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The Expansion of Telemedicine During COVID-19 and Prospects for its Continued Use

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The COVID-19 pandemic has resulted in an unprecedented series of actions by government regulators to allow for the expansion of telemedicine. Although those actions have resulted in the expansion that proponents were hoping for, whether that expansion will be sustained in the longer term is less clear. There has, however, been an unprecedented amount of attention to the utilization of telemedicine, and extensive documentation in the news media, on professional websites, and from regulatory agencies.

Background

In 1997, Medicare began reimbursement for telemedicine services following passage of the Balanced Budget Act with the hope that patients in rural communities and those without reasonable access to medical specialists could receive adequate medical evaluations, and thus improved health care at a reasonable cost.

Prior to COVID-19, telemedicine was most often used in rural and remote areas where patients would otherwise have to travel long distances to receive care. As the COVID-19 crisis developed, a concern arose among public health officials that without the ability to receive health care over the phone or on video chat, some patients would not seek treatment at all. In fact, health officials in many jurisdictions actively discouraged individuals from going to the hospital for non-emergencies, since the likelihood of contracting COVID-19 is higher at a health care facility, where infected patients have gone to seek treatment, and the growth in patients resulting from such exposure could soon overwhelm the health care system. The ability to utilize telemedicine was viewed by many as a means of addressing this concern, allowing physicians to evaluate and triage patients without those patients being unnecessarily exposed to infection.

Telemedicine is simply defined as, "the remote delivery of healthcare services." There are three common types of telemedicine, which are generally identified as:

- ***Interactive Medicine*** – Audio-video communication tools allow patients and physicians to communicate in real-time while maintaining Health Insurance Portability and Accountability Act (HIPAA) compliance (also called "live telemedicine").
- ***Store and Forward*** – Technologies that collect images and data to be transmitted and interpreted later, which permits providers to share patient information with other health care professionals or specialists in another location.

- ***Remote Patient Monitoring*** – Remote patient monitoring tools that communicate biometric data, such as blood sugar or blood pressure, allowing remote caregivers to monitor patients that reside at home by using mobile medical devices to collect data.

Telemedicine is defined by the Institute of Medicine as "the use of electronic information and communications technology to provide and support health care when distance separates participants," and it comes in various forms from inexpensive smartphones to more complex equipment. The term telehealth is "sometimes used to refer to a broader definition of remote health care that does not always involve clinical services, but the American Telemedicine Association (ATA) uses "telehealth" and "telemedicine" in the same way one would refer to medicine or health in the common vernacular.

Within these parameters, each state defines "telemedicine" somewhat differently.[1] Some appear to be more restrictive than others, as there is no universally used definition. As just one example, Rhode Island defines telemedicine as:

> "...the delivery of clinical health-care services by means of real time, two-way electronic audiovisual communications, including the application of secure video conferencing or store-and-forward technology to provide or support health-care delivery, which facilitate the assessment, diagnosis, treatment, and care management of a patient's health care while such patient is at an originating site and the health-care provider is at a distant site, consistent with applicable federal laws and regulations. Telemedicine does not include an audio-only telephone conversation, email message, or facsimile transmission between the provider and patient, or an automated computer program used to diagnose and/or treat ocular or refractive conditions."[2]

In Massachusetts, which has not statutorily defined telemedicine, the Board of Registration in Medicine (BRM) regulates physician licensing and includes telemedicine in their definition of the "practice of medicine." This means that a physician must have a license to practice medicine in Massachusetts to be able to provide telemedicine services. Additionally, the state BRM requirements require an established physician-patient relationship, which requires a "face-to-face visit."

According to the Massachusetts Medical Society's 2016 publication entitled, "A Guide to Telemedicine for the Physician Practice," there are few established laws or regulations regarding the practice of telemedicine in Massachusetts: "Currently, the BRM and other Massachusetts governing or regulating entities have not formulated any well-defined regulations as to what medical services can be provided via tele-communication. The line as to what requires an in-person visit and what is appropriate for telemedicine services remains blurred."

