

CARE IN THE TIME OF COVID:
HOW THE PANDEMIC HAS MOVED
TELEMEDICINE FORWARD

STATE BAR OF MICHIGAN HEALTH CARE LAW SECTION

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I. Introduction

Since the early 2000s, many parts of our lives have steadily migrated to online platforms. Many of us grocery shop, bank, read, and communicate with friends and family through our phones, computers, and other devices. To realize how reliant you are on technology, all you need to do is try leaving your house without your smart phone for one hour. Suddenly you are without the map, wallet, communication device and research tool you rely on to get you through your every day.

With minor exceptions, health care has remained resistant to this transition to the online world. The modality of in-person care—one where you drive to a doctor's office or hospital, sit in a waiting room after checking in with a receptionist, are then escorted back to your own room by a medical assistant, triaged by a nurse and then seen by a doctor—remains a very similar experience to one you would have had in the 1980s. We have some infiltration of technology, like electronic health records, but even that technology remains artificially constrained with information unable to flow between providers on different platforms.

The technology-barren island of health care has been surrounded by a heretofore impenetrable moat; that moat was dug by CMS and filled with reimbursement restrictions. As recently as January of 2020, a Medicare patient could not see their physician via telemedicine from their home. Such an encounter was not reimbursable. All patients, regardless of disability or social situation, were required to attend in person appointments at their physician's office, even if they had disabilities or social situations making this very difficult or impossible. Because much of our healthcare infrastructure is derivative of Medicare reimbursement policies, the infrastructure of health care remained static—large offices with large parking lots, high staff to physician ratio, and resources devoted to the needs of a predominantly in-person provided service.

Then, the pandemic hit, and one of the very first actions taken by the federal government was to drain the moat, and allow the forces of technology to assist in bringing medical care to patients in an environment where being in the same room with someone meant undue risk for those in the room and each person they each encountered thereafter.

Telemedicine, in a matter of weeks, became likely the predominant means of delivering outpatient care for the foreseeable future. With a vaccine for COVID-19 likely months or even years away, telemedicine is a modality of service delivery for which we will have a continuing need. Even when the dangers of this pandemic have faded, there are a myriad of reasons why telemedicine will persist. Virtual care can eliminate the fear of disease transmission, it can save patients time and gas, for providers it can even allow them to decrease overhead costs by reducing their space needs. While clearly all care cannot be done via telemedicine, there is a segment of patients and a distinct set of health problems for which telemedicine will offer the most efficient and satisfactory means of delivering care. It will not go away because patients will continue to demand that it be an option.

Telemedicine's explosive growth in response to the COVID-19 pandemic, however, was permitted by a series of temporary emergency restrictions at the federal and state levels—restrictions we

must assume will sunset or be removed as the immediate threat of COVID-19 wanes. What, then, are the structural changes to our legal framework that need to happen to allow telemedicine to take the position in our healthcare delivery system that it can and should occupy in the future?

II. CMS Changes

As previously mentioned, CMS is clearly the force that has constrained telemedicine in the past. Telemedicine billing under Medicare involves two different components: (1) an “originating site” which is the patient’s location, and (2) a “distant site” which is the location of the practitioner with whom the patient is connecting.

Pre-COVID, originating sites were very limited. With some exceptions for rural areas, if a Medicare patient wanted to see a physician via telemedicine, that patient would still need to travel to a healthcare facility to engage in that telemedicine visit. During the COVID-19 pandemic, CMS expanded allowable originating sites to basically anywhere the patient happened to be. A patient can be at home, in their car, wherever, and still receive reimbursable telemedicine services. While all logic points towards the idea that CMS should permanently adopt this expansion post-pandemic, a failure to do so would almost certainly entirely roll back the provision of telehealth services to Medicare beneficiaries.

Additional regulatory flexibilities include¹:

- The type of providers that can provide services via telehealth. From a restricted pre-COVID state, now any provider that is eligible to bill Medicare (physical therapists, occupational therapists, speech pathologists, physical assistants, nurse practitioners, physicians, etc.) may bill for telehealth.
- Expansion in the types of services that are reimbursable if provided via telehealth (now includes emergency department visits, observation, etc.).²
- Removal of requirement of physician to be licensed in the state where the patient is located; however, as discussed in the next section, CMS’s waiver of licensure requirements is not tantamount to a state’s waiver of such a requirement.
- Allowance for various forms of supervision to be performed via audio-visual connections.

