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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

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COVID-19 UPDATE FOR HEALTHCARE PROVIDERS - MARCH 2020

Regulators Expand Opportunities for Telehealth Services Under COVID-19 Shadow

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As the COVID-19 pandemic surges and the social distancing imperative continues, regulators have responded with various guidelines and policies that impact and expand the opportunities for telehealth services. Telehealth, telemedicine, and related terms generally refer to the exchange of medical information from one site to another through electronic communication to improve a patient's health. With COVID-19, there is an urgency to expand the use of technology for routine care and to keep vulnerable patients and patients with mild symptoms in their homes while maintaining access to the care they need.

1. 135 Waiver for Existing Limitations on Medicare Coverage for Telehealth Services.

On March 13, 2020, the Secretary ("Secretary") of the U.S. Department of Health & Human Services ("HHS") authorized waivers and modifications under Section 1135 of the Social Security Act, retroactive to March 1, 2020. This authorization followed the Secretary's declaration of a public health emergency in the entire United States on January 31, 2020. Pursuant to this authorization, the Centers for Medicare & Medicaid Services (CMS) waived certain limitations on Medicare coverage for telehealth visits so that beneficiaries can receive a wider range of services from their doctors without having to travel to a healthcare facility.

Under the waiver, starting March 6, 2020 and continuing during the COVID-19 public health emergency, Medicare can pay for office, hospital, and other visits furnished via telehealth across the country and including in a patient's residence. Before the waiver, Medicare could only pay for telehealth on a limited basis: when the person receiving the service is in a designated rural area and when they leave their home and go to a clinic, hospital, or certain other types of medical facilities to receive the service. The waiver temporarily eliminates

the requirement that the originating site must be a physician's office or other authorized healthcare facility and allows Medicare to pay for telehealth services when beneficiaries are in their homes or any setting of care.

Medicare patients may use telecommunication technology for office, hospital visits and other services that generally occur in-person. The services must be furnished consistent with applicable coverage and payment rules, but the telehealth services are not limited to services related to patients with COVID-19. The provider must use an interactive audio and video telecommunications system that permits real-time communication between the distant site and the patient at home. For example, to the extent that many mobile computing devices have audio and video capabilities that may be used for two-way, real-time interactive communication, they qualify as acceptable technology. The 1135 waiver also allows the Secretary to authorize use of telephones that have audio and video capabilities for the furnishing of Medicare telehealth services during the public health emergency. Distant site practitioners who can furnish and get payment for covered telehealth services (subject to state law) can include physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals.

Further, to the extent the 1135 waiver requires an established relationship between the provider and the patient, HHS has announced a policy of enforcement discretion for Medicare telehealth services furnished pursuant to the 1135 waiver. For claims submitted during the public health emergency, HHS will not conduct audits as to the existence of a prior relationship between the provider and the patient.

Medicare telehealth services are generally billed by professionals as if the service had been furnished in-person. For Medicare telehealth services, the claim should reflect the designated Place of Service (POS) code 02-Telehealth, to indicate the billed service was furnished as a professional telehealth service from a distant site.

The following CMS chart shows the three main types of virtual services physicians and other professionals can provide to Medicare beneficiaries.

Type of Service	What is the Service?	HCPCS/CPT Code	Patient Relationship with Provider
Medicare	A visit with a provider that uses telecommunication systems between a provider and a patient.	Common telehealth services include: • 99201-99215 (Office or other outpatient visits) • G0425-G0427 (Telehealth consultations, emergency department or initial inpatient) • G0406-G0408 (Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs). For a complete list: https://www.cms.gov/Medicare/Medicare-general-information/telehealth/telehealth-codes	For new* or established patients. *To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency.

Virtual Check-In	A brief (5-10 minutes) check-in with a practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by an established patient.	HCPCS code G2012 HCPCS code G2010	For established patients
E-Visit	A communication between a patient and their provider through an online patient portal	• 99421 • 99422 • 99423 • G2061 • G2062 • G2063	For established patients

In a separate 1135 waiver, HHS waived the requirement that physicians or other health care professionals hold licenses in the state in which they provide services if they have an equivalent license from another state. While these waivers only apply to Medicare, and do not address Medicaid or other state licensing law requirements, states may similarly broaden Medicaid reimbursement for telehealth services and remove certain licensing requirements for providers during this public health emergency. For more information, see the **Fact Sheet** and **FAQ**.

2. OIG Permits Waiver of Copays for Telehealth Services

On March 17, 2020, the HHS Office of Inspector General ("OIG") issued a policy statement permitting healthcare providers to reduce or waive beneficiary cost-sharing for telehealth visits paid for by federal healthcare programs during the COVID-19 public health emergency. Ordinarily, if healthcare providers routinely reduce or waive costs owed by federal healthcare program beneficiaries, including cost-sharing amounts such as coinsurance and deductibles, they would potentially implicate the federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries. However, the OIG is committed to ensuring that healthcare providers have the regulatory flexibility necessary to adequately respond to COVID-19, and will therefore not enforce these statutes if providers reduce or waive cost-sharing for telehealth visits during the public health emergency. For more information, see **Policy Statement** and **Fact Sheet**.

