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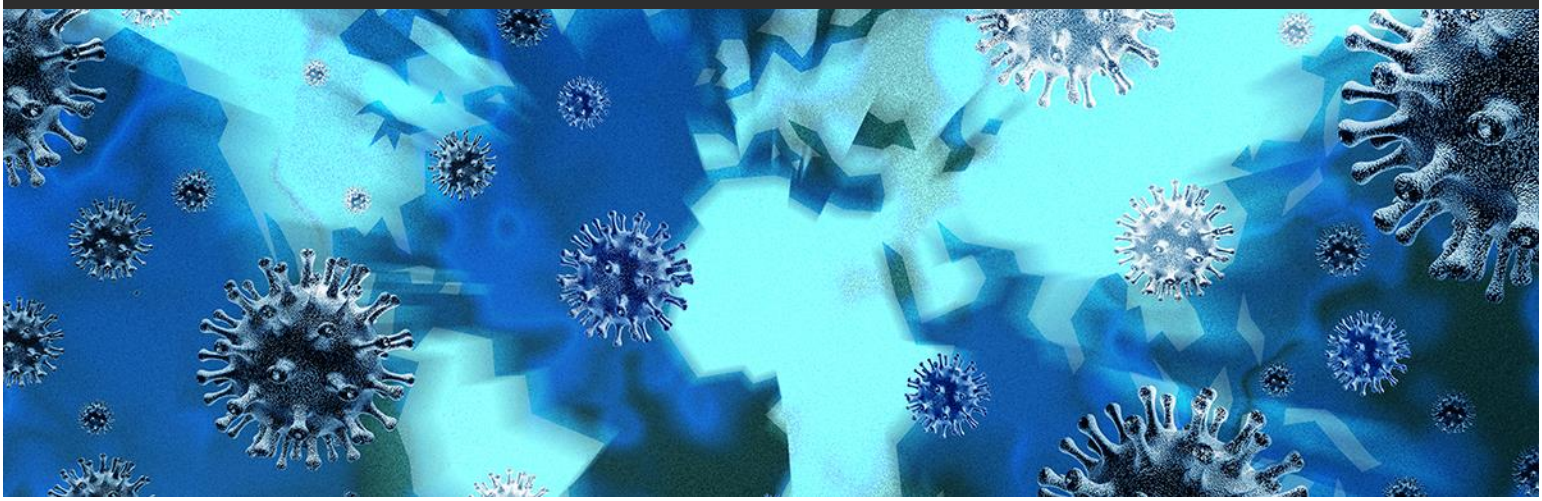
Alert | Health Emergency Preparedness Task Force: Coronavirus Disease 2019



March 2020

Promotion of Telemedicine to Respond to COVID-19 Emergency

The worldwide spread of COVID-19 has put a strain on virtually every industry throughout the world including the health care industry. In the United States, government regulators and health care organizations are working to reduce community exposure and prepare for the potential demands on personnel, equipment, and supplies. The use of telemedicine to deliver care to individuals in their home or residence has been identified as an effective response tool but has required government agencies on the federal and state level to issue emergency rules to waive certain regulatory barriers to delivery and reimbursement. New policies and waivers are being released on a rolling basis and additional changes are anticipated to be forthcoming. We have summarized below the current developments and public guidance designed to promote the use of telemedicine during the COVID-19 emergency period. We will provide additional updates as more information becomes available.

Medicare

The Social Security Act (42 U.S.C. 195m(m)) restricts coverage of "telehealth services" under the Medicare program within certain geographic areas (e.g., rural area) if the patient is located at a defined "originating site" (e.g., hospital, clinic, physician's offices, etc.) and the services must be delivered by a qualified provider (e.g., physician or advanced practitioner) through synchronous, interactive audio/visual telecommunications. As a result, treatment of Medicare beneficiaries via telehealth is severely limited.

