



COVID-19: Federal Waivers, Flexibilities, and Guidance Needed to Expand Telehealth and Ensure Virtual Care Delivery

Telehealth affords health care providers tools that enhance patient education, support triage and rapid deployment of testing, and allow for follow-up care for COVID-19, while protecting health care providers and other patients from exposure. Virtual care also enables expanded access to treatment services and on-going monitoring while supporting providers needing to scale across distances to deliver care where the need is greatest. Importantly, utilizing telehealth enables redirecting on-going delivery of certain non-COVID health services outside of health facilities and physician offices overloaded with COVID patients, preventing further exposure and stress on strained provider facilities.

Despite the technological capability to practice telehealth generally, and particularly in the context of COVID-19 (as highlighted in the utilization cases above), both providers currently using telehealth and health care providers who want to utilize telehealth in this context still face legal and regulatory challenges in operationalizing and deploying telehealth technologies.

At the policy level, these challenges include barriers to:

- Medicare and Medicaid coverage for telehealth services
- Specific Medicare and Medicaid rules that could inhibit the ability of providers to use telehealth
- State regulations that could inhibit the ability of providers to use telehealth

This document provides recommendations to the federal government, primarily the Department of Health and Human Services (HHS) and its sub agencies such as the Center for Medicare and Medicaid Services (CMS), on actions that can immediately be taken to facilitate the use of telehealth by health care providers during this public health emergency.¹ The recommendations below are a non-exhaustive list of waivers, flexibilities, and guidance the Federal government should consider in order to support health care providers seeking to scale telehealth services in response to the COVID-19 outbreak.

¹ The National Emergencies Act enables the Secretary to take action under section 1135 of the Social Security Act to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program requirements with the purpose of ensuring that sufficient health care items and services are available to meet the needs of Medicare beneficiaries and to ensure that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). More information on 1135 waivers is available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>.



Department of Health and Human Services (HHS)

CMS: Medicare Fee-for-Service

Waiver of Certain Coverage Requirements for Medicare Telehealth Services

The Secretary should take immediate action to implement waivers of certain requirements for Medicare telehealth services, as authorized by the recent "Coronavirus Preparedness and Response Supplemental Appropriation Act, 2020."² Specifically, the Secretary should waive the statutory patient geographic and originating site restrictions for Medicare Telehealth Services and the regulatory restrictions on using a "telephone" as an interactive telecommunications system (so long as the telephone has audio and video capabilities that are used for two-way, real-time interactive communication).

Medicare Part B Co-Payment Waivers

Many health plans and health systems have waived cost-sharing for telehealth services during the COVID-19 outbreak, and CMS has advised Medicare Advantage organizations that they may waive or reduce enrollee cost-sharing for all similarly situated plan enrollees on a uniform basis for COVID-19 laboratory tests, telehealth benefits or other services to address the outbreak.³ The Secretary should offer the same benefit to Medicare beneficiaries by waiving all Medicare deductibles, copayments, and coinsurance for Part B covered COVID-19-related services, including screenings, testing, and treatments; consider 1135 waiver authority for such action.

Waive Licensure Requirements for Providers Treating Medicare Beneficiaries

Current Medicare requirements may require health providers (including specialists) delivering care to program beneficiaries to be licensed in either or both of the location of the patient and the location of the provider. To facilitate delivery of care to patients residing in areas hardest hit by the virus and likely to experience provider shortages, the Secretary could exercise 1135 waiver authority as to requirements that health care professionals hold licenses in the state in which they provide services, if they have an equivalent license from another state. Such action will be particularly important to enable provider compliance with CMS conditions of participation where states provide alternative options for temporary or emergency exceptions to licensure.

² See <https://www.congress.gov/116/bills/hr6074/BILLS-116hr6074enr.pdf>.

³ See CMS Memo to All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans re: Information Related to Coronavirus Disease 2019 - COVID-19 (March 10, 2020), available at <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>.



Permit Tele-hospitalists and Tele-intensivists to Admit Patients to the Hospital by Adding CPT Codes to the Medicare Telehealth List and Updating the Medicare Claims Processing Manual

CMS does not currently permit a telephysician to be the admitting physician of record.⁴ Functionally, this means that telephysicians cannot directly admit patients to the hospital by placing admission orders even though the telephysician may be providing care to the patient in both the emergency room and as an inpatient. Instead, an on-site physician must provide admissions orders recommended by the telephysician, which proves logistically infeasible in many cases (especially in rural locations with low access to intensivists, hospitalists, or emergency physicians). The medical literature also indicates that telephysicians provide high quality hospital care services. As COVID-19 progresses, telehospitalist and teleintensivist services may become critical for increasing access for patients requiring hospital or intensive care admission. Since CMS currently covers similar high-acuity services that are typically more clinically complex than hospital admission orders, (e.g., TeleICU and Telestroke via codes G0425-G0427, G0508-G0509), telephysicians should also be permitted to provide admission orders and serve as the admitting physician of record. This is likely to require an update to the Medicare Claims Processing Manual as well as updates to the CPT Codes for telehealth services (e.g. addition of telehealth codes corresponding to CPT codes 99221-99223 for inpatient admissions; 99218-99220 for observation admissions; and 99234-99236 for same day observation admissions), although 1135 waivers could be explored.

