



# | Introduction to | Telemedicine

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## Telemedicine Considerations During the COVID-19 Emergency

*(as of April 1, 2020)*

This telemedicine resource is offered to provide a broad overview of the range of telemedicine applications as they relate to practitioners, providing general guidance as to the risks and liabilities of telemedicine. Topics include the establishment of a patient/provider relationship, informed consent, and payment considerations relating to telemedicine. The following section relates only to telemedicine considerations, waivers, reimbursement, and licensure during the COVID-19 emergency and may be significantly different than the remainder of the content. The federal government, along with most state and local governments, have suspended, waived, or relaxed telemedicine laws and regulations during the COVID-19 emergency. It is important to frequently check with your state department of health, medical professional liability carrier, state medical association, or other resource to ensure you are providing services according to applicable state law; as some of these measures will not apply in all of the states governing your telemedicine practice.

It is also essential that providers continue to meet standards of care when delivering care by telemedicine and comply with laws and regulations in the treatment of patients.

### Disclaimers

This resource is intended as guidance and does not constitute legal advice or the standard of care. Policyholders are encouraged to consult their personal attorney or an SVMIC Claims Attorney with specific questions.

This material was compiled on April 1, 2020, and reflects current industry practice as of that date. Please consult with an advisor about changes to the rules and regulations, and their application to your practice.

### Licensure

Many state medical boards have relaxed licensure requirements or offer expedited licensure during the COVID-19 emergency. The Federation of State Medical Boards maintains current requirements and emergency declarations at <https://www.fsmb.org/advocacy/covid-19/>.

### CMS Waivers & Reimbursement

Providers can bill for telehealth visits at the same rate as in-person visits (however, the reimbursement may be different by payers). Telehealth visits include emergency department visits, initial nursing facility and discharge visits, home visits, and therapy services, which must be provided by a clinician who is allowed to provide telehealth. New as well as established patients now may stay at home and have a telehealth visit with their provider.

According to CMS, these waivers and rule changes dramatically lessen administrative burdens, knowing that front line providers will be operating with high volumes and under extraordinary system stresses.

On March 30, 2020, CMS announced three key points: (1) you do not have to enroll physicians at their homes for telemedicine; (2) you can treat patients over the phone; and (3) providers can see both new and established patients via telemedicine.

Building on prior action to expand reimbursement for telehealth services to Medicare beneficiaries, CMS will now allow for more than 80 additional services to be furnished via telehealth. During the public health emergencies, individuals can use interactive apps with audio and video capabilities to visit with their clinician for an even broader range of services. Providers also can evaluate beneficiaries who have audio phones only. A broad range of clinicians, including physicians, can now provide certain services by telephone to their patients (CPT codes 98966 -98968; 99441-99443).

Beneficiary consent should not interfere with the provision of telehealth services. Annual consent may be obtained at the same time, and not necessarily before, the time that services are furnished.

This waiver does not have the effect of waiving state or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements.

These temporary changes will ensure that patients have access to physicians and other providers while remaining safely at home.

### **Important!** Tips for Billing CMS

Reacting to the many questions and concerns from providers about telemedicine payments, the Centers for Medicare & Medicaid Services (CMS) released Medicare IFC: Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC) (PDF) (retroactively dated to March 1). The new ruling addresses many issues; however, we will spotlight several that are relevant to the ambulatory environment, noting the page numbers of the ruling for quick reference. This ruling indicates a significant change in coding and reimbursement of digital health services. This ruling appears to address a multitude of outstanding issues:

In the rule, CMS addresses the issue of paying telemedicine visits at the facility rate. This rate is lower than the professional rate as it assumes that a separate payment is being made to the facility to cover the expenses of the facility and staff. CMS is instructing physicians and practitioners who bill for Medicare telehealth services to report the Place of Service (POS) code that would have been reported had the service been furnished in person. Therefore, CMS will pay at the professional (higher) rate for telemedicine visits if the service is billed using the POS 11 - Physicians' Office or 19/22 if you're organized as a Hospital Outpatient Clinic (whichever one you'd normally use if the services were provided in-person; the latter pays at the facility rate today). CMS is requesting that you append the -95 modifier to indicate that it was a service performed via telemedicine.

**IMPORTANT!** Do NOT use POS -02 as it will be paid at the lower, facility rate.

We encourage you to carefully read pages 14 and 15 from the Federal Register.

In addition, the ruling includes:

- A lengthy list of newly-added telemedicine services (starts on page 19).
- Confirmation that telemedicine requires an audio AND video platform (pages 48-49). In the case that two-way, audio and video technology required to furnish a Medicare telehealth service might not be available, CMS will pay for telephone-only visits (pages 122-125); for phone-only visits, use CPT codes 99441-99443; 98966- 98968. (Note that eVisits, Virtual Visits, and Remote Monitoring may also be options; see descriptions of those codes -- they are NOT considered telemedicine services.)
- To enhance beneficiary protection, for both new and established patients, CMS suggests that the physician or other health care practitioner review consent information with a beneficiary, obtain the beneficiary's verbal consent, and document in the medical record that consent was obtained. Consent can be documented by "auxiliary staff," and can be obtained at the time of service (page 52; pages 121-122).
- G0071 reimbursement for FQHCs and RHCs rises; includes new patients (pages 86-87).
- New rules about Teaching Physicians Services (starting on page 101).
- E/M levels can be based on TIME for telemedicine (pages 136-137).

This is not meant to be a replacement for your internal HIM/coding/billing/compliance experts, but rather to allow you to read the ruling first hand to help interpret the guidance for your organization.

### Additional CMS Waivers

Additionally, CMS is issuing waivers so that hospitals can use other practitioners, such as physician assistants and nurse practitioners, to the fullest extent possible, in accordance with a state's emergency preparedness or pandemic plan. These clinicians can perform services such as order tests and medications that may have previously required a physician's order where this is permitted under state law.

CMS is waiving the requirements that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician. This will allow CRNAs to function to the fullest extent allowed by the state, free up physicians from the supervisory requirement, and expand the capacity of both CRNAs and physicians. CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent.

CMS is allowing telehealth to fulfill many face-to-face visit requirements for clinicians to see their patients in inpatient rehabilitation facilities, hospice, and home health.

CMS is making it clear that clinicians can provide remote patient monitoring services to patients with acute and chronic conditions, and can be provided for patients with only one

disease. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry.

In addition, CMS is allowing physicians to supervise their clinical staff using virtual technologies when appropriate, instead of requiring in-person presence.

## HIPAA

The Office of Civil Rights (OCR) announced that covered health care providers subject to the HIPAA rules may communicate and provide telemedicine for any healthcare service to patients through services that may not fully comply with the requirements of the HIPAA rules. OCR will not impose penalties for noncompliance with the good faith provision of telehealth during the public health emergency effective immediately. This allows a provider to use many products to communicate with patients as long as they are not public-facing. See the [full statement from OCR](#) for details on communication methods allowed. Another useful resource is this [HHS FAQ](#).

## Drug Enforcement Agency

Please note: State restrictions on prescribing controlled substances via telemedicine may still be in effect in spite of the DEA's following announcement.

On January 31, 2020, Secretary of Health and Human Services Alex Azar declared a public health emergency in response to COVID-19. Following this announcement, DEA worked in consultation with HHS to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation. DEA-registered practitioners may continue this telemedicine practice for as long as the designation is in effect, if all required conditions are met:

- 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.

Provided the practitioner satisfies these requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available adhering to DEA regulations, including issuing a prescription electronically or calling in a prescription to the pharmacy.

## Important Reminders

- Check with your medical professional liability carrier to ensure coverage for telehealth
- Check [payer websites](#) for current telehealth reimbursement and requirement information
- Check the [Federation of State Medical Boards](#) for links to state medical board websites, COVID-19 dedicated webpages, current emergency declarations and licensure information and other board resources



- Currently states require a provider to stay within his/her scope of practice and specialty
- The provider is held to the same standard as an in-person visit
- Document informed consent for the visit via telehealth
- Even with HIPAA waivers, the expectation remains for provision of telehealth in private settings
- Speaker phones should not be used on either end of the encounter (on the provider's end or on the patient's end) if others can overhear
- The provider should arrange for appropriate follow-up care during the telemedicine visit
- For more COVID-19 updates, resources and links, visit SVMIC's COVID-19 page at <https://home.svmic.com/resources/covid-19>
- AMA telemedicine Quick Guide <https://www.ama-assn.org/delivering-care/public-health/ama-quick-guide-helps-doctors-boot-their-telemedicine-practice>

### CMS Sources

- <https://www.cms.gov/files/document/covid-final-ifc.pdf>
- <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>
- <https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19>
- For additional background information on the waivers and rule changes, go to: <https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient>
- For more information on the COVID-19 waivers and guidance, and the Interim Final Rule, please go to the CMS COVID-19 flexibilities webpage: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>
- For additional information about response to COVID-19, visit [www.coronavirus.gov](http://www.coronavirus.gov)
- Patient Access Collaborative, <https://www.patientaccesscollaborative.net/>
- <https://www.cms.gov/files/document/covid-flexibilities-overview-graphic.pdf>



## PART ONE

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### Introduction

Paradigm-shifting advances in the history of medicine have included anesthesia, X-ray, EKG, and antibiotics. Another will be telemedicine: the provision of healthcare at a distance through technology. Telemedicine (used here synonymously with “telehealth”) is emerging as the great equalizer of access and quality in both the developed world and the developing world, where adoption may be progressing even faster.

The term “telemedicine” was a pun on “television” when it was coined; but, in a masterpiece of irony, the most important consumer device in healthcare today is not the TV, but the mobile phone. Smartphones have overtaken PCs and even tablets, not only for entertainment and personal connectivity, but also as the primary transactional device for commerce and knowledge—especially for younger generations. If the concept of treating patients at a distance had been invented this afternoon, it might have been called, “mobimedicine”. More importantly, many laws and regulations addressing telemedicine still seem fixated on the concept of a “TV doctor” and do not yet contemplate legions of activities that entail healthcare information exchange without falling under the rubrics of telemedicine policy.

This article concerns itself predominantly with the legal, regulatory and liability implications of activities formally designated as telemedicine. It must be kept in mind that providers, patients, and organizations at every level are experimenting with connected health applications that reach far beyond the range of topics circumscribed by that rubric. The scope of this material is narrower than a comprehensive review of the full panoply of electronic healthcare communications today, let alone those impending tomorrow. Readers will not find the discussion here they may wish, if their concerns are about applications in clinical informatics beyond the borders of today's definitions.

The telemedicine revolution encourages providers in every specialty and setting to investigate the impact of telemedical services upon, and potential benefits for, their practices. The technical challenges of what might be called “Telemedicine 1.0” (real-time, audiovisual communication and data sharing between medical experts and patients) have been solved; or are at least fully understood. “Telemedicine 2.0” (remote, robotically-assisted services and procedures) are more than imminent. Services that once required an intimidating investment in hardware and support are now as cheap and available as social media. It has been speculated that virtual physician visits could outnumber traditional, face-to-face patient visits by 2025.<sup>1</sup>

The marriage of electronic communication with healthcare has produced a family of innovations that are disrupting traditional patterns of care delivery dramatically and permanently. This material will survey:

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<sup>1</sup> Dorsey ER, Glidden AM, Holloway MR, Birbeck GL and Schwamm LH. 2018. Teleneurology and mobile technologies: the future of neurological care. *Nature Reviews Neurology*, 14:285-297.