On March 6, 2020, the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 was passed which added 42 U.S.C. 1320b–5(b)(8) authorizing the Secretary of the Department of Health and Human Services ("HHS") in a national emergency to exercise temporary waivers of certain Medicare coverage requirements for telehealth services related to:

- **Geographic Area**: the geographic area restriction may be waived – meaning patients located in a defined emergency area will be covered;
- **Originating Site**: the restriction on the physical locations of patients may be waived – meaning patients can be treated in an at-home setting and avoid entering the community; and
- **Modality**: the telecommunications technology and equipment required to be used to deliver telehealth services may be waived – meaning providers can use telephone only communications to deliver telehealth services if the technology is capable of real-time, audio-visual communication if needed (e.g., smartphones).

Note a unique restriction under the waiver that requires a "qualified provider" to have had a pre-existing relationship with the patient (i.e., received payment from Medicare for treating the patient within the prior three years or be in the same practice as another provider who received payment from Medicare for treating the patient during that timeframe).

The statute requires the HHS Secretary to take an affirmative step to declare the waivers are effective, which have not been released to date but we anticipate will be forthcoming and apply retroactively to March 6, 2020. And while the waivers are technically limited to patients being treated in "emergency areas" during "emergency periods," the declaration of a nationwide public health emergency issued last week should effectively mean the waiver will apply throughout the United States for as long as the declaration remains in effect.

The Centers for Medicare and Medicaid Services (CMS) released guidance to address potential shortages in medical professionals needed to provide care to Medicare beneficiaries allowing qualified providers to: (1) enroll in the Medicare program in an expedited manner and stays all revalidations in the interim and (2) treat patients in states in which the providers may not hold a state license if the provider is in good standing with his or her state licensing agency. Moreover, the CMS guidance encourages Medicare enrolled providers to utilize telecommunications technology-based services to remotely care for patients in their home or residence, which are not subject to the same coverage limitations as telehealth services (e.g., virtual check-ins and remote patient monitoring (RMP)).

Medicare uses the current Physician Fee Schedule amount as a proxy for the amounts to be paid when such services are rendered via telehealth. CMS also provides a list of telehealth services payable under the CY 2020 Medicare Physician Fee Schedule.

Medicare Advantage

CMS released guidance to Medicare Advantage (MA) plans to encourage expanding covered telehealth services; eliminating referral or prior authorization requirements; and waiving or reducing all patient cost-sharing obligations for COVID-19-related treatment, including laboratory tests and telehealth benefits. The MA Plan changes may be implemented immediately and require no further approval. We anticipate MA Plans will be forthcoming with such expansions of coverage and waivers.

MA plans are already permitted to expand coverage of telehealth services to include "Additional Telehealth Services" deemed to be clinically appropriate for which benefits are available under Medicare

Part B but are not payable as telehealth services due to the statutory coverage restrictions (42 U.S.C. 1395w-22). In addition, MA Plans are already empowered to exercise permissive waiver authority for numerous other items and services, if the waivers apply uniformly to all similarly situated plan enrollees.

Medicaid

The state Medicaid programs already have broad authority to tailor coverage for telehealth services as they deem appropriate, which authority becomes even more flexible in disaster or emergency conditions. CMS released guidance with recommendations that states seek waivers to take advantage of this flexibility to remove administrative burdens and expand access to needed services in response to the COVID-19 outbreak. In addition, state Medicaid programs are encouraged to explore the full limits of their coverage authority applicable to home and community-based services, including:

- temporarily increasing individual eligibility cost limits;
- modifying service, scope, or coverage requirements;
- exceeding ordinarily applicable service limitations;
- expanding provider qualifications to maximize the pool of providers who can render services; and
- adding to the list of services covered by a state's Medicaid program.

Although states must submit a Section 1135 waiver request to CMS within certain timeframes in order to effectuate any of these waivers, the agency has already approved the waiver request submitted by Florida and has indicated that deficiencies in timeliness will be excused if the delays are traceable to difficulties in responding to COVID-19.