Telemedicine, according to its proponents, "enables providers to extend their reach, and improve their efficiency and effectiveness while still maintaining high quality care and attention to patient safety."[3] The ATA Guidelines published in 2014 were designed to "cover the provision of patient initiated primary and urgent care services by licensed healthcare providers using real-time, interactive technologies, including mobile devices." The Association was careful to stress that their guidelines "do not purport to establish legal standards for telemedicine services but on the quality, safety and effectiveness of telemedicine encounters."

The Association identified a variety of acute and chronic conditions that may be appropriate for primary care telemedicine, including diabetes, asthma, heart failure, and hypertension. Each of these conditions was identified as one in which "there is a reasonable level of certainty in establishing a diagnosis and generating a treatment plan, especially when visual information is coupled with access to a medical record with diagnostic studies and imagining is available." The practice guidelines also noted that some conditions are not suitable for telemedicine, including those "for which an in-person visit is required to evaluate the patient due to the severity of presenting symptoms, the necessity of haptic information (those requiring touch), the need for protocol driven procedures or the need for aggressive interventions." The guidelines also specifically noted that it would not be suitable to use telemedicine, "when patients do not have the requisite technology to complete a virtual visit."

Telemedicine services can include not only reviews of data or previously analyzed lab work, but more interactive patient consultations, clinical services such as prescription provisions and renewals, and a physical examination, albeit conducted without direct doctor/patient touching.

The Impact of COVID-19

Prior to COVID-19, telemedicine had not achieved the wide use and popularity that its supporters anticipated. An article entitled *COVID-19 and the Rise of Telemedicine* appearing in "The Medical Futurist" on March 31, 2020, examined the current state of telemedicine:

> Telemedicine has not had the success story it had hoped to achieve. The method, involving remote health related services such as monitoring, advice and education between doctors and patients online over a secure connection, promised to be at the forefront of the future of medicine. It promised to make state-of-the-art healthcare more accessible without the need to wait hours in line.
> However, the reality is that only a handful of countries and regions adopted the concept, but telemedicine remains merely a concept for many. In fact, a study showed that in the U.S. alone, 82 percent of consumers do not use such services. This sad reality can be attributed to the lack of improper (sic) infrastructure to support it and to the lack of awareness. Another factor is that cultural aspects haven't been taken into consideration. Moreover, some even question its reliability and effectiveness....But then came 2020 and the COVID-19

> pandemic…Telemedicine is presenting itself as the ideal solution to these woes by limiting patient displacement to hospitals, allocating hospital capacity to important cases, all while curbing the disease's spread.

Now, "Telehealth is bridging the gap between people, physicians and health systems, enabling everyone, especially symptomatic patients, to state and home and communicate with physicians through virtual channels, helping to reduce the spread of the virus to mass populations and the medical staff on the frontlines," according to Dedi Gilad, CEO and co-founder of Tyto Care, a telemedicine technology company.

Although proponents have long argued that longstanding shortages of physicians, particularly in rural areas, can be remedied, at least in part, by the use of telemedicine, the Centers for Medicare & Medicaid Services continued to place strict limits on the types of telemedicine it would reimburse. And, since the health care of a large number of potential patients is paid for through programs administered by CMS, these restrictions have limited the growth of telemedicine.

Before the COVID-19 pandemic, for example, CMS limited Medicare requirements for virtual services to a narrow set of circumstances, which typically required the patient to leave his or her home to receive the services. Medicare patients living in a designated rural area with limited access to care providers could utilize telemedicine, but Medicare required the patient to travel to a local health care facility for the virtual appointment. Although the treating or consulting physician was not present on site, other staff was with the patient at the remote location, often actively participating by helping to administer tests or other monitoring procedures. In addition, a telemedicine patient had to have a prior working relationship with the physician.