- Telemedicine use cases, applications and platforms
- The legal and regulatory framework for the practice of telemedicine in the U.S.
- Professional liability risks associated with telemedicine
- Some considerations regarding payment for telemedicine services

Like other major social transformations, the effects of telemedicine are reverberating across the healthcare ecology in many ways that can now be foreseen now, and in ways that cannot. Many strategic, economic, workforce, and logistic calculations that have long governed planning (especially by governments and large entities) in the healthcare industry will need to be recalibrated as the constraint of geography is replaced by the constraint of connectivity.

## What is Telemedicine?

Within the larger universe of “electronic applications that operate between separate sites in healthcare”, the ones deemed telemedicine are defined for different purposes by different authorities. However, from every standpoint, the two critical elements are: 1) *it comprises the practice of medicine, and 2) services are delivered to patients in a different location from the provider.* Definitions fall into the categories of **technological, regulatory, and financial.**

### Technological Definitions

From a technological and functional standpoint, the American Telemedicine Association (ATA) defines Telemedicine as, “[T]he use of medical information exchanged from one site to another via electronic communications to improve patients' health status.”<sup>2</sup>

The key term here is “electronic”. Ironically, this definition is generally understood to exclude telephone conversations. The reasons for this are historical rather than logical. Mirroring the HIPAA<sup>3</sup> Security Rule<sup>4</sup>, many telemedicine regulations treat telephonic communication as verbal, separately from other electronic transmission media. Frankly, special treatment of telephone calls makes less and less sense when the definition of telephone is radically different from what it was in 1996; as networked mobile devices serve multiple communications functions (including voice) simultaneously, and distinctions between real-time and stored data become fuzzy.

### Regulatory Definitions

The practice of medicine in the U.S. is regulated by state and federal laws administered by state medical boards and numerous agencies. This potentially allows 50 different state standards, plus

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<sup>2</sup> <http://thesource.americantelemed.org/resources/telemedicine-glossary> [7/16/18]

<sup>3</sup> Pub. L. No. 104-191, 110 Stat. 1936 (1996)

<sup>4</sup> <https://www.hhs.gov/hipaa/for-professionals/faq/2010/does-the-security-rule-apply-to-written-and-oral-communications/index.html> [7/16/18]

definitions and standards from Federal agencies including AHRQ, CDC, CMS, DEA, DOD, FDA, HRSA, IHS, NASA, NIST, OCR, VA, etc. (as of 2014, there were at least seven different federal legal definitions of telemedicine). Fortunately, vigorous efforts are underway by governmental and quasi-governmental working groups (such as the Federation of State Medical Boards) at several levels—assisted by technology vendors and other experts—to harmonize these.

At the federal level, probably the most widely-accepted definition comes from the Health Resources and Services Administration (HRSA/DHHS). This agency uses the term “telehealth” and defines it as, *“The use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health and health administration.”*<sup>5</sup>

It is important to recognize that electronic communication makes geopolitical boundaries nearly as porous as topographical ones. International authorities are just as concerned with overseeing extraterritorial medical practice as are the States of the U.S. The European Commission’s definition of telemedicine is, *“the provision of healthcare services, through the use of ICT [information and communication technology], in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images, or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.”*<sup>6</sup>

**For the purposes of practitioners and facilities, the first question that needs to be addressed is the legal framework governing the activity that is being contemplated. Is it telemedicine? And, is it legal?**

Criminal liability may arise from violating licensing or other laws; but, exposures to civil liability (i.e., malpractice) that go with the practice of medicine are not canceled when the practice happens at a distance—in fact, some may be amplified. A more detailed discussion of professional liability follows in a later section.

## Financial Definitions

After liability, the most pragmatic interest of providers and facilities is how they can be reimbursed by payers. The definitional issue for payment is not what constitutes telemedicine as a whole, but rather, the descriptions of specific procedures and services that can be recognized as claims by an adjudication system.

CPT and HCPCS codes for telehealth services eligible for Medicare reimbursement are enumerated in several publications (including <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf>). Of course, State Medicaid and private payers march to their own drummers, as do the DOD and VA.

<sup>5</sup> <https://www.healthit.gov/topic/health-it-initiatives/telemedicine-and-telehealth> [7/16/18]

<sup>6</sup> <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52008DC0689> [7/16/18]

Understanding and complying with the terms for coding and reimbursement for each payer is a well-known art form. It is important to recognize that describing items eligible for payment is a completely different matter from defining “telemedicine” or “telehealth” for legal or regulatory purposes.

### Telehealth, eHealth or mHealth?

The term telehealth often appears alongside telemedicine. Some authorities prefer one or the other, and there is currently no standard for reconciling them. Except when they appear explicitly in statutes, regulations, or contracts, telemedicine and telehealth are usually interchangeable. According to the ATA:

The term ‘telehealth’ is often used to encompass a broader definition of remote healthcare that does not always involve clinical services. Videoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education, and nursing call centers are all considered part of telemedicine and telehealth.<sup>2</sup>

Another term that appears frequently is “mHealth”. This typically refers to applications, which are often consumer-oriented, that operate on mobile devices (i.e. cell phones and tablets).

### Telemedicine vs. Other e-Communication

Today's users have a myriad of channels for connecting with each other. The previously-mentioned definitions present challenges for determining exactly what constitutes telemedicine. In fact, there are legitimate reasons for confusion.

The differences are increasingly blurry between modalities that fall under regulatory or payer definitions of “telemedicine” and other forms of electronic communication used by physicians and patients. In the early days, telemedicine implied a private television connection, often requiring special equipment and a dedicated network. Today, video calling capability, even across multiple sites, essentially comes free with every cell phone and computer. When is a video chat session telemedicine, and when is it just a social conversation? When a clinical problem is posed on a professional chat board by one physician, and a solution is suggested by an expert in another country, is that telemedicine?

## Electronic Communication Channels

- Telephone, Fax, Pager, Voicemail
- Standard Email, Webmail
- Wired/wireless network messaging
- Radio, "official" (e.g., fire, police)
- Radio, "civilian" (e.g., "Ham")
- Point-to-point videoconferencing
- Device feeds
- Encrypted Email
- Secure text messaging
- Photo/media sharing
- Websites, blogs, online chat
- Social Media sites (e.g., Facebook®)
- Secure EHR portals
- Video calling (e.g., Skype®)

Email, texting, file and photo sharing, online reference material, audio/video recording, and activity tracking have obvious medical uses but are much more widely used for social purposes. Which uses of these technologies constitute telemedicine? Applications with both dubious and bona fide healthcare purposes appeared early in the mobile device market and now number in the hundreds of thousands.<sup>7</sup> Even medical records are becoming virtualized; inexorably migrating from siloed repositories controlled by providers to multi-user, multi-access databases in cyberspace, increasingly controlled by patients.

### Standard Email, Webmail

In some sense, it's obvious when a doctor is "providing healthcare at a distance"; but, common sense does not determine whether a given scenario would be defined as "telemedicine" from a regulatory or financial perspective. From a legal standpoint, the answer starts with the question whether "practice of medicine" is occurring, but it does not end there. A telephone call between a doctor and a patient certainly can entail the practice of medicine and might meet every logical criterion for care at a distance, but it would probably not be defined as telemedicine under most official regulations. For that matter, the same is true for a postal letter with medical advice. Without reading the fine print in the definitions from legal authorities and payers, it is impossible to know.

This uncertainty challenges the regulatory infrastructure that healthcare has relied upon for generations. Authorities today are struggling to adapt to the implications of interstate electronic commerce in many areas, not just medicine, and the problem is accelerating. Technologies that were innovative just 10 years ago are being superseded by ones that are faster, cheaper and

<sup>7</sup> <https://research2guidance.com/325000-mobile-health-apps-available-in-2017/> [7/5/2018]

more versatile and are also available to entire populations, rather than just a few technologically privileged ones.

The wholesale democratization of e-communication has social and historical significance comparable to the invention of the printing press. It (literally) has revolutionary impact around the world. Not just healthcare, but many human institutions (education, law enforcement, journalism, banking, entertainment, gambling, etc.) are grappling with technology moving faster than policy makers can react. Regulators still tend to conceive of telemedicine under the somewhat quaint model of remote television, when this is already out of date.

Nevertheless, for healthcare providers, there are just four basic questions to ask yourself before engaging in telemedicine. Each of these is discussed in more detail in later sections.

**What channels will I use to engage with patients at a distance?**

Today, it's almost impossible to imagine a practice without telephone and fax. Even providers who eschew email often participate in electronic payments, e-prescribing, and electronic delivery of test results. These realities make it almost impossible to escape at least some of the legal, liability, and payment issues raised by telemedicine. Certainly, practices that have websites, email addresses, or whose providers (or staff) use social media, even for personal use, need to be fully aware of the liability these media entail.

**How do I comply with legal requirements when communicating with patients at a distance?**

The short answer is that providers need to be fully cognizant of federal rules, the regulations in the state(s) where they are licensed, and the regulations of each jurisdiction from which a patient is communicating with them. Whether their communications formally comprise telemedicine or are governed by other liability frameworks is simply a detail. Providers also need to be sure their professional liability insurance covers what they are doing.

**How do I minimize malpractice risk when treating patients at a distance?**

The standard of care requires a healthcare provider to exercise the degree of reasonable care, skill, and diligence as would ordinarily be exercised by a similarly situated healthcare provider for a similar patient under the same or similar circumstances. The analysis of most adverse events associated with telemedicine will begin with the question, "Was this a situation that could reasonably be managed this way?"