Perhaps most significantly, CMS is temporarily allowing telemedicine to be reimbursable to a large extent in equal value to the same service performed in person. CMS explained in the Interim Final Rule that the standard method for reimbursing Telehealth pre-COVID was to pay on a split bill basis where the originating site receives the facility payment and the provider receives the provider fee (at the lower facility rate as opposed to an office rate); as CMS explained:

For Medicare telehealth services, we currently make payment to the billing physician or practitioner at the PFS (Physician Fee Schedule) facility rate since the facility costs (clinical staff, supplies, and equipment) associated with furnishing the service would

*generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site; and because the statute requires Medicare to pay an originating site facility fee to the site that hosts the patient.*³

In modifying this pursuant to its waiver authority, CMS explained:

*Under the waiver authority exercised by the Secretary in response to the PHE (Public Health Emergency) for the COVID-19 pandemic, Medicare telehealth services can be furnished to patients wherever they are located, including in the patient's home. As provided by the amendments to section 1135(b)(8) of the Act, when telehealth services are furnished under the waiver to beneficiaries located in places that are not identified as permissible originating sites in section 1834(m)(4)(C)(ii)(I) through (IX) of the Act, no originating site facility fee is paid. We also recognize that as physician practices suddenly transition a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID-19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in person. For example, we expect that physician offices will continue to employ nursing staff to engage with patients during telehealth visits or to coordinate pre- or post-visit care, regardless of whether or not the visit takes place in person, as it would have outside of the PHE for the COVID-19 pandemic, or through telehealth in the context of the PHE for the COVID-19 pandemic. Consequently, the assumptions that have supported payment of telehealth services at the PFS facility rate would not apply in many circumstances for services furnished during the PHE for the COVID-19 pandemic. Instead, we believe that, as more telehealth services are furnished to patients wherever they are located rather than in statutory originating sites, it would be appropriate to assume that the relative resource costs of services furnished through telehealth should be reflected in the payment to the furnishing physician or practitioner as if they furnished the services in person, and to assign the payment rate that ordinarily would have been paid under the PFS were the services furnished in-person.*⁴

In other words, CMS appears to be signaling that it understands providers cannot immediately modify their overhead and staffing structure in response to the pandemic, even though providers have had to flip their care model (i.e. in person to telehealth) in order to address patient needs. On the other hand, one could argue that between the line CMS is saying, if a provider's care model

stays predominately telehealth, there is an expectation that the provider's overhead will shrink in proportion to that shift. CMS further justified this change as follows:

Given the potential importance of using telehealth services as means of minimizing exposure risks for patients, practitioners, and the community at large, we believe this interim change will maintain overall relativity under the PFS for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth.⁵

While this is a tremendously significant temporary change, it begs the question as to what CMS will do when its waiver authority ends. The waiver will expire when the CMS declares that the emergency related to the pandemic has ended;⁶ however, this may or may not coincide with the end of the pandemic and need for social distancing.

Will CMS decide to abandon the originating site concept and pay providers on a *pari passu* basis for services rendered in person or via telehealth? Will CMS, consistent with the foundational assumption that providers operating via telehealth require fewer overhead expenses, continue to pay telehealth services at a lower rate, albeit with less of a “penalty” than existed before?

As most could not have predicted the situation we are in now, we cannot predict the future course of the pandemic, nor what that will require of our healthcare system and how CMS will respond. History generally tells us that, once adopted, technology is not readily abandoned. Telemedicine has arrived, and it appears that patients and providers will not allow it to go away. If CMS adheres to its theory that providers who furnish services via telehealth require less overhead, one would hope that it will afford our healthcare institutions ample time to adjust their operations to achieve the leanness necessary to make care delivery, both in-person and via telehealth, financially sustainable despite decreased reimbursement. Healthcare providers cannot immediately make the changes necessary to decrease overhead—moving to smaller offices, reducing office staff—and unless CMS gives providers enough runway to make these changes, our already stressed healthcare system will be pushed even further to the edge.

III. State Licensure Restrictions

In its waivers for the pandemic, CMS no longer requires providers to be licensed in the state where he or she is providing care, as long as certain other requirements are satisfied.⁷ This has created significant confusion for providers. In the telehealth context, this means that for CMS billing purposes, a provider in State A can provide services via telehealth to a patient in State B, even though the provider is licensed to practice in State A but not in State B.

The complication, however, is that, even though such inter-state service provision is reimbursable by Medicare does not mean that it is legally permissible under the state laws of State A and B. Before COVID-19, the permissibility of providing care across state lines was already a veritable regulatory mess. States' stances are buried in state laws, medical board statements, and administrative rules. They varied from broad exceptions for limited interstate practice, to cryptic

one-off permissions, to silence. There has also been much ambiguity around what level of care was permissible. If a patient living in State B travels to State A and sees a provider in State A, how much follow-up care can that provider provide? One can quickly go down the rabbit hole of scenarios. Grey areas abound.

