The state of COVID-19 telehealth

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This blog post has been updated from its original publish date to reflect the April 30, 2020 press release by the Centers for Medicare & Medicaid Services (CMS) announcing expanded Medicare payments and coverage for telehealth services.

The onset of the COVID-19 public health crisis has brought about extraordinarily rapid and urgently needed changes throughout the healthcare landscape of this country. Changes have been particularly sweeping in the telehealth space through a series of federal agency waivers, with the most recent set on April 30, 2020, when CMS announced further expanding telehealth services, COVID-19 testing protocols, and increasing reimbursement rates at the direction of the current administration. It is imperative that providers keep up with these changes, as failure to properly abide by these relaxed and fluctuating guidelines could lead to enforcement issues as well as missed business and patient service opportunities.

This overview does not attempt to provide an in-depth description of all the telehealth changes that have taken place, but seeks to summarize relevant considerations so that providers can take note of the major changes occurring while providing telehealth services for the duration of the public health emergency. Please note that what is discussed in the following summary applies only during the COVID-19 emergency period and once it ends, providers will need to ensure that they are prepared to revert back to standard practices under federal and state laws and regulations.

Pre-COVID-19 telehealth payment restrictions

Prior to the COVID-19 emergency, Medicare telehealth payment policies presented substantial barriers based on the types of services and geographical location of the patient (generally limited to patients in a rural designated healthcare professional shortage areas), and requirements that the patient be in a healthcare facility at the time of service and that an interactive telecommunications system (not telephone, facsimile machines or email) be used. In recent years, Medicare coverage has expanded to include services such as remote patient monitoring (RPM), chronic care management, transitional care management and virtual check-ins that are provided remotely through telecommunication platforms but are not subject to Medicare telehealth restrictions.

Expanding telehealth payment opportunities

During this public health crisis, CMS and other government authorities are temporarily relaxing the barriers to telehealth following a number of executive and legislative directives. The Families First Coronavirus Response Act (FFCRA) authorized Medicare coverage for telehealth services at equivalent rates to in-office services and acknowledged Health Insurance Portability and Accountability Act (HIPAA) enforcement discretion so providers could begin treating more COVID-19 patients on devices using real-time streaming applications. The Coronavirus Relief and Economic Security (CARES) Act followed and included several key provisions to further expand telehealth services and reimbursement to providers and also allocated funding to support telehealth through the U.S. Department of Health and Human Services (HHS) Public Health and Social Services Emergency Fund, which aims to expand patient access and improve the existing telehealth infrastructure. However, providers must continue to take care to compliantly document, bill and code these telehealth encounters and understand what is now allowed and what is still restricted.

For some services, telehealth still requires electronic communications be an audio-visual, real-time, two-way synchronous interactive system, although smartphones (and in some cases, audio-only phones) are now also allowed. However, CMS has implemented several changes to how telehealth services may be billed, where telehealth services may be provided and what services may be provided. Importantly, providers should know that telehealth services can currently be performed in all areas of the country and in all settings, including in any healthcare facility or in a beneficiary's home.

Expanded telehealth services

CMS released additional guidance in the form of temporary regulatory waivers for providers and hospitals to enhance flexibilities in providing care for COVID-19 patients. This guidance further expands provider and healthcare facility options to provide telehealth services by:

- Waiving the medical staff and credentialing provisions related to hospitals and CAHs at 42 CFR 482.12(a)(8-9) and 42 CFR 485.616(c), making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care, including access to specialty care.
- Offering more than 80 additional telehealth services to help prevent the further spread of COVID-19 (All codes are located here). Primary categories include but are not limited to:
  - Emergency Department Visits (Levels 1-5)
  - Observation and Discharge
  - Critical Care Services
  - Home Visits

  - Psychological and Neurological Testing
  - Therapy Service
- **UPDATE:** On April 30, 2020 CMS announced further expanding telehealth services:
  - CMS is waiving limitations on the types of clinical practitioners who can furnish Medicare telehealth services, so physical therapists, occupational therapists, and speech language pathologists can now furnish telehealth services;
  - Hospitals can bill for services furnished remotely by hospital-based practitioners to registered outpatients, including when the patient is at home, even for therapy, counseling, and education services;
  - CMS is increasing payments for telephone visits to match similar office and outpatient visits and paying at these rates retroactive to March 1, 2020;
  - CMS will suspend rulemaking in considering new telehealth services requested by providers, which will allow CMS to add telehealth services at a faster pace;
  - As required by the CARES Act, CMS is now paying for telehealth services provided by rural health clinics (RHCs) and federally qualified health clinics (FQHCs);
  - CMS is broadening the services that can be provided using audio-only phones (for example, many behavioral health and patient education services are now included) and waiving the video requirement for certain telephone evaluation and management services so beneficiaries with audio-only phones have access.

