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Healthcare Alert

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OCR issues guidance on HIPAA-compliant use of audio-only telehealth

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The guidance addresses considerations for covered entities around use of audio-only telehealth services when OCR's pandemic-related enforcement discretion ends.

What's the Impact?

- OCR emphasizes the important role telehealth plays in expanding access to healthcare and the need to ensure compliance with HIPAA for these arrangements post-PHE
- The guidance clarifies when audio-only telehealth services and vendor agreements require compliance with the HIPAA Security Rule
- Covered entities should take the opportunity now, prior to the end of the PHE, to analyze changes needed in telehealth arrangements

On June 13, 2022, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) issued guidance to healthcare providers and health plans on how to use audio-only telehealth services in a HIPAA-compliant manner, particularly when OCR's telehealth enforcement discretion is no longer in effect.

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Acknowledging that healthcare providers had to rapidly pivot to the use of telehealth or expand their use of telehealth during the pandemic, on April 21, 2020, OCR published the Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency (Telehealth Notification). The Telehealth Notification advises healthcare providers that OCR will exercise enforcement discretion and not impose penalties for HIPAA noncompliance related to the good faith provision of telehealth during the COVID-19 public health emergency (PHE). Healthcare providers are able to use non-public-facing audio or video technologies for telehealth even when such arrangements are not in full compliance with HIPAA. The Telehealth Notification is set to expire with the declared PHE or when the Secretary of HHS declares that the COVID-19 PHE no longer exists.

In both the guidance and its press release, OCR emphasizes the important role telehealth and, in particular, audio-only telehealth plays in expanding access to healthcare. For example, audio-only telehealth is particularly helpful for certain consumers since it leverages technology that does not require broadband availability, thereby resolving some internet-related inaccessibility problems. As covered entities see the end of OCR's Telehealth Notification enforcement discretion on the horizon, the new guidance is intended to help healthcare providers and health plans structure their post-PHE, audio-only telehealth services in a HIPAA-compliant manner.

As reiterated in the guidance, the HIPAA Privacy Rule permits the use of audio-only telehealth services. The guidance reminds covered entities that OCR expects them to safeguard protected health information (PHI) when providing services via telehealth, such as by providing telehealth services in a private setting whenever feasible. If services cannot be provided in fully private settings, then covered entities must use reasonable safeguards to protect the confidentiality of PHI (e.g., using lowered voices) to prevent any inadvertent disclosure.

The guidance also addresses how covered entities should handle interactions with new patients or other individuals participating in telehealth services. Entities must verify the identity of individuals not known to them either orally or in writing. For an individual with limited English proficiency, covered entities must verify their identity using language assistance tools. Notably, the guidance references the requirement under civil rights laws that, as a general matter, communications with an individual who has a disability must be as effective as communications with others, and appropriate aids and services should be supplied when needed.

With respect to electronic protected health information (ePHI), the guidance clarifies when audio-only telehealth services require compliance with the HIPAA Security Rule. As the Security Rule applies to PHI transmitted or stored in electronic media, audio-only telehealth services conducted through a traditional landline do not trigger Security Rule compliance. In contrast, covered entities must comply with the HIPAA Security Rule and its safeguards when using modern electronic technologies for remote communications, including smartphone applications (apps), Voice over Internet Protocol (VoIP), messaging services that electronically store audio messages, and technologies that electronically record or transcribe a telehealth session. For services that capture ePHI, it is critical that covered entities implement and maintain rigorous risk analysis and risk management systems to identify and assess any potential risks or vulnerabilities to the confidentiality, integrity, and availability of data transmitted through such technologies.

This may mean that covered entities using such technologies during the PHE need to update their security risk analyses to include these remote communications technologies and that their subsequent risk management plans outline steps to eliminate or reduce any identified risks in using these technologies. The guidance cites use of a robust inventory and asset management process to ensure that the healthcare provider or health plan continuously identifies communication technologies and information systems that trigger HIPAA Security Rule compliance.

Finally, where the Telehealth Notification allowed covered entities to work with remote communication technology vendors without executing a HIPAA business associate agreement (BAA), covered entities should analyze whether BAAs are necessary for these arrangements when the OCR enforcement discretion ends. The guidance discusses scenarios in which the HIPAA regulations permit covered entities to conduct audio-only telehealth sessions without a BAA in place with the vendor. When a healthcare provider has an audio-only telehealth session with a patient using a smartphone, a BAA between the covered entity and the telecommunication service provider (TSP) is not needed as long as the TSP is solely connecting the call and does not create, receive, or maintain any PHI from the session. The opposite is true when TSPs or vendors go beyond providing mere data transmission services and instead store PHI, such as in the app developer's cloud infrastructure, via recordings or transcripts. In such circumstances, the healthcare provider must enter into a BAA with the app developer or other vendor before offering or utilizing the provider's subscribed smartphone app with patients. Covered entities should take the opportunity now, prior to the end of the PHE, to analyze their telehealth arrangements, including those that are audio-only, to identify the need for BAAs and prepare and execute any necessary agreements.

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