https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency/

Permanent Telehealth Changes

- Patients may receive telehealth treatment for substance use disorder (SUD) and co-occurring mental health conditions in their homes (no geographic restrictions on originating site).
- Behavioral/mental telehealth services can be delivered using audio-only communication platforms.

Permanent Expansion for SUD/Mental Health

- Patients may receive behavioral/mental telehealth services in their homes (no geographic restrictions):
  - *If the patient has been seen in-person in the 6 months prior to the first telehealth visit; and*
  - *The patient is seen in-person every 12 months.*
- Also applies to FQHCs and RHCs.

*In-person (6 months and 12-month) requirements delayed until January 1, 2025.

Temporary Changes Through December 31, 2024

- Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (December 29, 2022).
- No geographic restrictions on originating site for telehealth services (may continue to be in the patient's home) through **December 31, 2024**.
- Telehealth services may continue to be provided by a PT, OT, SLP or audiologist through **December 31, 2024**.

Temporary Changes Through December 31, 2024

- Certain services indicated in the Medicare Telehealth Services List may continue to be provided via audio-only technology (over the phone) through **December 31, 2024**.
- FQHCs and RHCs may continue to provide telehealth services through **December 31, 2024**.
- Acute Hospital Care at Home (AHCAH) program is extended through **December 31, 2024**.

Current uncertainty regarding telehealth codes

- Through rulemaking, CMS extended reimbursement for Category 3 codes through December 31, 2023.
- The Consolidated Appropriations Act of 2023 did not address the codes.
- Via rulemaking, CMS could extend the reimbursement period for services in Category 3 to align with the Consolidated Appropriations Act of 2023 (i.e., to be reimbursed through December 31, 2024).

After the Wind Down…

- Without legislation, after December 31, 2024, Medicare telehealth is left with:
  - *Originating site must be a health care facility and in a rural area; and*
  - *Both audio and video required for coverage.*
- HHS and Congress know it is just not possible to go back to pre-COVID with telehealth.
  - *Kim Brandt, former CMS.*
  - *CMS holding listening sessions, town halls.*

Controlled Substance Prescribing

- Drug Enforcement Administration (DEA).
  - *Controlled substance prescribing license/registration.*
  - *Registration required in each state where a practitioner prescribes a controlled substance via telemedicine.*
    - Waived for the PHE.
- Ryan Haight Act of 2008.
  - *In-person exam requirement – waived for PHE.*
  - *Exceptions & special registration.*

Proposed Rules

- DEA announced proposed rules to address controlled substance prescribing and the in-person exam requirement.
  - *88 Fed. Reg. 12875 (March 1, 2023).*
  - *Comment period open through March 31, 2023.*
- https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities

Proposed Telemedicine Rules Summary

Relationship between prescribing medical practitioner and patient	Prescribing a non-controlled medication	Prescribing Schedule III, IV, or V non-narcotic controlled medications	Prescribing buprenorphine as medication for opioid use disorder	Prescribing Schedule II and/or narcotic controlled medications
Prior in-person medical evaluation by prescribing medical practitioner	Permitted	Permitted	Permitted	Permitted
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	Permitted	Permitted	Permitted	Permitted
Telehealth visit without: • **Prior in-person medical evaluation by prescribing medical practitioner; or** • **Referral from a medical practitioner who conducted prior in-person medical evaluation**	Permitted	• Up to 30-day initial prescription • In-person visit required for additional prescription	• Up to 30-day initial prescription • In-person visit required for additional prescription	Not permitted

- *Telemedicine prescriptions must be otherwise consistent with applicable state and federal laws.*

Proposed Rules

- Defines “practice of telemedicine” to clarify that “interactive telecommunications system” is “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient and distant site physician or practitioner.”*
- *In most circumstances, the prescriber must use audio and video.

Proposed Rules

- Limited to 30-day supply.
- Within 30 days, the prescriber must examine the patient in-person (OR rely on the referring practitioner's in-person medical evaluation if prescriber received a "qualifying telemedicine referral.")

