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Public Health Emergency Ends May 11: What Telehealth Companies Need to Know

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The PHE has been in place for over three years during which time many telehealth and other health care related flexibilities were relied upon by both patients and clinicians. While some telehealth waivers will survive the end of the PHE, not every pandemic-era policy will continue. Digital health companies relying on the PHE waivers should take steps now to bring operations into compliance with the post-PHE world before the PHE ends in May.

Here are seven key takeaways on how the end of the PHE will affect the digital health industry:

1. Temporary Medicare Changes through December 31, 2024

The Consolidated Appropriations Act (CAA) of 2023 extended the following telehealth flexibilities authorized during the COVID-19 PHE through December 31, 2024:

- Health care providers eligible to bill Medicare can bill for telehealth services regardless of where the patient or provider is located (i.e., the patient can be at home).
- Audio-only telehealth visits will continue to be reimbursable.
- The list of providers eligible to deliver telehealth services remains expanded to include physical therapists, occupational therapists, speech language pathologists, and audiologists.
- The acute hospital care at home program can continue to be utilized to provide hospital services to patients in their homes, including through telehealth.
- Telehealth can be used to conduct recertification of eligibility for hospice care.
- Patients with High Deductible Health Plans coupled with Health Savings Accounts can utilize first dollar coverage for telehealth services without first having to meet their minimum deductible.

- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) can provide telehealth services to Medicare beneficiaries (i.e., can be distant site providers), rather than being limited to being an originating site provider for telehealth (i.e., where the beneficiary is located).

The CAA also delayed the imposition of the pre-requisite in-person requirement for mental health services furnished through telehealth until after December 31, 2024.

2. Medicare Payment Parity

During the pandemic the Centers for Medicare & Medicaid Services (CMS) initiated higher reimbursement for telehealth services at non-facilities, such as a patient's home. In other words, Medicare has been paying for telehealth services as if they were provided in-person, meaning the telehealth visits are being paid by Medicare at the same rate as regular, in-person visits. These higher reimbursement rates are scheduled to end this year. After that, rates could return to lower pre-pandemic levels unless lawmakers choose to extend the policy.

3. Telemedicine Controlled Substances and Ryan Haight Act

During the PHE, the Drug Enforcement Agency (DEA) acted swiftly to waive the Ryan Haight Act's in-person exam requirement for the prescribing of controlled substances, thereby ensuring millions of both established and new patients were able to receive medically necessary prescriptions via telemedicine.

There have been efforts to amend the Ryan Haight Act and encourage the DEA to activate the telemedicine special registration rule before the PHE expires, including pending federal legislation. However, to date, the Ryan Haight Act has not been changed and the DEA has not activated the telemedicine special registration rule.

Thus, when the PHE expires on May 11, without further action on the part of the DEA, the in-person requirement is set to revert, without any special registration rule or other process established to ensure continuity of care. Therefore, continued prescribing of controlled substances for patients never seen in-person, and only through virtual means during the PHE, will be prohibited and these patients would either need to be seen in-person or have their care transitioned to a local provider.

4. End of Telehealth & RPM Copayment Waivers

During the PHE the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a policy statement and FAQ notifying health care providers that they will not be subject to administrative sanctions under the federal Anti-Kickback Statute or the Civil Monetary Penalty and exclusion laws for reducing or waiving cost-sharing amounts (like copayments and deductibles) for telehealth services or remote patient monitoring (RPM) services furnished to Medicare beneficiaries during the PHE.

The guidance documents expressly tie this waiver to the duration of the PHE. Thus, unless the OIG issues additional guidance or an extension, after May 11, health care providers offering telehealth or RPM services to Medicare beneficiaries may no longer reduce or wave any cost-sharing obligations that patients may owe for such services. Digital health companies without payment and collection

mechanisms for these payments will need to act swiftly to operationalize new process to ensure these amounts are charged and collected.

5. RPM Services Again Limited to “established patients”

In 2021, CMS reiterated that outside of the PHE, RPM services are limited to “established patients.” However, for the duration of the PHE, CMS waived the “established patient” requirement and allowed practitioners to bill for RPM for new patients. When the PHE ends, CMS will require that RPM services be furnished only to established patients. CMS’ statements suggests after the PHE the physician must first conduct a new patient evaluation and management service before rendering RPM to such patient.

6. Virtual Direct Supervision Scheduled to End This Year

Among the PHE waivers, CMS temporarily changed the direct supervision rules to allow the supervising professional to be remote and use real-time, interactive audio-video technology. That change did not require the professional’s real-time presence at, or live observation of, the service via interactive audio-video technology throughout the performance of the procedure.

In the 2023 physician fee schedule, CMS declined to extend this temporary policy beyond the end of the calendar year in which the PHE ends. Therefore, virtual direct supervision will expire at the end of this year unless CMS revises its policy in future rulemaking.

7. End of HIPAA-related Enforcement Discretion

For the duration of the PHE, the HHS Office for Civil Rights (OCR) exercised enforcement discretion allowing providers to use telehealth in good faith even if their platforms or software did not follow Health Insurance Portability and Accountability Act (HIPAA) rules. However, this enforcement discretion only remains in effect until the end of the PHE.

Thus, after May 11, the OCR will resume enforcement of penalties on providers for noncompliance with HIPAA rules for technology use. Ahead of the end of the PHE, OCR has provided clarification on how and the circumstances under which the HIPAA rules apply to telehealth.

Conclusion

To mitigate legal risk, further continuity of care, and avoid issues of patient abandonment, digital health companies relying on the PHE waivers should take steps now to bring operations into full compliance with applicable requirements before the PHE ends in May. The Biden Administration has also announced its intent to continue to execute the process of a smooth operational wind down of the flexibilities enabled by the PHE and the intent to provide continual updates as the PHE comes to a close. Thus, digital health companies should also closely monitor further changes, or adjustments to expiring flexibilities that may be announced in the coming months.

We will continue to monitor for regulatory and legislative changes as well as informal guidance on how the end of the PHE will impact digital health companies and the health care industry as whole.

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