On March 13, 2020, with the COVID-19 pandemic sweeping the nation, the Secretary of the Department of Health and Human Services (HHS) used the waiver authority granted by Section 1135 of the Social Security Act to permit CMS to expand the permissible range of services provided by telemedicine that qualify for federal reimbursement. The two most significant relaxations allow the provision of telehealth services regardless of zip code, and within the recipient's own home. Although clearly these modifications limit the exposure of both patients and physicians to infectious disease, even telemedicine's advocates recognize the potential for fraudulent claims raised by these relaxed standards. At the time, the stated reason for the expansion of the rules was to make sure "urgent needs" of patients who could not otherwise see a physician could be seen, continuity of care was preserved, and providers and patients protected.

Although many governors have relaxed state laws and regulations related to the provision of telemedicine as part of emergency declarations, most of these modifications have addressed who may provide services (in terms of professional licensing), to whom they may be provided (and where the patient must be situated), and whether those services will be paid for by the government. CMS, for example, has expanded access to telemedicine services for all Medicare

beneficiaries, not just those who may be suffering from COVID-19, for the duration of the federally declared medical emergency. In addition to existing coverage for originating sites including physician offices, hospitals, and skilled nursing facilities, Medicare will also now make payments for telehealth services furnished in any health care facility, as well as in the home. Under the temporary rules, CMS will reimburse participating providers for any virtual services rendered to a patient, if the services replicate those normally performed in a hospital or office setting. Providers are also permitted (though not required) to reduce or waive cost-sharing arrangements (co-payments) during the pandemic, without the risk of incurring administrative sanctions. Waiver of payments may otherwise be considered an unlawful inducement in violation of the federal Anti-Kickback Statute.

Obviously, many homes in which a telemedicine patient will be located lack the capacity to engage in real-time audio and visual communication with the health care provider. In those circumstances, CMS is temporarily allowing providers to be compensated for providing services as a "virtual check-in or an e-visit."

A "virtual check in" is defined by CMS as "a brief conversation, lasting between five and ten minutes, between an established patient and a participating Medicare provider." Although CMS has not waived the requirement that a virtual check-in be conducted with a patient with whom the physician has a pre-existing relationship, it has indicated that it will not be conducting audits to ensure that such a relationship existed during the COVID-19 emergency. This is particularly significant because McKinsey & Company estimates that the largest growth of telemedicine during the pandemic has been in the "virtual urgent care" segment, in which consumers get on-demand instant telehealth visits with physicians, most likely one with whom they have no prior relationship.

One of the goals of expanding access to telemedicine during COVID-19 was to specifically allow patients to seek medical advice without risking exposure to infectious disease. Allowing telephone consultation also supports guidance from the Centers for Disease Control to have patients call their health care providers before seeking in-person care.

Among the actions taken by CMS was to temporarily waive requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. The Federation of State Medical Boards website is tracking licensing modifications made by executive order as the result of COVID-19. Forty-nine states have relaxed licensing requirements. Many, although not all, states have specifically addressed telemedicine in these licensing regulations.[4]

Although the CMS guidance has not modified the substantive standards of care related to telemedicine services, "(T)he COVID-related changes to the virtual healthcare landscape offer tantalizing opportunity for physicians facing financial shortfalls due to state-issued stay-at-home orders and offer Medicare patients the opportunity to address health care concerns without risking infection."[5] Even the relaxed rules, however, contain numerous complex

requirements that telehealth providers must comply with, particularly to receive payment from CMS. A number of these requirements focus upon how a visit is characterized, and the proper coding for the services provided.

Practitioners must also ensure that even with these relaxed rules, the medium of communication used with the patient corresponds with CMS requirements. It is noteworthy that the HHS Office for Civil Rights has issued a "Notification of Enforcement Discretion" to allow covered health care providers to use widely available communications applications without the risk of penalties imposed by OCR for violations of HIPAA rules for good faith provision of telehealth services. Although OCR may permit certain communications during a telemedicine visit during the COVID-19 emergency without running afoul of HIPAA, other privacy rules still apply. CMS still generally requires real time communications capacity. And, it is important to note that state attorneys general, which also have the jurisdiction to enforce HIPAA, have not announced a similar relaxation of the law's requirements.