Proposed Rules

- “Qualifying telemedicine referral” =
  - *Enables a prescriber to issue prescriptions in excess of the 30-day limit if the referring practitioner has conducted at least one medical evaluation of the patient in the physical presence of the referring practitioner, without regard to whether portions of the evaluation are conducted by other practitioners.*
  - *Must be a written referral and must include the results of the medical evaluation, including any diagnosis, evaluation, or treatment, prior to the prescribing practitioner issuing a prescription.*
- Prescribing practitioner must consult the Prescription Drug Monitoring Program (PDMP) prior to issuing Rx (limit to 7-day supply if PDMP is non-operational).

Proposed Rules

- Recordkeeping requirements.
- Prescribing practitioner must include a notation on the face of the Rx, or within the Rx order if prescribed electronically, that the Rx has been issued via a telemedicine encounter.
  - *Full name and address of patient; drug name, strength, dosage form, quantity prescribed, and directions for use; address at which the practitioner was located; city and State in which the patient was located; if issued through a qualifying telemedicine referral, the name and NPI of referring practitioner, a copy of the referral and any communications; efforts to comply with the PDMP system.*

Proposed Rules

- What about relationships established during the PHE exclusively based on telemedicine encounters?
  - *Proposed 180 days after the end of the PHE to transition the relationship to an in-person encounter scenario or other qualifying telemedicine referral.*

Other Medicare Waivers

Remote Physiologic Monitoring (RPM)

- During the PHE, clinicians may bill for RPM services:
  - *Furnished to both new and established patients;*
  - *To patients with both acute and chronic conditions; and*
  - *With as few as two days of data collected.*
- Post-PHE, clinicians may bill for RPM services:
  - *Only when the clinician has an established relationship with the patient prior to providing RPM services;*
  - *To patients with both acute and chronic conditions; and*
  - *With at least 16 days of data collected.*

Remote Supervision/Incident To

- CMS's waiver to allow direct supervision, which requires the supervising physician or practitioner to be "immediately available," to include "virtual presence" of the supervising clinician through the use of real-time audio and video technology, will end at the end of the calendar year that the PHE ends, i.e., **December 31, 2023**.

Supervision for Non-Surgical Extended Duration Therapeutic Services (NSEDTS)

- Pre-PHE, initiation of NSEDTS provided in hospital outpatient departments and critical access hospitals required direct supervision, followed by general supervision at the discretion of the supervising physician or the appropriate NPP.
- During the PHE, a general level of supervision could be provided for the entire duration of these services, so the supervising physician or practitioner has not been required to be immediately available.
- Policy was made permanent in the 2021 OPPS/ASC Final Rule.

Teaching Physicians

- Note: This is NOT under supervision!
- During PHE: Remote availability allowed.
- Normal: Billing physician must be present during the portion that determines billing. Remote presence allowed outside of Metropolitan Statistical Areas (MSAs).
- Primary Care Exception: Physician must “during or immediately after each visit” review history, examination, diagnosis, tests and therapies with resident. During the PHE, could be remote. Post-PHE: Remote only outside of MSA.

Hospital Waivers

Hospitals Without Walls

- During PHE, expansion to other hospitals / locations such as parking lots and hotels was permitted.
- Post-PHE: All services must be in hospital space.

ASC’s Enrolled as Hospitals

- ASC’s that opted to enroll as a hospital must choose whether to meet hospital standards or return to ASC status.
- Submit notification to the CMS Survey and Operations Group via email/mail by 5/11. Return to ASC status is immediate.
- To remain as a hospital, a survey is required.

Off-Campus Provider Based Expansion

- During PHE: relocation was allowed.
- Post-PHE: most relocations will lose provider-based status. Most locations would need to use the “BN” modifier and be paid under the physician fee schedule.
- Hospital may seek “an extraordinary circumstances relocation exception” but difficult to obtain.
- “The pandemic” won’t be considered an extraordinary circumstance.
- On-Campus PBE relocating off-campus not eligible.

Critical Access Hospitals (CAH)

- Resume requirements for bed limit (25) and length of stay ("96 hours").
- Reinstates rural area requirement, § 485.610(e) and similar requirements for sole community hospitals in small rural hospitals.

Miscellaneous Waivers

- EMATLA: The ability to screen patients off-site ends.
- Access to medical record in “reasonable” time: §482.13(d)(2).
- Patient visitation: § 482.13(h).
- Physical environment / life safety: § 482.41/485.623.
- Alcohol-based handrub dispensers (flammability issue) 2012 LSC.
- Fire drills.
- Patient’s home will not qualify as out-patient department.