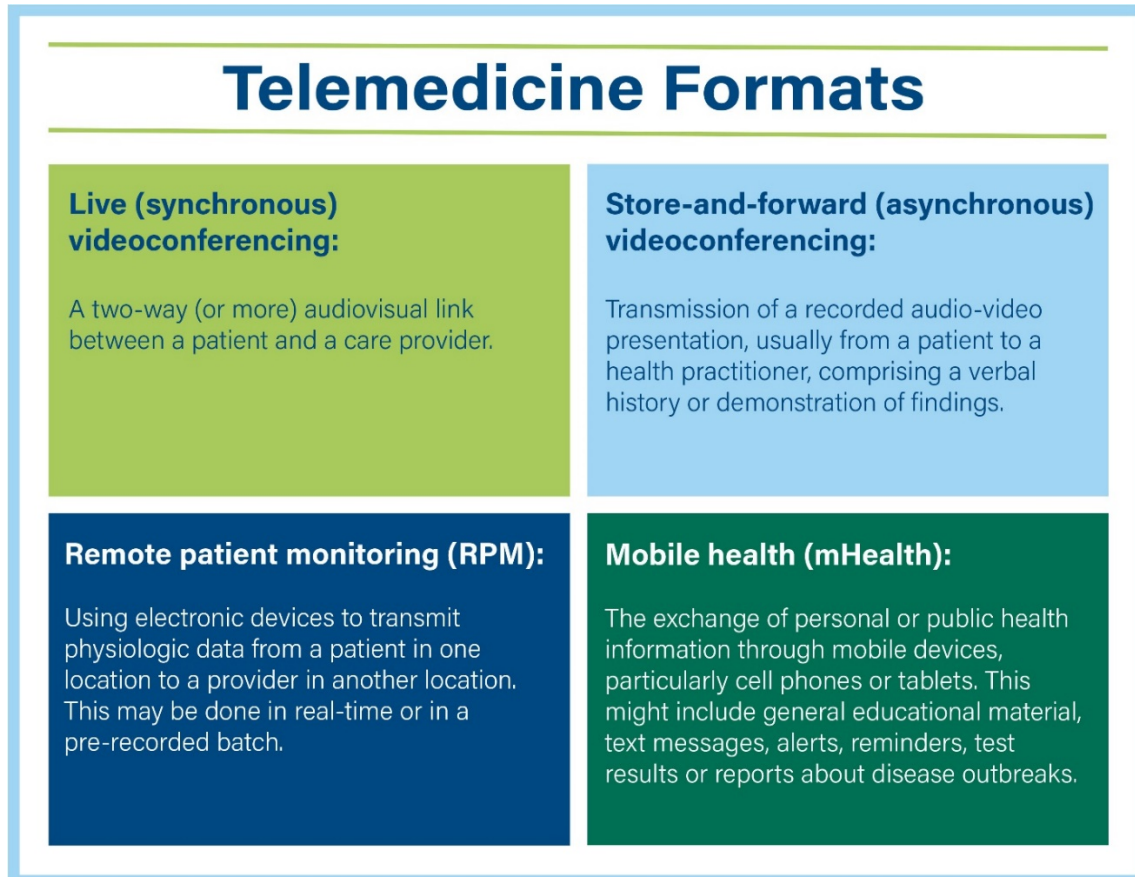
**How do I get paid for services rendered to patients at a distance?**

This question can be central to decisions about the role of telemedicine for a given organization, but, the multiplicity and volatility of payer policies and strategic solutions make it impossible for this article to give detailed guidance.



## Scope and Effect

Taking into account the earlier ambiguities, telemedicine applications are understood by some authorities to fall into a number of specific formats:<sup>8</sup>



However, these categories may operate concurrently and may overlap. As mentioned, many clinical communications that might not be defined strictly as telemedicine (like email, or messaging through an EHR portal) nevertheless are widely used with powerful value and implications for medical practice.

<sup>8</sup>[http://www.cchpca.org/sites/default/files/uploader/Telehealth%20Definintion%20Framework%20for%20TRCs\\_0.pdf](http://www.cchpca.org/sites/default/files/uploader/Telehealth%20Definintion%20Framework%20for%20TRCs_0.pdf) [7/16/18]

## A Few Use Cases

Even a decade ago, it might have been possible to hear a debate in the doctors' lounge whether practicing medicine over the telephone is ethical; but, today's practitioner makes use of so many data channels that the fact that some of them are remote or asynchronous is taken for granted.

Complex care management increasingly involves splitting expertise across time and space. No one today blinks at the idea that an EMT on an ambulance could attach EKG leads to a patient in transit, and transmit the tracing to a cardiologist miles away. Nothing in the cardiology skill set requires them to apply the leads personally, and nothing in the EMT skill set would make them question the value of the cardiologist's remote interpretation. What difference does it make if the radiologist reading the midnight ultrasound is in the next room, in their bedroom at home, or in a country where the local time is noon?

This doesn't mean that a hands-on exam by an expert neurologist or surgeon isn't sometimes necessary for adequate decision-making. What it does mean is that some components of excellent care do not require physical presence, as long as the information needed is present.

The universe of proven and potential applications of e-communication in healthcare is constantly expanding. Following are some illustrations across a range of uses, including both provider-patient and provider-provider formats. Again, some of these activities are telemedicine, and some are not.

### E-Visits

Employers (especially with self-funded insurance) and patients are sharply aware of the inefficiency of travel to physician offices for minor acute illnesses. A simple UTI or sinusitis that might entail 10 minutes of provider time can amount to a half day off work when travel, waiting, lab, and pharmacy are involved. This represents serious lost productivity for businesses and often requires workers to use limited sick leave. Some patients need to arrange childcare, transportation, and other support services that are invisible to providers but meaningfully impactful for patients. A proportion of after-hours and Emergency Department visits can be directly attributed to patient's reluctance (or inability) to schedule physical office visits. E-visits for common conditions that don't always depend on physical examinations are well-accepted by patients and increasingly covered by payors. A virtual physician network with several hundred practitioners lists top conditions treated as acute bronchitis, cough, sinusitis, acute pharyngitis, acute cystitis, urinary tract infection, abdominal pain, diarrhea, fever, acute conjunctivitis, painful urination, influenza, respiratory infection, headache, and smoking cessation.<sup>9</sup>

### Rural Access

The burden of distance is a critical factor in rural healthcare. Direct-to-patient services like e-visits, telepsychiatry, and welfare checks for the elderly and provider-provider specialty consultations like teleradiology and teleneurology can save not only hours (or days) of time, but

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<sup>9</sup> [https://www.medscape.com/viewarticle/833254\\_1](https://www.medscape.com/viewarticle/833254_1) [7/16/18]

also provide access to high-level specialty resources that would be impossible to provide in person.

### **Specialty Access**

It is simply impossible to provide immediate physical access to the full range of medical experts for every American; the geography is just too great. When the problem depends solely on the transfer of information, it is absurd to transport the patient when transmitting the information between providers is so easy. This logic has been successfully applied used by both rural and urban practitioners to gain access to specialties like toxicology (poison control), neurology, dermatology, cardiology, pathology, radiology, wound care, rehabilitation, occupational medicine, and even critical care.

Telestroke services are a poster child for the successful provision of highly specialized expertise in emergency settings, even to hospitals well-equipped with diagnostic and treatment resources. Having an experienced expert available 24 hours a day, who can conduct a precise video examination (through the proxy of a local clinician), review online imaging studies, and recommend intervention at the highest standard has improved treatment times and outcomes for acute neurological conditions across the U.S.<sup>1</sup> Similar approaches have been taken in other critical care and emergency specialties. Other specialty services (both doctor-to-patient and doctor-to-doctor) that can be delivered at a distance include triage, urgent evaluation, transfer decisions, supervision of care by non-physician providers, consultation, second opinions, and shared decision-making.

### **Teleradiology**

One of the most widely-embraced services in the field of healthcare at a distance is the remote reading of medical images. This practice is intuitively appealing; however, it has also sometimes been seriously disruptive to pre-existing professional and financial relationships. When the procedure does not require direct patient contact, it should not make any difference whether the data file is reviewed five feet or 5,000 miles away. The provider is dealing purely with information, which is independent of location. Teleradiology removes barriers of time, distance and expertise. It reduces response time after-hours. It allows smaller hospitals and groups to maintain adequate coverage around the clock. It allows efficient access to qualified radiologists and sub-specialty experts by facilities that cannot afford to provide this workforce because of location, volume, or other factors.<sup>10</sup> Since reading images does not involve interacting with patients, teleradiology does not constitute telemedicine under most regulatory schemes and is usually reimbursed differently. Because some authorities consider the practice of medicine in radiology to occur both at the originating site and the receiving site, issues of quality management, and oversight of equipment and technicians, as well as the qualifications of providers, are important and complex.

### **Remote Monitoring**

Patients who are geographically isolated or mobility impaired may be able to maintain closer relationships with providers—and other caregivers—through telemedical applications. Many devices (e.g., arrhythmia monitors, glucose monitors, spirometers, oximeters, etc.) that once

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<sup>10</sup> Silva E, Breslau J, Barr RM, et al. 2013. ACR White Paper on Teleradiology Practice: A Report from the Task Force on Teleradiology Practice. *J Am Coll Radiol*, 10:575-585.

produced data only readable by physically delivering the file to a provider or vendor, are now internet enabled.

### **Correctional Medicine**

Costs and risks of transporting incarcerated offenders, plus the sometimes remote location of facilities, make a strong case for telemedical visits with qualified clinicians.

### **Military Medicine**

Some of the earliest innovations in telemedicine were developed for the military, which remains a pioneer in the field. Telemedicine allows deployed medics and physicians to deliver quicker and more expert care to a wider range of patients, both on the battlefield and in environments where general medical resources are limited. This has been proven to reduce mortality and disability related to combat injuries, and it also improves the quality of care for a wide range of medical and surgical conditions. It enables consultation between front line providers and almost any specialty. The DOD is also actively testing systems for telerobotic surgery.

### **Telepsychiatry and Behavioral Health**

The provider's physical presence is less critical than his or her expertise for managing many issues in behavioral health. Shortages of services and lack of access to specialists impacts nearly every aspect of behavioral medicine, from the most basic screening and triage, to interventions for specialized problems like substance abuse, suicide risk, and domestic violence, to ongoing care of chronic illness. One telepsychiatry vendor claims that 57 percent of patients presenting to the ED with a behavioral health problem leave the facility without treatment.<sup>11</sup> Tele-behavioral health creates access where it was unavailable before, stretches resources efficiently and is highly acceptable to patients.

### **Limited English Proficiency and Hearing Impaired**

TTY services<sup>12</sup> for deaf and hard of hearing patients have been available for decades; but, a quantum leap in effectiveness can be provided by an expert sign language interpreter, participating via videoconferencing. This identical format can also be used for foreign language translation. The Affordable Care Act specifies standards for video remote interpretation services:<sup>13</sup>

A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities shall provide:

- 1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

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<sup>11</sup> Avizia. 2018. Tele-behavioral health: reducing the mental health burden on emergency departments. <https://www.avizia.com/clinical-use-cases/behavioral-health> [7/16/18]

<sup>12</sup> Teletypewriter, developed in the 1960s, transmits text characters to special terminals over phone lines.

<sup>13</sup> 45 CFR Part 92 Nondiscrimination in Health Programs and Activities; Final Rule. Federal Register Vol. 81, No. 96 Wednesday, May 18, 2016, p. 31470

- 2) A sharply delineated image that is large enough to display the interpreter's face and the participating individual's face regardless of the individual's body position;
- 3) A clear, audible transmission of voices; and
- 4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

### **Distance Education**

While medical education may not precisely fit the definition of telemedicine (although trainees certainly participate in telemedical services), telecommunication capabilities allow expert teachers to deliver knowledge and training without the impediment of geographical barriers.

### **Telerobotics and Telesurgery**

While remote surgery is not contemplated in current definitions of telemedicine and not included in the present analysis, it sits like an elephant in the room for future consideration.

These are just samples of the myriad creative uses that providers, patients, social services, and families are finding for telehealth.