It is important to remember that the changes implemented by executive orders in response to COVID-19 will expire by operation of law once the crisis has subsided. (In many states, executive orders based upon an emergency declaration expire in 30 days.) Longer term changes will require legislative or more permanent regulatory action.

Will there be a demand to do that? There has been no ability to examine patient outcomes for those who have utilized telemedicine during this crisis, and no true measure – yet – of how many people chose to utilize telemedicine once that option was presented to them. But the initial evidence regarding the increased use of telemedicine is staggering. As but one example, the number of telemedicine visits conducted by the University of Pittsburgh Medical Center (UPMC), which is the largest medical care provider in its region, jumped from 250 per day in early March to nearly 9,500 per day by mid-April, an increase of 3,800%. Prior to COVID-19, UPMC's Endocrinology Department was conducting about eight telemedicine appointments weekly. Since the pandemic developed, the number suddenly jumped to about 500.[6]

Dr. Joseph Kvedar, a Harvard Medical School professor and president-elect of the ATA, has said that virtual visits at Partners HealthCare where he is senior advisor jumped from 1,600 virtual visits in February, 2020 to 90,000 the following month.

Whether the demand for telemedicine services outlasts the pandemic has yet to be seen. Once the crisis is over, the system will inevitably begin to rebalance itself. Despite technical challenges caused by the huge increase in demand, the question remains whether patients who utilized telemedicine services for the first time during COVID-19 were satisfied enough with the medical care they received that they will want to continue to use telemedicine for routine health care visits.

The CARES Act, however, provided funding to solidify telemedicine's infrastructure by awarding $200 million through the Federal Communications Commission to medical groups to help them install the technology and fund broadband installations.

Because payment for telemedicine services will be a driving factor in the extent to which wide use of telemedicine continues, CMS will be play a major role in navigating the immediate future of telehealth. The agency has not yet decided whether all, or even some, of its present policies will continue.

Opportunities for Fraud

Prior to COVID-19, the federal government's focus on fraud in telehealth focused upon three main areas:

- The Anti-Kickback Statute – which prohibits the knowing and willful offer or payment of, or the solicitation or receipt of, "renumeration" to induce or reward patient referrals or generation of business involving any item or service payable by the federal health care programs, including Medicare, Medicaid, and TRICARE.
- The Stark Law – which prohibits a physician from referring Medicare or Medicaid patients for designated health services to an entity with which the physician or physician's immediate family member has a financial relationship.
- The False Claims Act – which prohibits the knowing submission of false or fraudulent claims, and knowingly making, using, or causing to made or used, false records or statements material to a false or fraudulent claim.

Improper billing was generally based upon one or more of the following practices:

- Claims from patients who were listed as coming from rural areas, but who came from non-qualifying areas instead.
- Claims from non-eligible or non-listed institutional providers.
- Claims for services that were provided by unacceptable means of communication.
- Claims from prescriptions that were not legally made or tampered with.

As the federal government and many states loosened restrictions on billing for telemedicine services during the COVID-19 pandemic, the opportunities for fraud grew as well, despite the fact that relaxed regulations had eliminated some of the prohibitions that led to earlier billing fraud schemes.

"Anytime you open a program of this importance in such a short period of time, you are opening the door to all types of fraud," says retired FBI agent, forensics expert and attorney Jason G. Weiss. "COVID-19 was thrust upon us, and medical providers as well as law enforcement are all trying to adapt to this new virtual reality. With the creation of any new

program in a rapidly condensed period of time, there will be some level of organized chaos involved, and cybercriminals will try and take advantage of it as was allegedly done here."

