COVID-19: U.S., State Governments Expand Access to Telehealth Services; Reduce Other Barriers to Care

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In response to the COVID-19 pandemic, the U.S. and many state governments have taken a number of steps to expand access to telehealth services and reduce other barriers to care. Among other things, the U.S. Centers for Medicare and Medicaid Services (CMS) has eliminated a number of restrictions on the coverage of telehealth services under Medicare to enable coverage of services provided to patients, including new patients, located in their homes. Many commercial payors have also taken action to expand access to telehealth, including by eliminating co-payments for such services. Many states have temporarily waived in-state licensure requirements to enable physicians, registered nurses, licensed practical nurses, nurse practitioners, and other medical personnel licensed in any state to provide telehealth services to their residents. The Department of Health and Human Services (HHS), Office of Inspector General (OIG) announced that physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services. The HHS Office for Civil Rights (OCR) additionally announced that during the pandemic, it will allow healthcare providers to provide telehealth services to patients through any non-public facing communication applications such as Apple FaceTime, Facebook Messenger, Google Hangout, and Skype. Finally, the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) have both taken steps in response to the COVID-19 pandemic to remove barriers restricting patient access to controlled substances and medicines. We review these developments below.

MEDICARE AND OTHER PAYORS EXPANDED COVERAGE OF TELEHEALTH SERVICES

On March 6, Congress passed The Coronavirus Preparedness and Response Supplemental Appropriations Act (HR 6074). HR 6074 allows the Secretary of HHS to lift certain restrictions on Medicare coverage for telehealth services. On March 17, 2020, the Secretary of HHS, issued waivers of a number of limitations on Medicare coverage of telehealth services that will apply to services furnished from March 6, 2020 through the end of the COVID-19 public health emergency. The waivers apply to Medicare beneficiaries regardless of their diagnosis (i.e., they do not have to have a COVID-19 diagnosis).

Prior to the enactment of HR 6074, Medicare coverage of telehealth services was limited to services furnished in very limited circumstances. Among other things, the patient receiving the services needed to be at originating site (*i.e.*, the location of the Medicare beneficiary at the time the services are provided) (i) located in a health professional shortage area (HPSA) that met certain requirements; (ii) located in a county that was not included in a Metropolitan Statistical Area as of December 31st of the preceding year, or (iii) in an entity participating in a Federal telemedicine demonstration project. In addition, the healthcare provider was required to have an existing relationship with the patient and needed to be licensed in the state where the patient was located. In response to the COVID-19 public health emergency, the Secretary of HHS has waived each of these requirements. Consequently, healthcare providers may now be reimbursed under Medicare for providing telehealth services that are covered by Medicare to patients located in their homes, even when the healthcare provider is not licensed in in the state where the patient is located. These services include, among others, evaluation and management services, psychiatric diagnosis and evaluation, psychotherapy, diabetes

management, and certain end-stage renal disease services. Moreover, the waiver allows healthcare providers to waive copayments, coinsurance, and deductibles related to such telehealth services.

Note that while the federal government has loosened restrictions for telehealth reimbursement, healthcare providers must establish a physician-patient relationship as defined in the state where the patient is located and obtain sufficient information to make a diagnosis or treatment recommendation. Other federal and state laws may also restrict how providers issue prescriptions via telehealth.

CMS has also allowed Medicare Advantage Organizations to expand their coverage of telehealth services during the COVID-19 public health emergency. Similarly, Medicare Part D Sponsors may take the following actions to ensure pharmacy access for enrollees: (i) relax their "refill-too-soon" edits if circumstances are reasonably expected to result in a disruption in access to drugs; (ii) reimburse enrollees for prescriptions dispensed at out-of-network pharmacies (Part D sponsors must ensure enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy); (iii) relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery; and (iv) waive prior authorization requirements at any time that they otherwise would apply to Part D drugs used to treat or prevent COVID-19.

Several commercial payors, including as Aetna, Cigna and Blue Cross Blue Shield (BCBS) have announced they will make telehealth services more widely available to enrollees. Aetna is offering $0 co-pays for all telemedicine visits until June 4, 2020. Cigna is offering telehealth visits with physicians with $0 co-pays for all COVID-19 related care. Cigna will offer telehealth visits not related to COVID-19 through May 31, 2020, but out-of-pocket costs may apply. The BCBS Association announced that its network will expand access to telehealth until June 17, 2020 (90 days from March 19, 2020), waiving cost-sharing for telehealth services for fully-insured members and expanding its coverage to in network telehealth providers who are providing appropriate medical services. Each insurer is also offering free COVID-19 testing. Further information on commercial payors and their COVID-19 policies may be found here.

STATES WAIVE IN-STATE LICENSE REQUIREMENTS TO ALLOW INTERSTATE PRACTICE

Subject to certain limited exceptions, states typically require a healthcare provider furnishing telemedicine services to be licensed in the state where the patient is located. As noted above, HHS announced on March 13, 2020 that, during the COVID-19 public health emergency, Medicare will not require physicians and other healthcare professionals to hold a license in the state where they provide services so long as they have an equivalent license from another state (and are not affirmatively barred from practice in that state or any state a part of which is included in the emergency area). Many states have announced additional action to waive requirements for health care providers licensed anywhere in the United States to furnish telehealth services to patients located in such states. For example, New York has waived license requirements for physicians, registered nurses, licensed practical nurses, nurse practitioners, and physician assistants "to the extent necessary to allow [such professionals who are] licensed and in current good standing in any state in the United States to practice medicine in New York State without civil or criminal penalty related to lack of licensure." The Federation of State Medical Boards is maintaining a list of similar state waivers.