### **Effectiveness**

Formal research on telemedicine outcomes and effectiveness is expensive and slow; there is a significant lag time between research and publication. Most active telemedical programs were implemented before proof was readily available for benefits or cost impacts. It is likely that the proliferation of telemedicine will continue to outpace rigorous evidence, because the concept has such appealing face value.

However, the literature that exists has been supportive. According to a 2016 analysis of 58 systematic reviews of telehealth literature by the Agency for Healthcare Research and Quality (AHRQ):<sup>14</sup>

A large volume of research reported that telehealth interventions produce positive outcomes when used for remote patient monitoring, broadly defined, for several chronic conditions and for psychotherapy as part of behavioral health. The most consistent benefit has been reported when telehealth is used for communication and counseling or remote monitoring in chronic conditions such as cardiovascular and respiratory disease, with improvements in outcomes such as mortality, quality of life, and reductions in hospital admissions.

The AHRQ report concluded that there is sufficient evidence to support the effectiveness of telehealth for:

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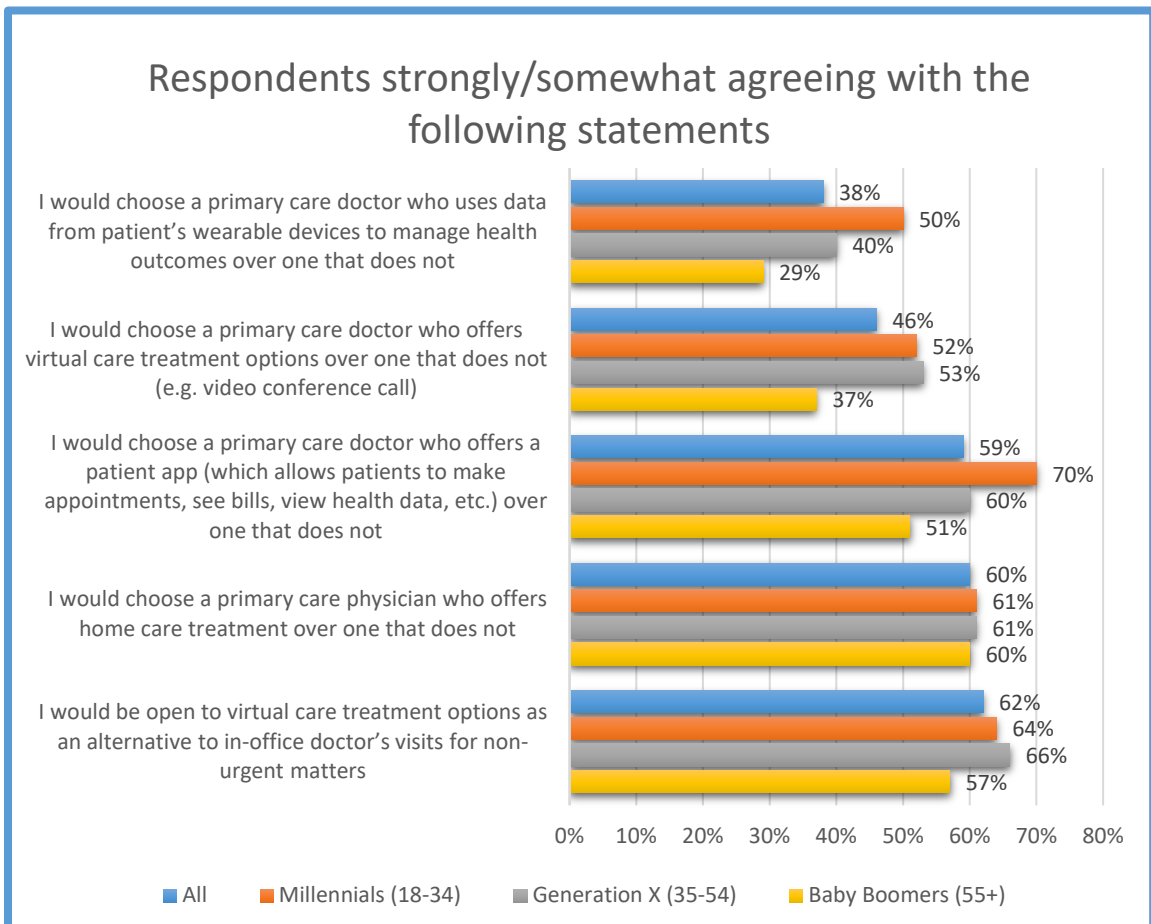
<sup>14</sup> Totten AM, Womack DM, Eden KB, McDonagh MS, Griffin JC, Grusing S, Hersh WR. Telehealth: Mapping the evidence for patient outcomes from systematic reviews. Technical Brief No. 26. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No.16-EHC034-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2016. [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).

- Remote patient monitoring for patients with chronic conditions
- Communication and counseling for patients with chronic conditions
- Psychotherapy as a part of behavioral health

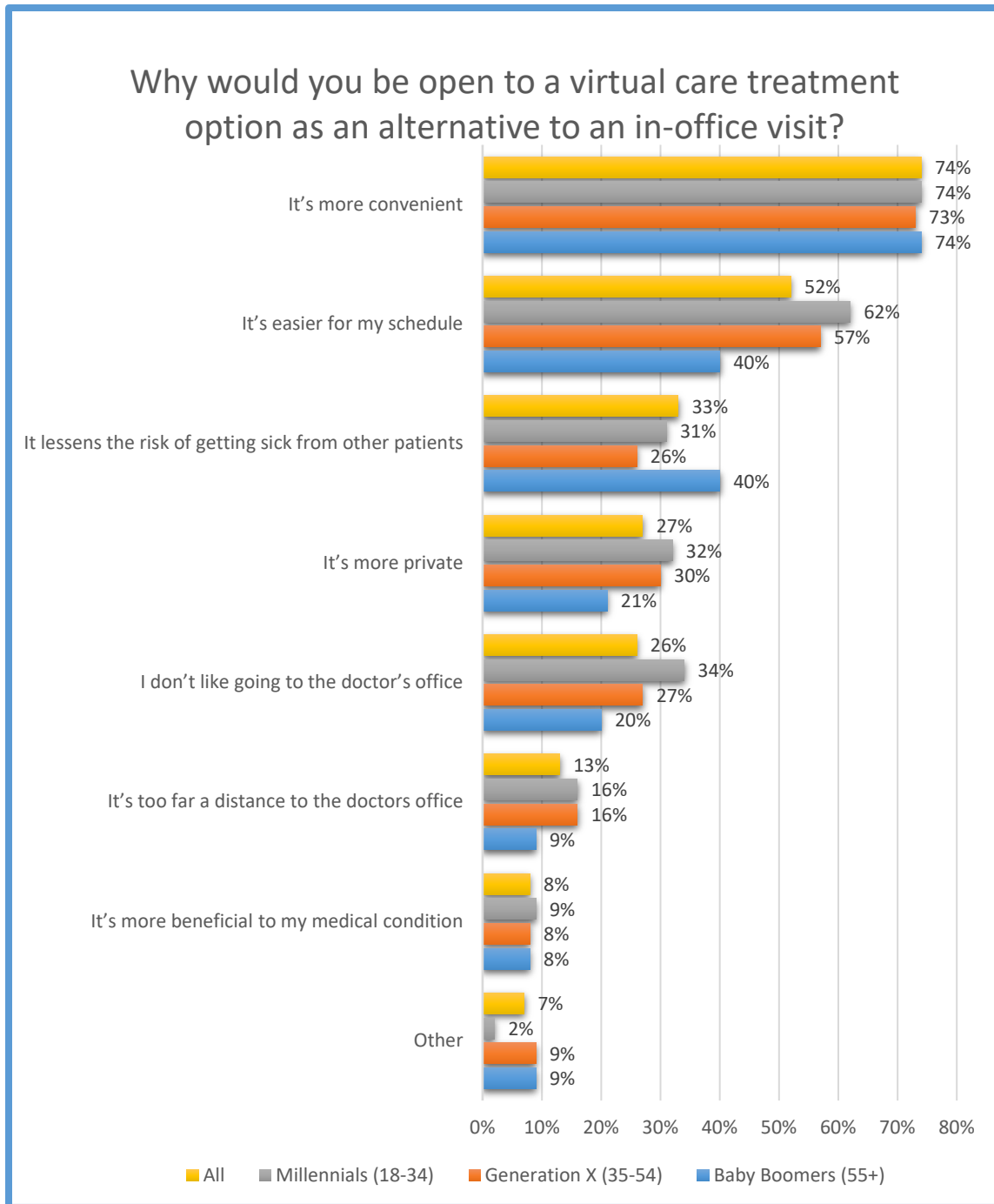
AHRQ noted a suggestion of value for specialist consultation and maternal/child health. It suggested more studies were needed to support triage for urgent care.