Telehealth billing and coding guidance

- Providers should not use place of service 02 (telehealth) and instead the provider should use the place of service code where the provider would regularly provide face-to-face services.
- Providers should use modifier 95 to signify telehealth services.
- CMS expanded the originating site for telehealth services to include beneficiaries' homes and waived other related requirements.
- Telehealth services must be initiated and chosen by the beneficiaries and there must be patient consent (verbal consent is allowed, but documenting the consent clearly including consent to the particular type of telehealth system utilized is important; written consent is best practice).
- Telehealth services can be used for new or established patients and for all manner of services, including mental health counseling, preventative health screenings, emergency department visits, home visits, etc.
- Providers can document telehealth services either through medical decision making or time. Start/stop times are not required but as best practices we recommend documenting them.
- CMS updated the typical times for evaluation and management (E/M) visits for both new (CPT codes 99201-99205) and established patients (CPT codes 99211-99215) and allows expanded uses of telehealth and phones for E/M services.
- Physicians may supervise clinical staff using virtual technologies instead of in-person, where suitable.
- Telehealth services will be reimbursed at the same rate as face-to-face encounters; and
- Virtual check-ins, e-visits, telephone, and telemonitoring services are expanded and allowed as reimbursable under certain conditions.

NOTE: Medical necessity documentation requirements have not changed and are still required for

reimbursement.

UPDATE: On April 30, 2020, CMS announced that a treating provider's order is no longer required for a beneficiary's COVID-19 tests and that these tests may be ordered by any healthcare professional authorized under state law.

In addition, pharmacists can work with providers for specimen collection and performing certain COVID-19 tests if enrolled in Medicare as a laboratory so beneficiaries can be tested at more pharmacy test sites, including in adjacent parking lots, to maximize testing capacity.

Providers can receive separate payment for testing as the only service provided to a beneficiary. CMS has also acknowledged coverage for FDA authorized tests that individuals can use to self-collect samples at home.

Important codes:

- ICD-10CM diagnosis code: U07.1, effective since April 1, 2020
- COVID-19 testing codes:
  - HCPCS code U0001 (CDC test) since February 4, 2020.
  - HCPCS code U0002 (non-CDC test) since February 4, 2020
  - CPT code 87365, for the detection of SARS-CoV-2 (COVID-19) and any pan-coronavirus types or subtype since March 13, 2020
  - HCPCS code U0003 (high-throughput test) since April 14, 2020
  - HCPCS code U0004 (high-throughput test) since April 14, 2020
  - CPT code 86328 (serology – antibody test; one step method) since April 10, 2020CPT code 86769 (serology – antibody test; multiple step method) since April 10, 2020

NOTE: Prior authorizations are not required and copays are waived for these tests.

State licensure and scope of practice

Following the President's national emergency declaration on March 13, HHS finalized telehealth licensure waivers that allow physicians participating in federal healthcare programs to receive payment for telemedicine services in states where they do not hold a license during the public health emergency. These waivers were retroactive to March 1, 2020. While physicians are usually required to be licensed in the state of the patient they are treating, CMS and most states have waived this requirement to better accommodate treatment of COVID-19 cases.

States have acted expeditiously in enacting waivers for providers of telehealth services, with 44 states as of May 1, 2020, having waivers in place according to the current Federation of State Medical Board's state telehealth waiver website. These waivers have been enacted primarily through governors' executive or public health orders while some include additional guidance from states' respective medical and pharmacy boards or other regulatory authorities. Most states now allow physicians to practice from neighboring states without an in-state license or further permit providers from any other state with a valid license in good standing to assist in providing telehealth services for COVID-19 patients. Some states restrict the type of provider permitted to engage in telehealth services, while others restrict the types of telehealth services permitted to be provided.

Providers must continue to be aware of individual states' scope of practice restrictions unless expressly

waived by a state order or medical board authority, in addition to adhering to existing prescribing restrictions under state and federal laws.

CMS § 1135 state waivers

Following the national emergency declaration, HHS issued a Waiver or Modification of Requirements under § 1135 of the Social Security Act (full text available here) that waives or modifies certain healthcare laws and regulations during the COVID-19 emergency period. Benefits to providers include waivers for:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Emergency Medical Treatment and Labor Act (EMTALA)
- Stark self-referral sanctions
- Performance deadlines and timetables (may be adjusted but not waived)
- Limitations on payment to permit Medicare enrollees to use out of network providers in an emergency situation

Currently, all states have received approved § 1135 waivers from CMS. See the following for additional information on these state waivers and for a list of all states' approved waivers. Guidance on how to apply for these waivers through the Medicaid Disaster Response Tool Kit can be found here. These §1135 waivers will likely end at the termination of the emergency period unless otherwise extended for a specific period of time by HHS.

OCR temporarily loosens HIPAA privacy and information security standards

Since the start of the COVID-19 pandemic, the Office for Civil Rights (OCR) at HHS has loosened HIPAA standards to allow more flexibility. With regard to telehealth, OCR announced on March 17, 2020, that it will waive potential HIPAA penalties against healthcare providers who treat patients in good faith through telehealth during the COVID-19 emergency. This will allow the use of non-public facing audio or video communication products (such as video chats using Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype) even if these platforms or the manner in which they are used fail to satisfy HIPAA requirements. See a prior alert on these OCR penalty waivers.