Add Medicare Part B Coverage for Remote Patient Monitoring for COVID-19

For patients who test positive for COVID 19, home-based monitoring for symptom escalation using FDA approved/cleared connected devices could help reduce transmission risk and more accurately target patients who transition to needing a higher level of care. Remote monitoring for patients with COVID-19 would include things such as asynchronous digital communication of clinical information such as patient temperature, pulmonary function testing, and blood pressure, using FDA cleared/approved devices. Currently, Medicare pays for remote patient monitoring via CPT Code 99091 only if the services are initiated during a face-to-face visit or only if ordered by a provider who has had a face-to-face visit with the patient in the prior year.⁵ CMS also limits use of the code to once in a 30-day period. These limitations significantly limit the ability of telemedicine providers engaging with patients for the first time to use remote patient monitoring to assess for symptoms of COVID-19 over a period of days or weeks. CMS should consider expanding its definition of remote monitoring by eliminating the face-to-face requirement and the 30-day

⁴ See, e.g., Medicare Claims Processing Manual, Ch. 12, § 190.3.2 (explicitly dictating that a telehealth physician “cannot be the physician of record or the attending physician, and the emergency department or initial inpatient telehealth consultation would be distinct from the care provided by the physician of record or the attending physician”); see *also*, 82 Fed. Reg. at 53,009 (describing initial hospital and concluding that “[b]ased on the description of the services for these codes, . . . the initial hospital visit by the admitting practitioner [must] be conducted in-person . . .”).

⁵ Department of Health and Human Services, Centers for Medicare and Medicaid; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, 82 Fed. Reg. 52,976, 53,013 (November 15, 2017).



limitation. Alternatively, CMS should consider instituting a separate CPT code for remote patient monitoring related to public health emergencies, which would facilitate telemedicine providers to utilize remote patient monitoring for COVID-19 telemedicine evaluation and management.

Rapid Medicare Enrollment Processes Streamlined Across Medicare Administrative Contractors (MACs)

Even in the context of Medicare covered telehealth services, telehealth providers licensed and delivering services across the US are required to complete separate enrollment filings with each MAC (and often individual states within a MAC). Further, CMS policy and mechanics of PECOS enrollment can require health providers delivering telehealth services to include personal residence information as the “primary practice address.” The administrative burden of individual MAC and state filings, in addition to, provider concerns from public disclosure of home address, are likely to chill Medicare enrollment and ultimate COVID-19 services by telemedicine providers. CMS should consider methods for streamlining enrollment across all MACs through a single centralized intake process, and such process should categorize potentially sensitive information, such as provider home address, so it can be redacted from public CMS databases.

Flexibility on Meeting Quality Metrics

If providers continue to care for patients at home due to public health risk, they will have challenges meeting MIPS/HEDIS by obtaining vital signs or other diagnostics in the home. For this public health situation, the definitions should include care delivered in the home (for instance obtaining a blood pressure in the home should count to meet our Hypertension metrics). This is a particularly important use case should the crisis be prolonged.

Medicare Home Health

Guidance is needed around whether people who are quarantined due to possible or confirmed COVID-19 would qualify for Medicare home health services.

CMS: Medicaid

Guidance is needed on what state Medicaid programs should cover during this public health emergency. For example, CMS could recommend to state Medicaid programs that telehealth services be covered services in order to ensure continuity of care. This will be particularly important for children as schools close and for people with disabilities who may be required to stay home due to high risk of complications with exposure.



HHS OIG: Stark and Anti-Kickback

Coordination with OIG Regarding Telehealth Services Provided at Reduced or for Free Cost

Cost-sharing waivers for Medicare beneficiaries may constitute prohibited remuneration under the federal Anti-Kickback Statute (“AKS”)⁶ or prohibited inducements under the Civil Monetary Penalties (“CMP”) Statute.⁷ Uncertainty regarding the applicability of these laws and regulations in the context of cost-sharing waivers for COVID-19 telehealth services could impede the provision of such services. The Secretary should coordinate with OIG to issue clear guidance on allowable practices to health care providers.