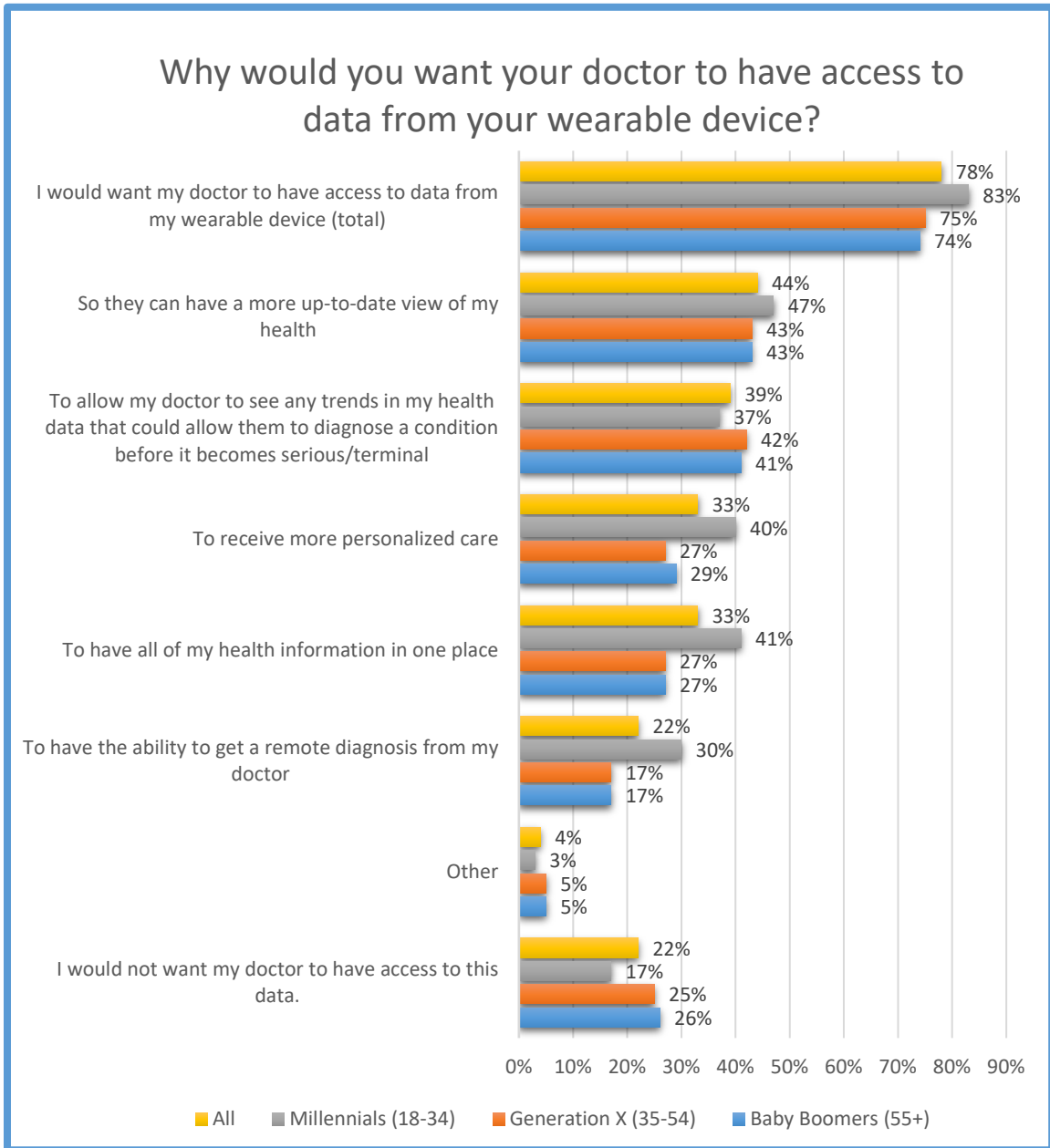
**Patient acceptance**

Surveys have shown patients are comfortable with sharing data with providers electronically and, increasingly, expecting that their providers will offer virtual care treatment options. Predictably, the willingness to engage in care at a distance is somewhat a factor of patient age. A few results from the 2016 Connected Patient Report sponsored by Salesforce Research and conducted by Harris Poll<sup>15</sup> follow:



<sup>15</sup> Salesforce Research, 2016 Connected Patient Report, <https://www.salesforce.com/company/news-press/press-releases/2016/06/160627/>.







## A Closer Look at Technology

The telegraph was used in the 1860s by the military to order medical supplies and transmit casualty lists. This was likely among the earliest uses of e-communication technology in healthcare. According to legend, Alexander Graham Bell's first phone call (in 1876) was for medical help after burning himself with acid.<sup>17</sup> (So, the first call was telemedicine!) In 1879, a doctor listened to the cough of an infant over the phone and reassured the grandmother that it was not croup (and declined a house call).<sup>18</sup>

For over 100 years, communication technology has been continuously re-shaping almost every aspect of human life. While safety and prudence make it appropriate for healthcare applications to lag behind the fastest innovators, medical practitioners today are energetically exploring new communication channels to improve access, efficiency, and quality of care – and to employ these benefits in the service of patients.

It took a while for physicians to adopt telephones, pagers, and faxes as essential tools. From the beginning, doctors recognized that telephones had the potential for both great benefits and great burdens, as well as some foreseeable hazards. A similar calculus applies to every new medical invention, whether it be EHRs, email, mobile devices, robotics, clinical decision support programs, or the latest advance in imaging or pharmacotherapy. This tension between enthusiasm and skepticism is currently being negotiated in the realm of telehealth. President Rutherford B. Hayes to Alexander Graham Bell in 1876 on viewing the telephone for the first time:

“That’s an amazing invention, but who would ever want to use one of them?”<sup>19</sup>

It is important that both patient and providers understand the capabilities and limitations of the platforms for electronic communication.

### Live, Real-Time (Synchronous) Audio/Video Recording

This can operate between high-end, institutional teleconferencing systems, desktop computers, laptops, tablets, or smartphones. All that’s needed are a camera, microphone, and conferencing software. It can be between two locations or multiple and often allows a recording to be made and screenshots to be taken. Typically, there is also a second channel for exchanging text messages or documents. Sharing of screens can allow real-time remote viewing of content from either device (such as X-rays, monitor strips, or images from attached cameras or instruments). The connections for all participants need to have enough speed and bandwidth to allow smooth

<sup>17</sup> Carr J and Sheikh A. 2003. Telephone consultations. *British Medical Journal*, 326:966-969.

<sup>18</sup> Eikelboom RH. 2012. The telegraph and the beginnings of telemedicine in Australia. In: *Global Telehealth*, AC Smith et al. (eds), IOS Press. This article is published online with Open Access by IOS Press and distributed under the terms of the Creative Commons Attribution Non-Commercial License. doi:10.3233/978-1-61499-152-6-67.

<sup>19</sup> Elon University School of Communications. *Imagining the Internet*. <http://www.elon.edu/e-web/predictions/150/1870.xhtml> [6/24/18]

transmission at acceptable screen resolutions. Videoconferencing is the platform classically associated with telemedicine. More sophisticated data streams, such as feeds from operating room or ICU equipment, are becoming increasingly available.

### **Store-and-Forward (Asynchronous) Audio/Video Recording**

The capabilities of this method are essentially the same as those of real-time systems; except data files are exchanged offline. This can allow transmission over slower connections or background exchange of large files (e.g., MRI, angiography). In principle, this is no different from transmitting any data file between systems.

The regulatory definition of telemedicine in most states (and Medicare) includes store-and-forward technology. In instances where asynchronous data is intended for remote clinical assessment, that activity may be deemed telemedicine, even if real-time communication with the patient is taking place only via telephone. Some states exclude this activity from their definitions of telemedicine, stating that simply receiving a file does not constitute a telemedicine encounter. However, if the information was expressly created for the purpose of assessment by a remote physician, the chances are that this activity could be construed as telemedicine.

### **Remote Monitoring**

Telemedicine includes interpretation of data transmitted from devices over networks (“connected devices”). Remote access capabilities are becoming incorporated into just about every piece of equipment used in healthcare, from physiologic monitors (glucose, BP, pulse oximetry, fetal heart rate, intracranial pressure, etc.) to endoscopes, imaging systems, lab equipment, security cameras, and, of course, anything stored in an EHR. Data feeds can originate outside healthcare facilities from smartphones (sometimes using attachments, but often using native functions) and wearable devices. Data may be received on practically any device with a display screen. Data are transmitted on myriad channels, including wired and wireless internet, cell networks, near-field wi-fi, Bluetooth, infrared, and others.

### **mHealth Applications**

The term “mHealth” originally referred to medically-related apps marketed to consumers for use on smartphones. In 2017, 50 percent of households had no landline telephone service; of the remaining half, 39 percent had both a cell phone and a landline.<sup>20</sup> In the decade from 2001 to 2010, society transformed from one where 13 percent of carried a mobile phone, to one where 70 percent carry one.<sup>21</sup> The human impact of this revolution has not been upon voice communication, but on the prevalence of social media and mobile software applications. Applications with both dubious and bona fide healthcare purposes now tally in the hundreds of thousands.<sup>22</sup> They range from exercise and sleep tracking to nutrition records, medication reminders, fertility advisors, and suicide risk calculators. This technology, which is not regulated by the FDA, presents opportunities for enormous potential benefits to patients (as well as mischief). It can be useful to think of many of these apps like “patient-generated data”

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<sup>20</sup> <https://www.theverge.com/2017/5/4/15544596/american-households-now-use-cellphones-more-than-landlines> [7/5/2018]

<sup>21</sup> <https://newatlas.com/mobile-phone-penetration/8831/> [7/5/2018]

<sup>22</sup> <https://research2guidance.com/325000-mobile-health-apps-available-in-2017/> [7/5/2018]

comparable to lists and logs that patients might keep on paper. Technical questions surround the quality of the device and the reliability of the programming and medical knowledge that power the application.

As previously mentioned, these categories do not represent all the technologies that patients and providers can use to exchange information. Similar technical, regulatory, and liability issues apply to channels like email, texting, portals, and social media that are not necessarily contemplated in current definitions of telemedicine. (It is actually a little artificial to separate them, because the technologies are the same for most purposes.)

For any platform or modality, providers are responsible for understanding, at least at a clinician level, how the technology works and how to operate it effectively. This is basically the same expectation as for any medical device, such as an EKG machine, ultrasound, or electrocautery. This doesn't mean being able to answer questions at a technician level, but it does imply for applications like EHRs, email, text messaging, etc., that professional users are demonstrably competent to run them.

On the patient side, there is also an obvious requirement that the technology be understood well enough to be properly used. This requirement can often be met by having a qualified assistant on the patient end of the system. When success depends on data entry by patients or third parties, human factors need to be taken into account.

For clinicians, an important factor is the reliability and limitations of the information being transmitted. For instance:

- How accurate is the blood pressure monitor? What is the resolution of the cellphone image of a skin lesion? (Actually, this could be better than direct, human vision.)
- How reliable is a home cardiac rhythm monitor?
- Does the webcam show a clear enough view of the patient to detect a slight facial droop?
- What factors might cause alteration or degradation of the transmitted data?
- Is the algorithm used by the patient's diabetes advisor based on current guidelines?

These are the kinds of questions that might be asked in a legal deposition.

While a few systems (like lab equipment and medical imaging viewers) are subject to FDA standards, most conferencing platforms are consumer quality. Networks notoriously vary in speed and bandwidth. Transmission quality is subject to environmental variables like data load and weather. Device failures and data interruptions are normal events.

For unregulated applications, the phrase, "Wild West" should be kept in mind. There is certainly no doubt about the potential usefulness of connecting patients (and their physiology) to doctors electronically. However, analogous to caring for patients who take unregulated nutritional supplements or who use alternative medicine, providers have an obligation either to become familiar with the specific apps in question or to exercise due diligence in relying on them for medical decision-making or treatment. It is likely that consumer-managed health applications will increasingly become certified by trusted organizations, and supplied by trusted vendors.

When looking at adverse events related to electronic communications, technical risk management questions fall into four general categories: machine, mode, message, and medium. See the following:

## Technical Risk Management

- 1. What is the Machine (device)?**  
Dedicated studio? Special sensors? Imaging device? Laptop, tablet, phone?  
Video resolution? Audio quality? Recording?
  
- 2. What is the Mode (synchronous/asynchronous)?**  
Talking in real-time or using a store-and-forward process?
  
- 3. What is the Message (content)?**  
PHI? Confidential non-PHI? Medical advice?  
General information? Advertising? Digital stream?  
HL7 file? DICOM file?
  
- 4. What is the Medium (technical channel)?**  
Wired? Wireless? Cell? Consumer platform (e.g., Skype®?) Texting?

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Addressing each of these in the planning stages for each telemedical service will help reduce the need to address them in a failure mode analysis.