Commercial Payors

Commercial health insurers have been proactive in their efforts to combat the virus. Some major health insurers have implemented temporary reimbursement policies designed to expand their members' access to telehealth services (e.g., waiving cost sharing obligations and prior authorization requirements for COVID-19 testing and telehealth treatment) and to ensure their continued receipt of medications for unrelated illnesses without a pharmacy visit (e.g., allowing home delivery or early refills of medications). We anticipate similar announcements to be forthcoming, which may include collaborations with diagnostic laboratories to increase the availability of COVID-19 tests.

Fraud and Abuse

The HHS Office of Inspector General ("OIG") released a Policy Statement that the provision of free telehealth services and waiver of patient cost-sharing obligations for any federal health care program beneficiaries will not be subject to administrative sanctions during the time period subject to the COVID19 Declaration. This policy applies retroactive to conduct on or after January 27, 2020. OIG makes clear that this policy does not obligate physicians or other practitioners to offer free services or reduce or waive any cost-sharing obligations for telehealth services during the time period.

Regulatory Reminders

While the regulatory landscape is rapidly evolving – even if temporarily – to expand access and use of telehealth services, it is imperative that health care providers remain cognizant of applicable rules that remain unchanged. In general, these restrictions are found under state law and include:

- **Licensure requirements**, which dictate the types of providers (e.g., physicians, nurse practitioners, physician assistants) who are eligible to treat patients via telemedicine. In addition, many states do not have emergency waivers in place that would allow out-of-state providers to treat patients located in-state;
- **Informed consent requirements**, which set forth what information must be communicated to patients, when it must be communicated, and how to document their consent in order to receive treatment via telemedicine; and
- **Remote prescription requirements**, which may enable or inhibit telemedicine providers' ability to prescribe medications or supplies when their only interaction with a patient is via telemedicine.

While changes may be on the way to these and other statutes and regulations, providers should limit any changes they make to their practices, to those that are explicitly authorized at this time. We will provide additional updates as more information becomes available.

HIPAA Privacy Rules

The HHS Office for Civil Rights ("OCR") responsible for enforcing certain regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) released a Notification of Enforcement Discretion for telehealth services during the COVID-19 emergency. The OCR indicated its desire to promote the use of audio or video telecommunications to provide telehealth services to patients, even if not related to COVID-19, and intent to exercise its enforcement discretion and not impose penalties for use of telehealth platforms and non-public communication products that may not fully comply with the requirements under HIPAA privacy and security rules (e.g. no Business Associate Agreement). OCR encourages providers to notify patients that these third-party applications potentially introduce privacy risks and instructs providers should enable all available encryption and privacy modes when using such applications.

Impact on Telehealth Industry

The clear priorities at this time for government regulators and health care providers is to contain the spread of COVID-19 and to mitigate its effects where containment is no longer feasible. A secondary goal, however, should be to learn as much as possible from this experience, so that future regulatory policies can be crafted in a way that truly expands the use of telemedicine services as an effective tool to address strains on resources and access to care. These events could have greater implications for the promotion of telemedicine services and alternative care delivery models in the future.

Whereas before the pandemic, conventional wisdom held that any proposed changes to reimbursement policy would inevitably become mired in bureaucracy, this crisis has already demonstrated that does not have to be the case. Once the scope and severity of the crisis became apparent at the federal level, lawmakers in Congress demonstrated their ability to coalesce around policies that enjoy broad support and, when implemented, should have a dramatic effect on individuals' ability to obtain needed treatment from their homes via telemedicine. Further, the tacit admission that cost-sharing obligations often inhibit willingness to seek care may cause lawmakers to address high deductible plans. If these temporary changes work as they are intended – by increasing access to care while also easing the resource burdens on health care organizations and providers – this crisis could pave the way to permanent changes in access to telemedicine services in our health care system.

Authors

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