HHS: Recommendations to States

Guidance to States on Topics for Emergency Declarations (Provider Licensure Exceptions, Telemedicine Modality and Practice Standard Waivers, & Physician Extender Permissions)

State licensure, registration, and certification requirements of health providers are typically governed by the location of the patient at the time of the service. Health providers holding an active license, registration, or certification, as applicable, in a state other than the state of the patient may be helpful resources to augment health provider needs where greatest. Further, state-specific telehealth modality and practice standards can limit certain types of telehealth offerings that otherwise meet the applicable standard of care for COVID.⁸ Consider making available information on these topics and recommending that state authorities consider and incorporate appropriate waivers or permissions as part of emergency declarations:

⁶ See 42 U.S.C. § 1320a-7b(b); 42 C.F.R. § 1001.952.

⁷ See 42 U.S.C. § 1320a-7a(a)(5); 42 C.F.R. § 1003.110.

⁸ The following includes a few examples of such state-specific telehealth modality requirements (although a number of others exist in other states requiring, regardless of the applicable standard of care, either (i) a real-time video or audio encounter to establish the provider/patient relationship or prescribe or (ii) more than patient supplied information. Arizona’s medical practice act prohibits the prescribing of a drug or device unless the provider has previously established a physician-patient relationship or conducts a physical or mental health status examination, which “may be conducted during a real-time telemedicine encounter with audio and video capability.” See Ariz. Rev. Stat. § 32-1401(27)(tt). Delaware’s medical practice act provides that physicians using telemedicine technologies to provide medical care to patients located in Delaware must, prior to a diagnosis and treatment, utilize “both audio and visual communication,” unless the service “meets standards of establishing a patient-physician relationship included as part of evidenced-based clinical practice guidelines in telemedicine developed by major medical specialty societies.” See Del. Code Ann. tit. 24, § 1769D(h). DC’s medical board regulations provide that a physician “may use real-time telemedicine to allow a free exchange of protected health information between the patient and the physician to establish the physician-patient relationship and perform the patient evaluation.” See 17 D.C. Mun. Regs. § 4618. However, DC pharmacy board regulations define a “patient-practitioner relationship,” which is required for a valid prescription, to mean that, at a minimum “the practitioner has met face to face with the patient, has obtained a patient history, and conducted a physical examination or evaluation adequate to establish a diagnosis, identify underlying conditions and contraindications to the treatment recommended.” The “face to face” language suggesting, at least, that a video is required. See 22 D.C. Mun. Regs. §§ 1300.7, 1399. Maryland medical board regulations require a telehealth practitioner to



- Encourage states to accept, on a temporary basis (through the tenure of the emergency period), health providers licensed, registered, or certified in good standing with another state, and as one specific option, consider utilizing the Uniform Emergency Volunteer Health Practitioner Act or the Emergency Management Assistance Compact, but extending limited day temporary licenses through the tenure of the emergency declaration period.
- Encourage states to waive statutes and regulatory mandating telehealth modalities and/or practice standards not necessary for the applicable standard of care to establish a patient-provider relationship, diagnose, and deliver treatment recommendations utilizing telehealth technologies.
- Encourage states to waive geographic restrictions on physicians supervising Nurse Practitioners (“NP”) or Physician Assistants (“PA”) (i.e. temporarily waive any requirements that the supervising physician be physically co-located with or within a certain geographic distance to the NP or PA that he/she is supervising). This would permit supervising physicians from any state to supervise remote telemedicine services via electronic or telephonic means. Encourage states to temporarily suspend any requirements for written supervision or collaboration agreements in order to avoid significant delays in the provision of services while providers engage experts to draft these documents of their behalf. Encourage states to consider temporarily expanding the number of non-physician providers that a physician may supervise to permit greater use of these non-physician providers.

OTHER FEDERAL AGENCY ACTIONS

Drug Enforcement Administration (DEA)

Promulgate DEA Special Registration Rule for Prescribing Controlled Substances via Telemedicine

The U.S. Drug Enforcement Agency (“DEA”) is under a statutory obligation⁹ to promulgate regulations to provide for a Special Registration for qualifying telemedicine providers to prescribe controlled substances under the Ryan Haight Act. The statutory deadline for DEA to issue these regulations passed as of October 24, 2019. DEA has still not fulfilled its obligation. As COVID-19 spreads, the need to prevent low-acuity patients from seeking care in clinics and hospital care units by treating those patients remotely becomes more critical. This Special Registration would permit qualified telemedicine providers to manage the low-acuity, chronic, and ongoing needs of numerous psychiatric and primary care patients with legitimate

perform a “synchronous, audio-visual patient evaluation adequate to establish diagnoses and identify underlying conditions or contraindications to recommended treatment options before providing treatment or prescribing medication.” See Md. Code Regs. 10.32.05.06.

⁹ P.L. 115-271, Section 3232.



medication needs for serious, disabling, and debilitating conditions (many of whom are in high-risk COVID-19 categories – making it important to prevent those patients from unnecessary exposures by delivering their care remotely).