A particular consideration for non-face-to-face medicine might be called attenuation. There are collateral signals present in the room during an in-person visit that may be lost through a video viewing window. This can make the exchange more transactional and less interactive. Some positive benefits of transactional communication are that it may make it easier to:

- Remain focused on specific goals and tasks
- Direct the discussion according to the needs of the provider (or even shut it off abruptly)
- Cut off threads that aren't goal-directed
- Manage time

Some negative aspects of trading transactions for interactions are that:

- Tightly-managed dialog often gives patients the feeling of being rushed, not fully heard
- It can sacrifice the high value of silence
- It can preempt the surfacing of ideas that are not yet fully articulated

- It can lose the opportunity for the well-recognized phenomenon of the “by-the-way” moment at the doorway that reveals critical information

The differences in subliminal and non-verbal communication between in-person and virtual visits are not completely understood, and likely depend on technical variables like sound and video quality and viewing distance. These nuances become appreciated with experience, and good tele-providers accommodate for them.

The question often arises asking whether especially secure, encrypted channels are mandatory for telemedical communication. The answer is technically complex. Encryption is not strictly mandatory under HIPAA. The situation faced by providers is that, in the face of an actual breach, or even a complaint or inquiry about a potential unauthorized disclosure, the investigating agency will *retrospectively* ask, “Could this have been prevented if a better level of security had been used?” The answer will almost always be, “Yes.” In that case, the event may be viewed as a violation. The good news is that security has been a paramount concern for teleconferencing and health information technology vendors for a decade, and many applications that were originally distributed with almost no protection now use the same safeguards as “secure” applications. The bad news is that installing and configuring applications may require some technical expertise, for which the provider is responsible.

From a strictly technical standpoint, the responsibilities of telemedical practitioners pertain to:

- Appropriate selection, installation, and maintenance of equipment and software
- Training users in safe and effective operation
- Protecting and securing infrastructure from natural and human hazards
- Assuring confidentiality, integrity, and availability of systems and information
- Assuring that information from telemedical transactions is linked to the patient record in a timely way, labeled with valid metadata, securely stored and backed up, monitored for loss and alteration, and available for production when required by other providers or legal authorities
- Data and technology governance; storage/hosting, security, retention/production, access/provisioning and de-provisioning of credentials, disaster plan, backup, recovery, alternative modes during downtime, upgrades, migration, deprecation
- Having appropriate fallback strategies for unplanned events

## PART TWO

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### A Closer Look at Law and Regulation

It is important to understand the thinking behind the regulatory and liability frameworks that surround telemedicine. This makes compliance more than merely obedience; it becomes a matter of good practice.

For most legal purposes, the practice of medicine is held to occur at the location of the patient. State medical boards are charged with protecting their citizens from malpractice, fraud, and quackery. Their dilemma for telemedicine is that they have no jurisdiction over the license or performance of a doctor located in another state. Discussion has been ongoing for decades about national licensure, reciprocity/portability agreements, limited telemedicine licenses, and uniform standards. So far, states have tended to protect their autonomy, with considerable variation in laws and regulations.

However, in 2014 the Federation of State Medical Boards (FSMB) published a Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine (a copy of this can be found at [www.svmic.com](http://www.svmic.com)). Many states have incorporated principles from this model in their own regulations. Typical provisions include:

- Definition of telemedicine
- How a physician-patient relationship is established
- Licensure requirements
- Documentation requirements
- Informed consent requirements
- Prescription of medications
- Parity of professional and ethical standards for in-person and online services

A summary of general telemedicine concepts and terms, practice considerations, and summaries of telemedicine regulations in the states of Arkansas, Kentucky, and Tennessee can be found at [www.svmic.com](http://www.svmic.com).

### State Definitions of Telemedicine

As previously mentioned, each state can define what it considers to be telemedicine. It is very important for practitioners to understand what this means in any state where they will be interacting with patients at a distance. This includes communications within their own state borders, and especially communications across state lines. Violating state laws may entail administrative or criminal penalties, including the risk of practicing medicine without a license.

**Tennessee**

Telemedicine is the practice of medicine using electronic communication, information technology, or other means, between a licensee in one location and a patient in another location. Telemedicine is not an audio-only telephone conversation, email/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store-and-forward to provide or support healthcare delivery by replicating the interaction of a traditional encounter between a provider and a patient. [Tenn. Comp. R. & Regs. 0880-02-.16 (effective Oct. 31, 2016).]

**Arkansas**

Telemedicine means the use of electronic information and communication technology to deliver healthcare services, including without limitation the assessment, diagnosis, consultation, treatment, education, care management, and self-management of a patient. Telemedicine includes store-and-forward technology and remote patient monitoring. For the purposes of this subchapter, "telemedicine" does not include the use of: (i) Audio-only communication, including without limitation interactive audio; (ii) facsimile machine; (iii) Text messaging; or (iv) Electronic mail systems. [A.C.A. § 23-79-1601.]

**Kentucky**

Telehealth is the delivery of healthcare-related services by a healthcare provider who is licensed in Kentucky to a patient or client through a face-to-face encounter with access to real-time interactive audio and video technology or store-and-forward services that are provided via asynchronous technologies as the standard practice of care where images are sent to a specialist for evaluation. The requirement for a face-to-face encounter shall be satisfied with the use of asynchronous telecommunications technologies in which the healthcare provider has access to the patient's or client's medical history prior to the telehealth encounter.

As mentioned previously, video conferences between a doctor and a patient (for clinical purposes) will fit the definition of telemedicine in most jurisdictions.

**Establishing a Physician-Patient Relationship**

For many legal purposes, it is critical to know whether a bona fide provider-patient relationship existed at the time of a given event. This relationship entails specific duties and accountability. Most authorities are clear that telemedical activity, including consultation, diagnosis, treatment, or rendering advice, occurs in the context of a professional relationship that falls under the applicable rules and standards for the practice of medicine. However, states differ about whether the patient-provider relationship can be established for the first time via telemedicine without a prior in-person visit. In Arkansas, for example, a patient must be seen in the office, subject to some exceptions, prior to the establishment of a relationship by telemedicine.<sup>23</sup> In Tennessee, for

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<sup>23</sup> Arkansas Code Annotated section 17-80-403 (2017) provides when "the establishment of the professional relationship is permitted via telemedicine[,] . . . telemedicine may be used to establish the professional relationship only for situations in which the standard of care does not require an in-person encounter." Arkansas State Medical Board Regulation No. 2.8 (cross-

example, this is not a requirement. In Kentucky, the relationship is “clearly established when the physician agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an encounter in person between the physician . . . and patient.” The physician-patient relationship may be established using telemedicine.

In general, if a provider provides services that meet the definition of telemedicine, that may be enough to create a patient-provider relationship. Neither express, written consent nor an agreement about payment are requirements for establishing a professional relationship, and the duties that come with it.

## Additional Requirements

### Licensure Requirements

The default position is that a provider is fully licensed to practice medicine in the state where the patient is located at the time of the encounter. (Federally licensed physicians who exclusively treat federal beneficiaries may be exempt from this requirement.) Some states have issued special, limited licenses for telemedicine or expedited credentialing for telemedicine practice. (Tennessee issued a number of limited telemedicine licenses which it will continue to honor—without prescribing privileges—but has frozen this program.)<sup>24</sup>

The Interstate Medical Licensure Compact (IMLC) an agreement between 29 states, the District of Columbia and the Territory of Guam, where physicians are licensed by 43 different Medical and Osteopathic Boards. Under this agreement, licensed physicians can qualify to practice medicine across state lines within the IMLC if they meet the agreed upon eligibility requirements.<sup>25</sup>

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referenced in Regulation No. 38) requires, in the telemedicine context, in order to establish a patient-physician relationship, that the “physician performs a face to face examination using real time audio and visual telemedicine technology that provides information at least equal to such information as would have been obtained by an in-person examination.”

Full text of Kentucky Board of medical licensure’s Board Opinion Regarding the Use of Telemedicine Technologies:

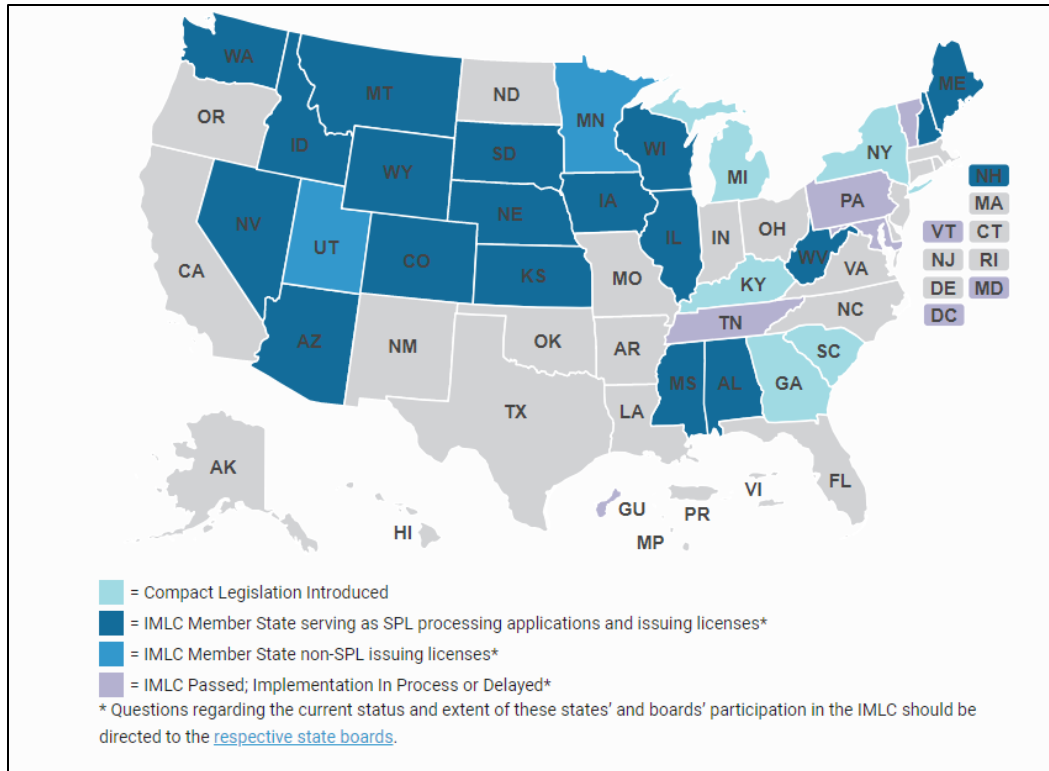
<https://kbml.ky.gov/board/Documents/Board%20Opinion%20regarding%20The%20Use%20of%20Telemedicine%20Technologies%20in%20the%20Practice%20of%20Medicine.pdf>.

Full text of Senate Bill No. 112: <http://apps.sos.ky.gov/Executive/Journal/execjournalimages/2018-Reg-SB-0112-2550.pdf>.

<sup>24</sup> [https://www.tn.gov/content/dam/tn/health/documents/Telemedicine\\_FAQs.pdf](https://www.tn.gov/content/dam/tn/health/documents/Telemedicine_FAQs.pdf)

<sup>25</sup> <https://imlcc.org/>, accessed 3/31/2020





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## Credentialing Requirements

Apart from licensure, medical practitioners are also subject to credentialing and privileging requirements in facilities where they work, in groups that employ them and sometimes by payers who reimburse them. Obtaining and maintaining credentials can be more rigorous than licensing. In addition, many facilities and groups enforce privileging requirements to perform specific procedures. All of these are considerations for telemedical practice.