Expanded use of telehealth for treating substance use disorders

In late March, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance encouraging the use of telehealth for substance use disorder (SUD) patients during the COVID-19 pandemic national emergency period. SAMHSA has also offered recommendations to decrease COVID-19 transmission risks while addressing the behavioral health needs of SUD patients. In particular, SAMHSA advised "that outpatient treatment options be used to the greatest extent possible" and that inpatient treatment be reserved for patients with life-threating mental disorders. SAMHSA "strongly recommends" the use of telehealth or telephonic services for evaluation and management, such as initial evaluations for buprenorphine opioid use disorder (OUD) treatment and for implementing individual or group therapies for mental or substance use disorders. In addition, SAMHSA published FAQ guidance exempting opioid treatment programs (OTPs) from the physical examination requirement for new OUD patients who are treated with buprenorphine (but not methadone).

The Drug Enforcement Administration (DEA) has also issued guidance allowing DEA-registered

practitioners to prescribe controlled substances remotely (e.g., through telehealth) during the COVID-19 national emergency period if the following conditions are satisfied:

- 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 law.

Prior to the emergency an in-person examination was typically required in order for a physician to prescribe controlled substances remotely (via telehealth). This change temporarily removes substantial federal barriers to remote prescribing of controlled substances, although it will continue to be important to review state law and satisfy professional standards, keeping in mind that many states place limits on prescribing. See the following alert for additional information.

Stark and AKS considerations

CMS recently released additional guidance in the form of blanket regulatory waivers in conjunction with expanded flexibilities specific to clinicians and hospitals providing care for COVID-19 patients. One of the most significant provisions of these waivers is the Stark Law waiver examples, which list certain referrals and related claims to include:

1. Hospitals and providers can pay each other above or below fair market value (FMV) to rent equipment or receive services.
2. Providers can support each other financially to maintain healthcare operations.
3. Hospitals can provide benefits to medical staff for basic needs such as food, laundry or child care while physicians are working at a hospital.
4. Provision of items or services for COVID-19 that would exceed annual non-monetary compensation cap are allowed.
5. Physician-owned hospitals can temporarily increase the number of licensed beds, operating and procedure rooms.
6. CMS reduced restrictions on group practice furnishing medically necessary designated health services (DHS) in a patient's home.
7. Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from temporary sites like mobile vans in a lot rented by the practice on a part-time basis.

The Office of the Inspector General (OIG) issued a policy statement in response to the CMS Blanket Waivers to clarify that the OIG seeks to avoid the need for parties to undertake a separate legal review under the Federal anti-kickback statute for arrangements protected by 11 of the 17 Blanket Waivers but that the Policy Statement has no bearing on arrangements that implicate the Federal anti-kickback statute not covered by the Blanket Waivers and that providers should consider separate review of such arrangements not included in Blanket Waiver models. The statement invited questions on arrangements covered under the other six Blanket Waivers. Providers should also be aware that following the end of the emergency period, any retroactive review and auditing will likely scrutinize services provided and claims for reimbursement that may exist outside the permitted guidelines of expanded waivers.

Cost-sharing and audits

The OIG has released guidance regarding providers' ability to reduce or waive cost-sharing expenses for federal healthcare program beneficiaries, as an exception for telehealth services provided during the COVID-19 emergency period. Normally, a provider's waiver of beneficiary cost-sharing obligations, such as co-pays, could implicate the federal anti-kickback statute, civil monetary penalty and exclusion laws. The OIG's guidance addresses a number of questions from healthcare providers seeking to clarify the scope of the cost-sharing waiver policy exception.

In addition, telehealth services furnished under a states' § 1135 waiver authority can be provided both to new and established patients as HHS has ensured that it will not conduct audits following the emergency period to verify whether a prior relationship existed for these claims submitted during the COVID-19 public health emergency.

Department of Justice (DOJ) enforcement action on telehealth fraud

The COVID-19 pandemic has had many effects on telehealth expansion, including the potential for fraud and abuse. On March 24, 2020 Attorney General Barr directed all U.S. Attorneys to prioritize the investigation and prosecution of COVID-19 related fraudulent activity and the DOJ has taken a number of actions and issued advisories which are listed on their website. Common examples of fraudulent activity exposed by DOJ task forces have involved internet or phone application phishing scams and fraudulent COVID-19 testing and vaccines available to consumers through websites.

Where does telehealth go from here?

In light of the numerous existing obligations that providers have in addition to the increased focus on COVID-19 response efforts, it is imperative to keep up to date on these quickly changing regulations and guidance. These federal and state regulatory changes have essentially accelerated necessary and inevitable developments for the future of the healthcare system, however, it is not clear which of these temporary changes will remain once the emergency period is over. While providers have embraced the flexibility of telehealth and hope it is here to stay, they should continue exercising caution during and following the emergency period as agency guidance has not always been exceedingly clear. State and federal authorities will likely engage in heavy review of potential fraud and abuse once the emergency period ends and for this reason, providers should still make reasonable efforts to maintain documentation and continue acting within their permitted scope of practice.

Should you have further questions or concerns, please reach out to the attorneys below.

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