OIG ALLOWS REDUCTION OR WAIVER OF COST-SHARING OBLIGATIONS FOR TELEHEALTH SERVICES FURNISHED TO FEDERAL HEALTH CARE PROGRAM BENEFICIARIES

Typically, routine reductions or waivers of cost-sharing obligations, such as coinsurance and deductibles, for Federal health care program beneficiaries are likely to implicate the Federal Anti-Kickback Statute.

On March 17, 2020, the OIG announced physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services, provided the following conditions are satisfied:

1. A physician or other practitioner reduces or waives cost-sharing obligations (i.e., coinsurance and deductibles) that a beneficiary may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules.
2. The telehealth services are furnished while the COVID-19 public health emergency declaration is in effect.

On March 24, 2020, the OIG clarified that "telehealth services" includes a broad category of non-face-to-face services provided for various purposes, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. It is not limited to services governed by 42 C.F.R. § 410.78 and referred to by CMS as "telehealth visits." Further, the OIG Policy Statement clarifies that physicians and other practitioners are not required to reduce or waive any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services during the COVID-19 public health emergency. However, while the COVID-19 public health emergency declaration is in effect, the OIG will not view the provision of free telehealth services alone to be an inducement or as likely to influence future referrals (i.e., OIG will not view the furnishing of subsequent services occurring as a result of the free telehealth services, without more, as evidence of an inducement).

The OIG Policy Statement applies (1) to a physician or other licensed practitioner billing for services provided remotely through information or communication technology or (2) a hospital or other eligible individual or entity billing on behalf of the physician or practitioner for such services if the physician or other practitioner has reassigned his or her right to receive payments to such individual or entity.

WAIVER OF HIPAA REQUIREMENTS RELATED TO TELEHEALTH SERVICES

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule generally prohibits communication with patients via unsecured platforms. It further requires a healthcare provider to enter into a business associate agreement with a technology company when it would use the company's platform to communicate with patients. The requirements of these agreements generally foreclose the use of unsecure applications like FaceTime for telehealth.

As part of the announcement on March 17, OCR announced that it would exercise "enforcement discretion" and will not impose penalties for noncompliance with HIPAA against covered healthcare providers in connection with the good faith provision of telehealth services during the COVID-19 public health emergency. During the COVID-19 public health emergency, a covered healthcare provider may use any non-public facing remote communication product (e.g. Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype) that is available to communicate with patients to provide telehealth to patients during the COVID-19 public health emergency. OCR will not impose penalties for noncompliance with the HIPAA Rules in connection with the good faith provision of telehealth services using such products during the COVID-19 nationwide public health emergency. This applies to telehealth services provided for any reason, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19. However, healthcare providers are encouraged to inform patients that use of non-HIPAA compliant third-party applications may introduce privacy risks. Healthcare providers should enable all available encryption and privacy modes when using such non-HIPAA compliant applications.

HHS ALLOWS PRESCRIPTION OF CONTROLLED SUBSTANCES VIA TELEMEDICINE

Under the Ryan Haight Act of 2008, prior to prescribing controlled substances by means of the Internet, the prescribing practitioner must conduct at least one in-person medical evaluation of the patient. HHS has now taken action under one of the exceptions to the Ryan Haight Act to permit DEA-registered practitioners to issue prescriptions for controlled substances without a prior in-person medical evaluation provided:

- The practitioner is acting in the usual course of his/her professional practice and the prescription is issued for a legitimate medical purpose.
- The telehealth 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.

ADDITIONAL GOVERNMENT ACTION TO REDUCE BARRIERS TO CARE DURING COVID-19 PUBLIC HEALTH EMERGENCY

In addition to taking action to enhance access to telehealth services, the Federal government and many states have taken action to waive additional requirements for in-person interactions with patients to reduce barriers to care during the COVD-19 public health emergency. For example, on March 16, 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) announced:

- For all states with declared states of emergency, the state may request blanket exceptions for all stable patients in an opioid treatment program (OTP) to receive 28 days of take-home doses of the patient's opioid use disorder medication. The state may request a blanket exception of up to 14 days of take-home medication for less stable patients who the OTP believes can handle the requested level of take-home medication.
- For states without a declared emergency, each OTP may provide a request a blanked exception for its clinic according to the parameters for states with declared states of emergency.

Similarly, on March 22, 2019, the Food and Drug Administration (FDA) issued to sponsors and healthcare providers guidance regarding certain Risk Evaluation and Mitigation Strategy (REMS) laboratory testing and imaging study requirements during the COVID-19 public health emergency. As background, section 505-1 of the Federal Food, Drug, and Cosmetic Act authorizes FDA to require REMS for certain drugs to limit the serious risks associated with those drugs. The FDA also may require elements to assure safe use (ETASU) as part of a REMS for drugs associated with specific serious risks. ETASU generally more onerous requirements, such as a requirement that each patient using a drug be subject to ongoing monitoring. Accordingly, some drugs are subject to REMS with ETASU that require periodic, in-person laboratory testing or imaging studies before patients can be given their drug. Recognizing the difficulties associated with completing in-person, REMS-required laboratory testing or imaging studies during the COVID-19 pandemic, FDA announced that healthcare providers are permitted to waive such laboratory testing or imaging study requirements during the public health emergency. As such, the Agency stated that it does not intend to take enforcement action against sponsors or others for accommodations made regarding laboratory testing or imaging study requirements. However, the FDA advised that healthcare providers should, however, continue to use their best medical judgment in weighing the benefits and risks of continuing treatment in the absence of these laboratory testing and imaging studies. Healthcare providers should also discuss with their patients these judgments and the associated risks. FDA also noted that manufacturers should document in their next REMS Assessment Report the actions that were implemented to accommodate patient access to drugs subject to REMS during the COVID-19 public health emergency.

Please reach out to Goodwin's **Life Sciences** and **Healthcare** teams to review or continue the discussion.

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