## Documentation Requirements

Some states require specific items be documented in a telemedicine encounter; for example, Tennessee requires that the type of technology utilized for the encounter must be specified in the encounter note. Since any later question or dispute about the course or outcome of treatment would involve determining the setting of the encounter, it should almost go without saying that the record ought to include:

- Identification of all individuals participating, including scribes, assistants, technicians, interpreters, family members, etc.
- The geographic location of each participant
- The technology employed, including the communication medium

- Any sources of information used apart from audiovisual channels, such as devices, monitors, records exchanged, images reviewed, etc.
- Any unexpected occurrences or technology failures

In addition, when recordings are created or external data are received, it is essential to incorporate them into the permanent record.

Finally, while documenting follow-up plans and recommendations is an expected part of good practice in any context, it is especially important for telemedicine encounters. Treatment at a distance requires particular attention to handoffs, transitions, and continuity of care.

### **Informed Consent Requirements**

Some states have specific informed consent requirements including disclosures of risks specifically associated with telemedicine, such as equipment failure or privacy breach. Consideration should also be given to what technology will be used to record the patient's agreement. Providers should offer details about risks of diagnosis and treatment via electronic media. Many states require documentation of the virtual platform utilized in the visit (i.e., Zoom, Skype, other encrypted and non-public facing mode).

### **Prescription of Medications**

Prescribing laws and rules have a special status within the regulation of medical practice. These vary greatly among the states and may have provisions that differ by drug, specialty, and setting. It is essential that practitioners who intend to prescribe or dispense drugs for patients who are not seen in person—whether in-state or out-of-state—fully inform themselves of the applicable rules. Particularly for controlled substances, there may be specific restrictions for initial prescriptions or managing prescriptions by telemedicine. The high level of legal attention being focused on fraud, abuse, diversion, and inappropriate prescribing of scheduled drugs, combined with a perception that electronic communication may facilitate these risks, makes this an area of particular peril for careless practitioners.

### **Self-Referral**

The **Stark law**<sup>26</sup> and the **anti-kickback statute**<sup>27</sup> apply to telemedicine just as they do in in-person care. Several Office of the Inspector General (OIG) opinions deal explicitly with telemedical arrangements (e.g. [11-12](#), [99-14](#), and [02-12](#)), and these should be reviewed if, for example, a hospital wishes to provide a physician with some of the equipment needed to perform distance care services.

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<sup>26</sup> 42 U.S.C. § 1395nn - Limitation on certain physician referrals

<sup>27</sup> 42 U.S. Code § 1320a-7b - Criminal penalties for acts involving Federal healthcare programs

## Parity of Professional and Ethical Standards for In-Person and Online Services

States that have adopted the FSMB Model Policy generally share the consensus that the standard of care for physicians is the same for telemedicine as for practice in person. This includes adherence to national and international codes of ethics and quality standards applicable to each specialty.

A physician's professional discretion as to the diagnoses, scope of care, or treatment should not be limited or influenced by non-clinical considerations of telemedicine technologies, and physician remuneration or treatment recommendations should not be materially based on the delivery of patient-desired outcomes (i.e. a prescription or referral) or the utilization of telemedicine technologies.<sup>28</sup>

However, some states impose ethical requirements on telemedicine above what they require for in-person visits. For example, Tennessee (among others), stipulates that a facilitator must be present for telemedicine visits with individuals under the age of 18.

## A Closer Look at Liability

Malpractice is generally defined as the failure to exercise the degree of reasonable care, skill, and diligence as would ordinarily be exercised by a similarly situated healthcare provider for a similar patient under the same or similar circumstances. The defense generally depends on showing that the provider's actions fell within the range of an acceptable standard of care.

So far, there are relatively few reports of medical malpractice cases related to telemedicine. This is somewhat a matter of volume, but is also the case because the early adopters of telemedicine have been, for the most part, conservative regarding the kinds of cases they consider appropriate for remote management. Careful fallback and backup options have been built into most published trials. Screening out high-risk patients tends to limit the severity of injuries that might result from e-misadventures. Lower severity claims may skew obtainable data by excluding unreported settlements. Moreover, higher-risk patients tend to be managed by high-capability systems, with detailed guidelines and documentation. These and other factors bias the outcome data from telemedical practices in a positive direction and may limit the visibility of adverse occurrences.

Misdiagnosis and treatment failures in telemedicine are currently thought to be comparable to rates for traditional office visits. One study found a higher rate of antibiotic prescribing (for

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<sup>28</sup> Federation of State Medical Boards. 2014. Model policy for the appropriate use of telemedicine technologies in the practice of medicine. Report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup. Adopted as policy by the Federation of State Medical Boards in April, 2014.

sinusitis) in e-visits than office visits and a lower rate of urinalysis (for UTI).<sup>29</sup> Like outcome data in any ambulatory setting, it is difficult to know what findings can be generalized.

The Medical Professional Liability Association (MPL) compared *telephone* treatment claims versus overall malpractice experience.<sup>30</sup>

- Of 94,228 total claims in its database from 2004-2013, only 196 were associated with telephone treatment
- Of those claims, 56 resulted in some form of payment
- Telephone treatment claims thus represented 0.21 percent of all indemnity costs

Note that this data is for telephone-related events. Data are currently being collected for telemedicine; however, the problems of definition previously discussed make interpretation difficult. The highest-level summary of the liability issue boils down to two opposite edges of the same sword:

- For some conditions, the benefits to patients of availability, access to higher levels of expertise and other advantages outweigh the potential limitations of the modality
- For some conditions, the risks of remote treatment outweigh the advantages

Liability allegations arising from telemedicine are largely going to be the same as the common exposures for each specialty. In general, the principle of “parity” means that the same standards for acceptable practice apply to virtual visits that would apply in-person. However, there are some twists that need to be considered when treating patients at a distance. Many are related to the functions of technology; some arise from opportunities for human error and mischief provided by technology. These fall into technical, administrative, and clinical categories.

### **Jurisdiction**

Most civil claims for negligence associated with telemedical practice are going to begin by determining (or contesting) what jurisdiction governs the action. As previously mentioned, the *sine qua non* of telemedicine is licensure where the patient is located.

### **Qualifications**

There is clear liability risk for practitioners who fail to maintain proper licensure and credentials, or who misrepresent these to patients or authorities.

### **Failure to Examine**

One theory of negligence telemedicine practitioners need to keep at the forefront of their thinking is the allegation of failing to perform an adequate examination. This issue is often raised for in-person encounters where something has been missed, and it is an obvious vulnerability for

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<sup>29</sup> Mehrotra A, Paone S and Martich D. 2013. A comparison of care at e-visits and physician office visits for sinusitis and urinary tract infection. *JAMA Intern Med* 173:72-74.

<sup>30</sup> Medical Professional Liability Association. Telemedicine and MPL: The story so far. <https://www.mplassociation.org/>

telemedicine. It is important to document the findings available from the channels in use that support each clinical assessment and to be ready to terminate a session—and redirect it to an in-person provider—when a clinical question can't be resolved using remote technology.

### **Failure to Disclose**

For any emerging modality, a bit of extra care is called for in the informed consent process. Providers should offer details about risks of diagnosis and treatment via electronic media to help forestall misunderstandings about what is to be expected. One particular risk that might be important to mention is that of needing to switch from telemedical mode to in-person mode. It should be clear that this decision is a matter of provider judgment (This is analogous to the risk of converting a laparoscopic procedure to an open one). The telemedical practitioner should be prepared with a response if the patient is reluctant to follow medical advice, and prepared with a plan, if a fallback contingency becomes necessary.

### **Confusion with Social Media**

A growing liability risk for healthcare providers comes with their own and their patients' participation in social media, such as Facebook®, Twitter®, Instagram®, Sermo®, etc. These platforms invite privacy, security, and boundary violations not only by providers, but also by staff and even family members. Since patients probably use the same devices to engage with their doctors that they use to engage with online friends (and antagonists), it would be natural to expect them to transfer communication habits from the more informal settings to the more formal. Providers need to be conscientious about professionalism, keeping the content, style, and culture prevalent in today's social media carefully firewalled outside their encounters with patients. Providers and their staff need to learn how to maintain professional demeanor and accountable practices even when challenged by patients who don't exhibit the same values. It is important to remember that records are almost always retrievable from online systems, and may become evidence in legal proceedings.

### **Failure to Document**

Inadequate documentation is not often raised as a plaintiff allegation, but it frequently becomes an issue for the defense. The convenience of real-time recordings of telemedical encounters is definitely two-edged; but, failing to record, not linking to the patient record or not preserving a usable account of the clinician's findings and thought process can still be an issue.

### **Misidentification**

While impersonation and identity theft can certainly be threats in the traditional office environment, the electronic environment makes these higher risks. It is important to have ways to verify the identity of persons with whom electronic transactions are being conducted. One practice, where policy requires an in-person visit before patients are eligible for telemedical treatment, is to capture a photo ID. This obviously isn't fail-proof and doesn't help much when initial contact is online. Of course, inadvertent misidentification and misrouting of patients, records, prescriptions, results, and messages through multiple error pathways remains an ever-present concern.

## **Confidentiality**

The extensive thought that covered entities are required to put into protecting health information needs to be applied to real-time and stored data from telemedical encounters. Privacy and security policies should address these in some detail, and patients should be provided with them. There are no special HIPAA concerns about telemedicine beyond those that apply to in-person care. The exceptions for “treatment, payment, and healthcare operations” apply. It is important to comply with special provisions that apply to behavioral health information.

## **Scope of Practice**

Another allegation that can arise in any patient encounter is practicing outside the scope of one’s training, experience, or authority. Practitioners (including physicians, advanced practice providers, nurses, and assistants) need to stay aware of the boundaries of their skills in the telemedicine setting, just as they do in the in-person setting. There is something about electronic communication that loosens inhibitions. It is important to know when to fold up the encounter and move to another venue, even when the impulse on both sides might be to press on with the wrong plan.

## **Failure to Use the Necessary Technology**

This allegation could arise: if some piece of equipment was not functioning quite right, if a superior diagnostic or treatment modality was potentially available but not employed or (as in the case of failure to examine) if a proper decision process required another venue or more help. Ironically, this allegation might apply to a case where a practice had telemedicine technology available, but used a less robust medium to manage a clinical problem that would have turned out differently if broadband communication had been used.

## **Guidelines**

Liability claims often invoke guidelines and standards, both on the plaintiff and defense side. It is essential that telemedicine practitioners remain well-versed in the (frequently changing) published guidance from relevant agencies and authorities.

## **Reliance**

In general, a physician who requests consultation from a colleague is allowed to rely on the advice rendered, with conditions. In one’s own state, this allows each doctor to assume the other is licensed and credentialed. When referral is made to, or consultation sought from an unknown expert, some diligence should be given to verifying these things; this duty can reasonably be satisfied by using reputable services. However, just as in face-to-face consulting, the requesting physician is responsible for choosing a proper source of advice and implementing recommendations appropriately. This implies that the requesting provider interpose professional judgment and is not immune from liability for negligent referral.