Miscellaneous Waivers

- IRFs may no longer place patients in acute care beds and the 60% Rule resumes (60% of patients must have one of 13 conditions.)
- Stark Law Waivers end. (If the agreement is dated 5/10 what happens???).
- COP requiring verbal orders signed within 48 hours: § 482.23, 24 and § 485.635(d)(3).
- Reporting where restraints may have contributed to patient death: § 482.13(g).

Miscellaneous Waivers

- Discharge planning: § 482.43(a)(8), § 482.61(e) and § 485.642(a)(8).
- Proof of delivery for Part B drugs and DME.
- Cost report extensions of 60 days.
- Provider enrollment hotlines ending.
- Ability of opted-out physicians to opt-in will end.

Swing Beds

- During the PHE: special requirements for swing bed reimbursement were waived.
- Post-PHE: the waiver will terminate and hospitals seeking to use swing beds will have to comply with § 482.58(a).

LTC/SNFs

Medicaid Redeterminations

- During the PHE: states were required to adopt “continuous enrollment” policies for Medicaid.
- States were directed during 2022 to begin winding down the continuous enrollment policies and resume Medicaid eligibility redeterminations by March 31, 2023.
- The details of how this transition has and will continue to unfold will vary depending on the state.
- SNFs should keep current on the guidance from the local Medicaid agency to avoid gaps in resident eligibility.

COVID-19 Reporting Requirements

- During the PHE: CMS promulgated an interim rule requiring LTCs to report COVID-19-related data (infections, deaths, resident/staff vaccination) and establishing CMPs for failure to comply.
- The 2022 CY Home Health PPS rule extended these reporting requirements until December 31, 2014.
- Under the current regulations, authority to impose CMPs for violations expires one year after the end of the PHE.

COVID-19 Testing Requirements

- During the PHE: under an interim final rule, LTCs were required to test residents and staff with known exposures, symptoms, or certain asymptomatic persons as directed by the Secretary.
- Post PHE: regulatory requirements specific to COVID-19 testing expire.
- Keep in mind that LTCs must still have adequate infection control procedures, so it would be safest to comply with the current CDC recommendations.

Waivers Expiring at the End of the PHE

- Waiver of the 3-day inpatient hospital stay requirement for Medicare coverage of SNFs if the patient met other SNF criteria.
- Waiver of requirement that pre-admission screening and resident review must be completed prior to SNF admission.
- Waiver of rules establishing resident rights to choose roommates or refuse relocation to allow cohorting.
- Waiver of certain rules limiting resident transfers and relocations.
- Waiver of Life Safety Code requirements limiting placement of alcohol-based rub dispensers.

Coverage for Vaccines, Testing and Treatment

Coverage and Payment for COVID-19 Vaccines

- Background:
  - *To date, all COVID-19 vaccines in the U.S. have been purchased, distributed and administered through the federal vaccine program.*
  - *Providers have been required to administer shots for free to everyone, regardless of insurance status.*
  - *Providers have been permitted to seek reimbursement for vaccine administration fees from public and private insurers, but not from vaccine recipients.*
  - *Insurers have been required to cover COVID-19 vaccines without cost sharing, even out-of-network.*

Coverage and Payment for COVID-19 Vaccines, Cont.

- What's changing when the PHE ends?
  - *No more requirement for insurers to reimburse out-of-network providers (though the federal vaccine program will still prohibit such providers from charging vaccine recipients).*
  - *Effective September 30, 2024 (last day of the first calendar quarter that begins one year after the last day of the PHE), no more special prohibition on cost sharing for Medicaid and CHIP enrollees.*
    - BUT…most enrollees will continue to receive all ACIP-recommended vaccines (including COVID-19 vaccines) without cost sharing.
  - *End of state option to extend Medicaid coverage for COVID-related services, including vaccines, to the uninsured with 100% federal match.*

Coverage and Payment for COVID-19 Vaccines, Cont.

- What's not changing when the PHE ends?
  - *Federal vaccine program.**
  - *Vaccine mandate(s).*
  - *FDA's emergency use authorizations (EUAs) for COVID-19 countermeasures, including vaccines.*
  - *Medicare payment rate for administering vaccines (approximately $40 per shot) will remain unchanged through the end of the calendar year in which the HHS Secretary terminates the EUA, after which they will align with the payment rate for administering other Medicare Part B preventive vaccines (approximately $30 per shot).*

Coverage and Payment for COVID-19 Vaccines, Cont.