Part of the opportunity for fraud by providers comes from the fact that insurers do not have a baseline model for the types, charges, and frequency of claims generally involving telehealth, and therefore fraud can become more challenging to detect. With the federally authorized expansion of telehealth, CMS approved dozens of new billing codes to allow medical professionals to bill for these services. Federal officials also allowed telemedicine providers to waive patient deductibles and copayments during the COVID-19 pandemic, actions that could otherwise be construed as a kickback because they discourage patients from complaining about charges or can lead to overuse of medical services. Observers have noted that the federal government apparently considers those lifted restrictions a calculated risk to promote telemedicine at a unique time when telemedicine is needed most. Even though it is far too early to fully evaluate the impact of telemedicine during the COVID-19 pandemic, notwithstanding its greatly increased use, there is substantial pressure to make those changes permanent.

Although many observers have focused upon the possibility of fraud being committed by providers who overbill or bill for services not provided—the "core" fraud—others have cautioned about the possibility of identity theft either by persons posing as a medical provider, or through the unlawful use of malware.

A person posing as the representative of a physician's office may contact "patients" to arrange non-existent appointments, while obtaining personal and financial information. In addition, persons can submit fabricated claims to an insurer in the name of an unsuspecting physician if the physician's information has been compromised.

Other potential targets of fraud are the sale of medically unnecessary durable medical equipment following telemedicine consultations, and the provision of medically unnecessary drugs through compounding pharmacies. Compounding pharmacies combine, mix, or alter the ingredients of drugs to create a unique drug for one particular patient, which tend to be very expensive.

In May, an article appeared in "Fraud" magazine, published by the Association of Certified Fraud Examiners, entitled, *Telemedicine Fraud Ripe During COVID-19 Pandemic*. In that article, several areas were identified as being particularly vulnerable to fraud:

- Office notes must substantiate the level of service billed. A patient's history must deem medically necessary any prescribed home regimen or recommended item of durable medical equipment despite the limited examination and the possibly limited ability of the physician to review prior medical records.
- Billing for non-existent physician visits, or "phantom visits" can occur because patients don't physically sign in to the physician's office. Patients may not specifically recall the

date of the visit, and almost certainly will be unable to recall its length. Even if a visit did occur, billing may be submitted for services that were not actually provided.
- Referral for diagnostic studies must be medically necessary and supported by documentation in the patient's file. Reviewers should be sensitive to widespread referrals to the same facility.

Conclusion

Although the use of telemedicine has greatly expanded in response to the COVID-19 pandemic, all rule changes supporting that expansion have been implemented on a temporary basis. No jurisdiction has attempted to modify the standard of care utilized by the treating physician.

The regulatory changes have focused upon who may practice telemedicine on a temporary basis, and more significantly, how telemedicine procedures must be documented in order to ensure payment through government sponsored programs or private insurance. The efficiency of the billing procedures utilized during the pandemic will likely lead to some modifications if the scope of telemedicine is permanently expanded.

Notwithstanding that the pandemic created an acute need for these expanded services, at least some of the physicians who have expanded their practice base into this area have done so out of economic necessity. Those pressures will likely continue to exist after the pandemic ends.

The largest concern posed by the expansion of telemedicine appears not to be related to the quality of care provided, but rather to the opportunities for improper or even fraudulent billing by providers. It is reasonable to expect that future monitoring work in this area will center around financial improprieties committed by physicians and those responsible for their billing.

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[1] The Advocacy Resource Center of the American Medical Association contains a summary of all state laws dealing with telemedicine, including executive orders issued in response to COVID-19, https://www.ama-assn.org/health-care-advocacy/access-care/state-advocacy.
[2] Rhode Island General Laws, §27-81-3 (12).
[3] *See*, *Practice Guidelines for Live, On Demand Primary and Urgent Care*, American Telemedicine Association (Nov. 2014).
[4] *See,* https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-COVID-19.pdf.
[5] *See*, *Tips for Providers to Avoid Telehealth Compliance Risk*, NATIONAL LAW REVIEW (Apr. 22, 2020).
[6] *See*, STAT Health Tech newsletter (Apr. 29, 2020).