While many states have followed CMS's lead and executed temporary orders permitting non-licensed practitioners to provide health care in their states, confusion among providers remains. Most of these temporary permissions are executive orders of governors that expire after short periods of time. Not to mention a governor can always choose to rescind his or her executive orders. Many of the orders contain language that is subject to different interpretations. If an attorney wants to advise its provider-client on whether he or she can provide services in a state where he or she is not licensed, such attorney must be prepared to check that state's law every day.

Even when a practitioner may ardently attempt to adhere to these restrictions, that practitioner actually has no control over their own compliance. What if the patient is not asked where he or she is located at the time of telehealth care? What if the patient lies? In a place only a lawyer's mind would go, one recent webinar on telehealth issues raised a situation where a patient started their telehealth visit in State A, but the patient was in a car during the visit and traveled to State B (where the telehealth provider was not licensed) during the course of the appointment. While this was a hypothetical example for illustrative purposes, it highlights the fact that the current state-regulated, fiefdom-oriented system of provider licensure is, at least when it comes to the provision of telehealth, unsustainable.

There are many reasons to consider the current system of state-controlled licensure an antiquated practice. The boards of medicine are national, the National Practitioner Databank is a national system, the OIG exclusion list is national. If anything, the segregation of state medical boards from one another provides greater opportunity for unqualified providers to continue to practice without appropriate remediation by moving from state to state.

Medical and nursing boards are presumably sources of both revenue and control for states; as such, any change to the current system would similarly have to come from the top down, i.e. a national solution. In the meantime, advising on telemedicine requires ongoing assessment and risk-benefit analysis. Even with the current COVID-19 related permissions in place, the boundaries of telemedicine are far from concrete.

IV. Regulatory Complications

Certain niches present an added layer of complexity, such as when providing care remotely includes the need to prescribe controlled substances. This raises problems not only when the patient is located in a different state than the provider (whether there temporarily or permanently), but can also raise problems in seemingly "simple" cases when the patient is located in the provider's state.

The Drug Enforcement Administration (DEA) reacted quickly to COVID-19, releasing guidance allowing Schedule II-V controlled substances to be prescribed via telemedicine:

DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following 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; and*
- The practitioner is acting in accordance with applicable Federal and State laws.⁸*

While Michigan did not have a stand-alone, umbrella requirement for in-person evaluation before a controlled substance prescription, Governor Whitmer echoed the DEA's approach in a May 14, 2020 executive order encouraging the use of telemedicine.⁹

Nonetheless, despite federal and state acceptance of controlled substance prescriptions issued based on telemedicine consultations, many states have additional regulatory burdens that have not explicitly been relaxed during COVID-19. Michigan, for example, enacted over a dozen pieces of legislation related to controlled substances and opioids in the last few years.¹⁰ While many of these state laws are similar and relatively simple, such as duration limits on opioid prescriptions, they can also include complex and burdensome requirements that do not easily translate into the telemedicine realm without further state intervention.

A prime example is Michigan's "Start Talking" education and form. Meant to ensure that patients are educated on the risks of opioids, the law includes a specific documentation requirement: patients must physically sign a stand-alone form acknowledging they received the education, and that document must be made a part of their medical record. In the wake of COVID-19, hospitals have created work-arounds in an attempt to comply with the "spirit" of Michigan's opioid law. For most, that has meant providing the education via telemedicine and documenting the patient's acknowledgement of the education in the patient's medical record. While facially noncompliant with the law, it is what most have found to be the only workable solution—and will likely remain the only workable solution for some time.

Such requirements—which were enacted with good intentions—are further examples of the challenges with the current state-based regulatory system. To continue with the example of a controlled substance prescription issued to a patient via telemedicine: if the patient happens to temporarily be in another state and have asked for their prescription to be sent to that other state, there may be Board of Pharmacy-based restrictions on accepting and filling such prescriptions for an out-of-state prescriber. These examples noted above are only the tip of the iceberg, as regulatory hurdles exist nearly every step of the way.

V. Provider Liability

The tremendous uncertainty regarding legal exposure from telemedicine is another barrier that has constrained telemedicine in the last decade. While traditional claims could arise in a telemedicine setting, such as a missed diagnosis or incorrect interpretation, miscommunication and technology-based errors are at the forefront of many providers' minds. The general fear is that, if you are not in the same room as the patient, you are more likely to miss something. Inspecting a wound or recognizing subtle signs could be hampered by poor video equipment, internet speed, or camera angle.

There are few reported cases that involve medical malpractice claims in a telemedicine setting, in part because telemedicine has historically been largely limited to low-risk care: allergies, flu symptoms, respiratory infections. Even when claims have arisen in such cases, they would likely be lower value claims, and more likely to be resolved in settlement (and thus not publicly reported). Telemedicine practice has also historically been practiced conservatively, further limiting malpractice claims. Patients whose work-up reveals that they are high risk may be asked to present for in-person consultation, or treatment regimens offered in a telemedicine environment may be lower risk than those that may be pursued in-person (e.g., not offering isotretinoin for acne patients).