- What will happen when the federal vaccine program ends?
  - *While not tied to the end of the PHE, lack of funding means the U.S. government will likely shift vaccine distribution to the private market as soon as summer or early fall.*
  - *U.S. government paid manufacturers approximately $21 per dose. Private market price may be $110 to $130 per dose.*
  - *Once federal stockpile is depleted, most patients (whether covered by private insurance, Medicare, Medicaid, CHIP, or the federally-funded Vaccines for Children Program) will continue to have access to COVID-19 vaccines without cost sharing (as with other ACIP-recommended vaccines).*
  - *Uninsured adults may have to pay full price, absent new safety net programs.*

Status of COVID-19 Vaccine Mandates

- CMS COVID-19 Vaccine Mandate (in effect nationwide).
  - *See December 8, 2021, webinar for background.*
  - *Upheld by SCOTUS on January 13, 2022.*
  - *Scheduled to remain in place until November 5, 2024 (three years after adoption of interim final rule on November 5, 2021).*
- Head Start Program Mandate (enjoined in 25 states; otherwise in effect).
- No other federal mandates are in effect, each having been struck down, repealed, or partially blocked:
  - *OSHA's mandate on employers with 100+ employees.*
  - *Federal employees.*
  - *Employees of federal contractors and subcontractors.*
  - *U.S. Military.*

Coverage and Payment for COVID-19 Testing

- During the PHE:
  - *Medicare covers one lab-conducted test without a physician order, any additional medically-necessary lab-conducted tests ordered by a provider and up to 8 home tests per month.*
  - *Private insurance is required to cover tests without cost-sharing (subject to the plan's coverage rules).*
  - *Medicaid covers lab-conducted tests without cost-sharing.*

Coverage and Payment for COVID-19 Testing

- Post PHE:
  - *Medicare will continue to cover medically-necessary lab-conducted tests ordered by a practitioner without cost sharing. Free home tests for Medicare beneficiaries will end.*
  - *Private insurance covers testing according to the terms of the plan and may impose cost-sharing.*
  - *Mandatory Medicaid coverage expires on the last day of the first calendar quarter that begins one year after the last day of the PHE (9/30/24). States may choose to continue to provide coverage.*

Coverage and Payment for COVID-19 Treatment

- Generally no change to Medicare coverage for COVID-19 treatments, but NCTAP adjustment to IPPS ends at the end of 2023.
- Private insurance will continue to cover COVID treatments according to the terms of the plan and in compliance with state law.

Impact to PREP Act

- COVID-19 PREP Act Declaration provides immunity to certain individuals and entities for losses relating to the manufacture, distribution, administration or use of covered countermeasures against COVID-19, except for claims involving “willful misconduct.”
- 10 Amendments expanded coverage of immunity and expanded the pool “covered persons” (e.g., health care providers administering COVID-19 vaccinations outside their state of licensure, those with lapsed or expired licenses, and those whose scope of practice would not traditionally include administration of vaccines).

PREP Act, Continued

- Coverage is generally not tied to the end of the PHE.
- Generally, liability protections extend through October 1, 2024 for vaccine administration.
- HHS is currently reviewing whether to continue to provide this coverage going forward.

HIPAA Enforcement Discretion

- OCR used its enforcement discretion to allow providers to use a broad set of non-public facing applications (e.g., FaceTime, Facebook Messenger video chat, Google Hangouts, Zoom, or Skype) for telehealth services during the PHE, despite potential HIPAA compliance issues or failure to execute a BAA.
- Providers were encouraged to notify patients of potential privacy risks and enable all available encryption and privacy modes when using such applications.
- “Good faith provision” of telehealth services.

Audio-Only Guidance

- New guidance for providers and health plans regarding the provision of audio-only telehealth and HIPAA compliance.
- Outlines steps that covered entities can take to ensure that audio-only telehealth services are delivered in a HIPAA compliant manner after the end of the PHE.
- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html

State Law

- Many states temporarily waived licensing requirements during the height of the pandemic.
- These waivers have largely expired.
- Many of these waivers were tied to state declarations of emergency.
- All but 7 states have discontinued their declarations of emergency and all are expected to be discontinued before May 11.

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