## **E-Discovery**

Since the medium in which telemedicine is transacted is electronic, providers should be prepared to produce electronic files in response to legal subpoenas and court orders, just as they

do for EHRs. In fact, telemedical platforms are essentially EHRs, if not actually embedded in them. Just as EHR files include metadata with time stamps and detailed logs identifying users and every kind of interaction they have with the system, telemedical files should be the same. However, the difference between most EHR content and telemedicine records is that the latter very likely include full motion audio and video of the entire encounter. The situation amounts to what a bank teller knows: Every action they take during their workday is available to an investigator on tape. This potential for public disclosure is a new culture for practitioners to deal with. It contrasts sharply with the old culture of privacy in the examining room and has far-reaching implications for how doctors and patients relate to each other.

### **Limits of Insurance Coverage**

Traditional professional liability (malpractice) insurance covers most usual allegations of medical negligence in standard settings, but it may explicitly exclude from coverage, or require additional riders to cover claims arising from telemedicine. It is critical for practitioners who plan to treat patients at a distance review their insurance policies.

### **Opting Out**

It should be clear to patients that they have the right to opt out of telemedical care, just as they have the right to decline other modalities.

### **Abandonment**

A part of the disclosure and agreement process with telemedicine patients should be some notice that access to telemedicine modalities is not necessarily guaranteed.

### **Referrals, Handoffs, and Transitions**

Providers tend to be acquainted with local specialists, pharmacies, and hospitals, as well as geographic factors that weigh on recommendations about referrals and transitions. Making poor referrals, or failing to make good ones, can create liability. Caring for patients in other cities, states, or countries means additional effort must be put into helping patients find appropriate services and resources in their own locales.

### **Technical Responsibilities**

Negligence can be alleged in connection with the selection, configuration, maintenance, and support of telemedical infrastructure. One risk unique to telemedicine is breaking the connection. Prior to an encounter, participants should understand what to do in the event of a disruption in service. Imagine if, as it becomes increasingly apparent that a patient needs urgent in-person care, the line goes dead. Protecting the system from hackers, malware, and other cyber threats is just as much a part of providing a safe environment as clearing ice from the parking lot.

### **Administrative Responsibilities**

Negligence can be alleged in connection with organizational policies, hiring and training of employees, use of outside contractors, security and privacy events, disaster response, and other matters related to the governance of systems.

## Ethical Issues

There are few ethical issues unique to telemedicine. The AMA addresses telemedicine in its Code of Medical Ethics, but finds nothing novel.<sup>31</sup> There are well-understood analogies to draw upon from a deep well of modern bioethical thinking.

Most commentary available to practitioners on telemedicine ethics offers sensible, but nearly self-evident advice about issues mentioned prior, such as assuring security, privacy, and technical quality, verifying the identities of participants, documenting adequately, and using good judgment about which conditions are amenable to telemedical management. While these are all ethical duties, they are qualitatively no different from the corresponding responsibilities in conventional medicine. Some authors suggest managing and disclosing substantive financial conflicts of interest, which, again, are duties that apply in all medical settings.

To the extent that there might be a controversy to deal with in telemedicine ethics, it would be whether or not telemedicine should be approached more as an investigational treatment, or simply standard treatment delivered in an innovative format. If telemedicine is actually investigational, then it calls for a full portfolio of special duties and protections that clinical researchers are familiar with. These include approval and oversight by Institutional Review Boards, rigorous data collection, and transparency processes, and most of all, compliance with intricate human subjects regulations, which are even more byzantine when minors are involved.

Some commentators say telemedicine imposes a duty on practitioners to include additional elements in their disclosures to patients, such as details about how the technology works, specific ways it can fail, and financial relationships specifically relevant to telemedicine. This perspective is problematic, because it neither fully asserts that telemedicine (taken as a whole) *is* investigational, nor explains—if it is *not* investigational—why it ought to recognize some research on human subjects regulations and not others.

There are important implications of the suggestion that telemedicine patients need to be informed about details of technical and environmental risks that are not normally addressed in standard care. By extension, this principle could be understood to mean rural practitioners should disclose risks inherent in geography. It might require obstetricians (or residents) seeing patients after a night on call to warn that their performance might be impaired. It might imply that specialists in smaller hospitals should urge their patients to go to facilities outfitted to manage extremely rare complications of common procedures.

While these risks and limitations are absolutely real, there has traditionally been no requirement to highlight them in the usual course of care. Most patients are not routinely asked to acknowledge that:

- The lab might contaminate their specimens
- Surgical sterilizers sometimes malfunction

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<sup>31</sup> American Medical Association, Code of Medical Ethics Opinion 1.2.12, <https://www.ama-assn.org/delivering-care/ethical-practice-telemedicine> [7/19/18]



- Drug addicted nurses sometimes dilute the narcotics
- Hackers might steal their credit card data

It might be worthwhile disclosing some general terms that make a telemedicine encounter different from face-to-face, like the possibility that the provider may not be able to complete the session remotely; but, the tendency should strongly be avoided to create legalistic Terms of Use for telemedicine that resemble those for software and other online services, which are deservingly derided (and never read) because of their absurd lack of usability.

The fundamental principle of medical ethics is that there is a fiduciary relationship between the doctor and patient. Nothing in telemedicine changes that a bit.

## A Quick Look at Payment

This material is not designed as a guide to reimbursement strategies. The multiplicity of payers and policies and their rapidly-changing nature makes that almost impossible to do in this format. Unquestionably, the future of telemedicine depends on the way services are valued and compensated within the totality of the healthcare economy. The following discussion has the limited goal of providing a general orientation to the issues surrounding payment, at the time of writing.

The payment landscape for telemedicine today is largely unsettled. A number of fast growing services have built their businesses entirely on direct patient payment or subscription models. Some self-insured employers were early adopters of telehealth benefits for their employees and provided telehealth coverage in conjunction with select providers. Some offered a single, per visit fee, and some created more complex tables of services and payments, including patient incentives in the form of reduced co-payments.

While a large number of private payers have implemented or are considering implementing payment mechanisms for telemedicine under many different models, the example of Medicare serves to illustrate some of the variables in play.

Under Medicare rules, telemedicine is eligible for reimbursement if it is provided at a “qualified site” where the patient is located. State Medicaid programs tend to follow this guideline, and additionally recognize (or don't recognize) telemedicine services in a myriad of ways.

### Medicare

Medicare covers telemedicine visits under limited circumstances. The beneficiary must reside in a health professional shortage area (HPSA) or outside of a metropolitan statistical area. CMS frequently changes its coverage policies. Providers need to study and frequently update their knowledge of telemedicine coding and reimbursement.<sup>32</sup>

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<sup>32</sup> <http://www.cchpca.org/telehealth-and-medicare> [7/16/18]

Medicare reimburses only for specific services when they are delivered via live video. Store-and-forward services are not eligible, except for CMS demonstration programs in Alaska and Hawaii. Medicare does not reimburse for remote patient monitoring services.

The specific telehealth services eligible for reimbursement under Medicare are identified by Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes. Each year, the US Department of Health and Human Services considers submissions for new telehealth-delivered services to be approved. CMS maintains a list of current CPT codes eligible for Medicare reimbursement for CY 2018.

Medicare limits the types of professionals who can provide telehealth-delivered services to:

- Physicians
- Nurse practitioners
- Physician assistants
- Nurse midwives
- Clinical nurse specialists
- Clinical psychologists and clinical social workers (these professionals cannot bill for psychotherapy services that include medical evaluation and management services)
- Registered dietitians or nutrition professionals

The patient's location at the time of service is known as the originating site. Medicare treats telehealth almost exclusively as a tool for rural areas, and narrowly restricts the geographic areas eligible to use it. The originating site must be in an HPSA as defined by Health Resources and Services Administration (HRSA), or in a county that is outside of any Metropolitan Statistical Area (MSA) as defined by the US Census Bureau.

## Facilities

In addition to the rural restriction, Medicare limits originating sites eligible for telehealth-delivered services to the following facilities:

- Provider offices
- Hospitals
- Critical access hospitals
- Rural health clinics
- Federally-qualified health centers
- Skilled nursing facilities
- Community mental health centers
- Hospital-based or critical access hospital-based renal dialysis centers

## Chronic Care Management and Remote Monitoring

In 2015, CMS created a new chronic care management (CCM) code, which provides for non-face-to-face consultation. This made reimbursement possible for virtual asynchronous remote monitoring of chronic conditions. Since then, CMS has released several instructional documents on billing the CCM codes and added reimbursement for complex CCM, as well as two add-on codes. Additionally, in the 2018 Physician Fee Schedule, CMS unbundled code allowing providers to get reimbursed separately for time spent on collection and interpretation of health data generated remotely. By not defining these codes as telehealth services, they are not subject to the restrictions other telehealth services currently face, such as geographic and location limitations and prohibitions on the use of asynchronous technology in most cases. For more information, see CMS' [CY 2018 Physician Fee Schedule](#), [FAQs on CCM](#), and [other resources](#) on the new codes.

## Medicare Advantage, APMs, and ACOs

Medicare offers some exceptions to its geographic and originating site requirements through special programs, including the Next Generation ACO, Shared Savings Program, Episode Payment Models, and Comprehensive Care for Joint Replacement Models. Factsheets are available on many of these models on under [CCHP's Resources tab](#). Medicare Advantage Plans may also offer telehealth as a supplemental benefit; however, patients who elect to receive the benefit may pay for it with higher premiums, additional co-pays, or from plan rebates.

## MIPS

Telemedicine is one of the options available for meeting the clinical improvement activity requirement in the CMS Merit-based Incentive Payment System (MIPS).

## Parity Laws for Commercial Insurers

According to a November 2016 NBC Nightly News report<sup>33</sup>, over 30 states had adopted some form of telemedicine payment parity law. These require commercial insurers to cover certain telemedicine visits that are comparable to the level of service as an office visit.

## Conclusion

Healthcare is communication. Telemedicine, or telehealth, is just a logical extension of the electronic network that has become pervasive throughout the world. In its early days, the idea of a "TV doctor" was a novelty, and regulators and payers struggled to differentiate television

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<sup>33</sup> NBC Nightly News, Growing U.S. Telemedicine Market Raises Questions About Cost (Nov. 24, 2016), <https://www.nbcnews.com/nightly-news/video/growing-u-s-telemedicine-market-raises-questions-about-cost-817215043553>.

medicine from the "regular" kind and build standards for it. This narrow view utterly failed to anticipate the explosion of applications that have erupted from a pool of creative developers and the speed of their adoption.

Law always lags technology. Once again, we are dealing with regulatory mechanisms and rules meticulously negotiated to solve problems that society has already progressed beyond. Luckily, healthcare is notoriously slow at incorporating new inventions into its routines. As we think collectively about the implications of merging e-communication into the medical workflow, we will need to adapt technical, legal, and administrative processes to deal with the benefits and hazards this will bring. We probably have roughly one generation before it's an entirely new game.