3. OCR Issues Notice of Enforcement Discretion for HIPAA Non-Compliance for Telehealth Services

Effective March 17, 2020, the HHS Office for Civil Rights ("OCR") issued a Notification of Enforcement Discretion ("Notice") stating that it will not impose penalties for noncompliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") against health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. This Notice applies to telehealth provided for any reason, regardless of whether the telehealth service is related to the diagnosis and treatment of COVID-19.

The OCR specified in its Notice that a covered health care provider may provide telehealth services to patients through any non-public facing remote communication product, including popular applications that allow for chats (e.g., Facebook Messenger video chat or Skype). A "non-public facing" remote communication product is one that, as a default, allows only the intended parties

to participate in the communication. However, health care providers should not use certain video communication that are public facing (e.g., Facebook Live, Twitch, and TikTok). The OCR further specified that telehealth services may be provided through audio, text messaging, or video communications technology, including videoconferencing software.

OCR would consider all facts and circumstances when determining whether a health care provider's use of telehealth services is provided in good faith and thereby covered by the Notice.Some examples of what OCR may consider a bad faith provision of telehealth services include:

- Conduct or furtherance of a criminal act, such as fraud, identity theft, and intentional invasion of privacy;
- Further uses or disclosures of patient data transmitted during a telehealth communication that are prohibited by the HIPAA Privacy Rule (e.g., sale of the data, or use of the data for marketing without authorization);
- Violations of state licensing laws or professional ethical standards that result in disciplinary actions related to the treatment offered or provided via telehealth (i.e., based on documented findings of a health care licensing or professional ethics board); or
- Use of public-facing remote communication products, such as TikTok, Facebook Live, Twitch, or a chat room like Slack, which OCR has identified in the Notification as unacceptable forms of remote communication for telehealth because they are designed to be open to the public or allow wide or indiscriminate access to the communication.

The OCR also noted that it will not impose penalties against healthcare providers for the lack of a business associate agreement ("BAA") with video communication vendors or any other noncompliance with the HIPAA regulations that relates to the good faith provision of telehealth services during the nationwide public health emergency. For healthcare providers seeking additional privacy protection, the Notice includes a list of vendors that represent that they provide HIPAA-compliant video communication products and will enter into a HIPAA-compliant BAA, including, among others, Skype for Business, Updox, VSee, Zoom for Healthcare, and Doxy.me. However, OCR does not endorse or recommend these vendors.

The Notice addresses the enforcement only of the HIPAA rules. It does not address violations of 42 CFR Part 2, the HHS regulation that protects the confidentiality of substance use disorder patient records, however, the Substance Abuse and Mental Health Services Administration has issued some guidance on COFID-19 and 42 CFR Part 2. For more information, see **Notice** and **FAQ.**

4. DEA Permits Prescribing Controlled Substances Via Telemedicine Without Prior In-Person Exam

According to guidance issued by the U.S. Drug Enforcement Administration ("DEA"), effective March 16, 2020 and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system
- The practitioner is acting in accordance with applicable Federal and State laws

Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for schedules II-V) or by calling in an emergency schedule II prescription

to the pharmacy, or by calling in a schedule III-V prescription to the pharmacy.

The term "practitioner" includes a physician, dentist, veterinarian, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which s/he practices to prescribe controlled substances in the course of his/her professional practice.

Typically, a prescription for a controlled substance issued using the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation. Importantly, despite the DEA's modification for COVID-19, the practitioner must still comply with any applicable state laws, which may prohibit or limit prescribing controlled substances via telemedicine. For more information, see **DEA COVID-19 Information Page**.

With this additional regulatory flexibility for telehealth services, healthcare providers will hopefully experience greater ability to provide patient care remotely, although there is still some disconnect between state and federal laws and requirements. For more information regarding telehealth or COVID-19, please contact Phil Kim, Kayla Cristales, or Jennifer Kreick.

HIPAA Guidance During COVID-19

Phil Kim and Jennifer Kreick

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Amidst continuing COVID-19 concerns, regulators issued certain waivers of HIPAA requirements and penalties as well as additional guidance applicable during this public health emergency.

HIPAA Enforcement Discretion for Telehealth. Effective March 17, 2020, the Office for Civil Rights ("OCR") at the Department of Health and Human Services ("HHS") issued a Notification of Enforcement Discretion ("Notice") stating that it will not impose penalties for noncompliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") against health care providers in connection with the good faith provision of telehealth services during the COVID-19 nationwide public health emergency. This Notice applies to telehealth services provided for any reason, regardless of whether the services relate to the diagnosis and treatment of COVID-19.

The OCR specified that a covered health care provider may provide telehealth services through any non-public facing remote communication product, including popular applications that allow for chats (e.g., Facebook Messenger video chat or Skype). However, health care providers should not use certain video communication that are public facing (e.g., Facebook Live, Twitch, and TikTok). OCR also will not impose penalties against healthcare providers for the lack of a business associate agreement ("BAA") with a video communication vendor or any other noncompliance with the HIPAA regulations that relates to the good faith provision of telehealth services during the COVID-19 nationwide public health emergency. For healthcare provider seeking additional privacy protections, the Notice provided a list of vendors that represent that they provide HIPAA-compliant video communication products and will enter into HIPAA-compliant BAAs. These vendors include, among others, Skype for Business, Zoom for Healthcare, and Doxy.me. See the **Notice** and **FAQ** for more information.

Limited Waiver of HIPAA Sanctions and Penalties. Effective March 15, 2020, in response to the President's declaration of a nationwide emergency and the Secretary of HHS' earlier declaration of a public health emergency on January 31, 2020, the Secretary exercised its authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:

- the requirement to obtain a patient's agreement to speak with family members or friends involved in the patient's care. *See* 45 CFR 164.510(b).
- the requirement to honor a request to opt out of the facility directory. *See* 45 CFR 164.510(a).

- the requirement to distribute a notice of privacy practices. *See* 45 CFR 164.520.
- the patient's right to request privacy restrictions. *See* 45 CFR 164.522(a).
- the patient's right to request confidential communications. *See* 45 CFR 164.522(b).

The waiver only applies (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. See the **Waiver** for more information.

HIPAA Privacy Guidance During COVID-19. In February 2020, OCR released a bulletin to remind covered entities and business associates of the ways patient information may be shared under HIPAA in an outbreak of infectious disease or emergency situation. For example:

- disclosures about the patient as necessary to treat that patient or another patient.See 45 CFR §§ 164.502(a)(1)(ii), 164.506(c), and the definition of "treatment" at 164.501.
    - disclosures for public health activities, including:
    - To a public health authority, such as the CDC or a state or local health department authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability. *See* 45 CFR §§ 164.501 and 164.512(b)(1)(i).
    - At the direction of a public health authority, to a foreign government agency that is acting in collaboration with the public health authority. *See* 45 CFR 164.512(b)(1)(i).
- To persons at risk of contracting or spreading a disease or condition if other law, such as state law, authorizes the covered entity to notify such persons as necessary to prevent or control the spread of the disease or otherwise to carry out public health interventions or investigations. *See* 45 CFR 164.512(b)(1)(iv).
- disclosures to a patient's family members, relatives, friends, or other persons identified by the patient as involved in the patient's care.A covered entity also may share information about a patient as necessary to identify, locate, and notify family members, guardians, or anyone else responsible for the patient's care, of the patient's location, general condition, or death. These disclosures, when necessary, could involve notification to the police, press or the public at large. *See* 45 CFR 164.510(b).
- disclosures to anyone as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public – consistent with applicable law (such as state statutes, regulations, or case law) and the provider's standards of ethical conduct. *See* 45 CFR 164.512(j).

The bulletin also reminded covered entities that except in limited circumstances, disclosures to the media or public at large about an identifiable patient are generally prohibited without the patient's written authorization, and providers are still expected to comply with the minimum necessary standard and implement reasonable safeguards to protect patient information during this time.

Finally, the bulletin reiterated that HIPAA applies only to covered entities (health plans, healthcare clearinghouses, and healthcare providers that conduct one or more covered healthcare transactions electronically) and business associates (persons or entities that perform functions or activities on behalf of, or provide certain services to, a covered entity that involve creating, receiving, maintaining, or transmitting protected health information). While HIPAA often does not apply to employers who receive health information directly from their employees (unless, for example, the employer is a healthcare provider providing

healthcare services to its own employees or the employer learned of the healthcare item or service through a health insurance claim filed by the employee), other state and federal privacy laws may apply. Accordingly, employers should exercise caution when sharing individually identifiable health information of their employees. See Guidance for more information.

Section 1135 Waivers Provide Some Regulatory Flexibility for Healthcare Providers

Phil Kim and Jennifer Kreick

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On March 13, 2020, the Secretary of the U.S. Department of Health & Human Services ("Secretary") authorized waivers and modifications under Section 1135 of the Social Security Act, retroactive to March 1, 2020. This authorization followed the Secretary's declaration of a public health emergency in the entire United States on January 31, 2020. These Section 1135 waivers waive certain statutory requirements of the Social Security Act for healthcare providers during the COVID-19 public health emergency. Several 1135 waivers have been issued so far. As discussed above, HHS has issued a limited waiver of sanctions and penalties for certain HIPAA non-compliance. In addition, as discussed more in this issue's feature article below, the Centers for Medicare & Medicaid Services (CMS) waived certain limitations on Medicare coverage for telehealth visits. Finally, CMS issued several nationwide blanket waivers. For more information regarding these blanket waivers, please see the Fact Sheet and MLN Article. In addition to the blanket waivers, CMS can issue waivers for EMTALA, HIPAA, Stark Law, Medicaid or other Medicare requirements for healthcare providers on a case-by-case basis.

CMS Issues Guidance for Healthcare Providers Grappling with COVID-19

Stacy Brainin and Taryn McDonald

Stacy Brainin

Taryn McDonald

As COVID-19 continues to spread, CMS has issued guidance to various healthcare providers, including, among others, home health agencies, nursing homes, and hospitals that are caring for the nation's most at-risk patient populations.The guidance is intended to curb transmission and ensure healthcare providers have the information and resources necessary to respond to patient needs.

Nursing Homes

On March 13, 2020, CMS issued updated guidance for nursing homes in light of the COVID-19 pandemic. That guidance, which aims to prevent or limit the transmission of COVID-19 within nursing homes by focusing on increased sanitization procedures, social distancing, and restrictions on visitors, can be found here. The guidance contains the following recommendations, among others:

- Facilities are advised to restrict visitors and non-essential health personnel except in end-of-life situations;
- Facilities should follow CDC guidelines with respect to the entry of other healthcare workers providing care to residents, including EMS personnel and dialysis technicians;
- Facilities should cancel communal dining and all group activities, implement social distancing, and remind residents to perform frequent hand hygiene;
- Facilities should screen all staff at the beginning of their shifts for fever and respiratory symptoms, focusing on staff who work at multiple facilities. Staff who are ill are to be provided with a mask and then sent home to self-isolate;

- For those allowed in the facility, the facility should provide strict instructions in line with CDC recommendations;
- Facilities should review and revise how they interact with vendors and other third parties;
- Facilities should ask those who enter the facility to monitor for symptoms for 14 days following entry and notify the facility if symptoms occur.

The guidance also provides recommendations for facilities regarding what to do if a resident has a suspected or confirmed case of COVID-19 and accepting a resident who was previously diagnosed with COVID-19. The current recommendation is to admit any individuals the facility would have normally admitted, including those with a previously-diagnosed case of COVID-19, with specific instructions.

Home Health Agencies

On March 10, 2020, CMS issued guidance to home health agencies ("HHAs") confronting the COVID-19 pandemic. That guidance, which can be found **here**, aims to help home health agencies address potential and confirmed cases and mitigate transmission through screening, treatment, and transfer to higher level care (when appropriate). The guidance contains the following recommendations, among others:

- HHAs should identify patients at risk for COVID-19 before or immediately upon arrival to the home by asking about international travel within the last 14 days, signs or symptoms of respiratory illness, recent contact with COVID-19 patients or patients ill with respiratory symptoms, and whether the patient has been residing in a community where community-based spread of COVID-19 is occurring.
- HHAs should implement source control measures for ill patients (such as placing a facemask over the patient's nose and mouth);
- HHA staff with signs or symptoms of a respiratory illness should not work, and those who become ill on the job should stop, immediately put on a face mask, self-isolate at home, and follow appropriate CDC guidelines.

CMS also provided guidance to HHAs as to when COVID-19 patients could be treated at home and when such patients receiving HHA services are considered safe to transfer to a hospital. CMS also addressed Medicare HHA discharge planning requirements for COVID-19 patients, as well as recommended infection prevention and control practices, including those for family members, when evaluating or caring for COVID-19 patients.

Hospitals

CMS continues to release guidance for hospitals and emergency departments. Specific guidance can be found **here** and **here**, but the CMS newsroom continues to be updated.

Much of the guidance focuses on screening procedures and recommendations for infection prevention and control. Guidance released on March 18, 2020 focuses on conservation of critical resources. CMS recommends that hospitals limit non-essential adult elective surgery and medical and surgical procedures, including all dental procedures. The following factors should be considered as to whether a planned surgery or other medical activity should proceed:

- Current and projected COVID-19 cases in the facility and region;
- Supply of personal protective equipment to the facilities in the system;
- Staffing availability;
- Bed availability, especially intensive care unit (ICU) beds;
- Ventilator availability;
- Health and age of the patient, especially given the risks of concurrent COVID-19 infection during recovery;
- Urgency of the procedure.

Given the evolving COVID-19 pandemic, we expect that CMS will continue to issue guidance and recommendations and update existing guidance and recommendations. All CMS guidance is regularly posted on CMS's website **here**.

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