Because telemedicine is still relatively new, and for the reasons listed above, there is limited data and history upon which to base underwriting decisions. A general principal of underwriting is that a premium is paid to shift the financial risk for an uncertain negative outcome from the insured to the insurer. Insurance premiums may then go up in response to increased use of telemedicine, especially if the state licensure laws remain unchanged, thus potentially exposing providers to situations in which they are illegally practicing medicine. The rapid expansion of telehealth is extremely helpful in terms of reducing the amount to which medical malpractice underwriting concerns are an impediment to adoption.

From a practical perspective, the validity of a malpractice claim will always depend on a simple test: did the provider act like a reasonably prudent provider would act under the same or similar circumstances? The twist here is that the country has never experienced anything like COVID-19, so the legal system offers little precedent. For example, facts such as the regional infection rate when the patient was seen, whether other providers were seeing similar patients in person, and the patient's individual risk factors might all play a role in determining the provider's "reasonableness" in the patient encounter.

In addition, certain immunities related to provider liability have also been extended specifically during the COVID-19 public health emergency. While Michigan has had long-standing immunity provisions that are applicable to "disaster relief workers," defined as certain providers who "render[] services during a state of disaster declared by the governor and at the express or implied request of a state official or agency or county or local coordinator or executive body,"¹¹ Executive Order 2020-30 (later replaced by 2020-61) extended this immunity to unlicensed volunteers and students supporting the COVID-19 response.¹² A bill currently pending in the Michigan Senate

also proposes a much broader set of immunities applicable to providers engaged in both COVID and non-COVID-related health care, with such immunity to apply retrospectively to March 10, 2020.¹³ Although such immunities are currently untested, they may serve to limit a provider's liability in a claim related to telemedicine malpractice in response to COVID-19.

The COVID-19 pandemic removed the choice around telemedicine and made it a necessity. As such, the necessary adoption of telemedicine is the proving ground needed to show that safe, effective care can be provided via telemedicine. Meanwhile, the legal and insurance frameworks to support telemedicine will be forced to rapidly develop in response.

VI. Privacy in the Telemedicine Environment

Along with the many sweeping changes made by CMS, HHS' temporary adoption of enforcement discretion as it relates to permissible telehealth platforms can largely be credited with opening the telemedicine floodgates during this pandemic period.

In its guidance, the Office of Civil Rights explained “covered healthcare providers may use popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype, to provide telehealth without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency.”¹⁴ This platform flexibility was extremely important in allowing providers to, in the initial days and weeks of the pandemic, connect with patients by whatever means they could.

As the pandemic continues, though, healthcare institutions are having to grapple with how to build up telemedicine delivery platforms under the assumption that HHS and OCR will revert to the prior restrictive HIPAA rules. In this real-time telemedicine experiment, the following platform-related challenges have emerged:

- Internet bandwidth of provider, especially when multiple providers are in the same office;
- Bandwidth of patient, especially for patients located in rural areas;
- Ability of patient to easily access chosen platform;
- Cost variability of platforms.
- Ability of providers to successfully negotiate and/or obtain a business associate agreements with available platform operators.

The evolution of wearable technologies and healthcare apps may offer some clues as to what may happen in the telemedicine platform space. HHS will permit healthcare providers to transmit PHI to healthcare apps, at the request of a patient, without the necessity of the healthcare provider having a BAA with the app or having liability with regard to any use or disclosure by the app. HHS determined that, as the PHI transfer was at the patient's request, HIPAA protections would not apply to the transmitted information.¹⁵ At the same time, the federal government is working

to effectuate the key provisions in Title IV of the 21st Century Cures Act (Cures Act), which, as the Office of the National Coordinator for Health Information Technology (ONC) stated “are designed to advance interoperability; support the access, exchange, and use of electronic health information (EHI); and address occurrences of information blocking.” As a result of the Cures Act, electronic medical record platforms are now required to have application programming interfaces (APIs) (digital messengers that work behind the scenes to help software programs communicate with one another). In March 2020 rulemaking, the ONC established standards for APIs, which means that EMR developers must ensure that their systems can communicate with third-party users, which include consumer apps.¹⁶

One can look at these interpretative movements and rulemaking as an attempt to shift PHI as something to be held, protected and managed by a provider to information to be owned, utilized and managed by the patient him or herself. The government appears to be understanding that protections for PHI do not have to all flow down from the provider, but may be in some instances be addressed via federally-mandated required technology standards and safeguards with patients then entrusted to make their own decisions regarding app use and PHI use and aggregation. There is an opportunity to think that, in the telemedicine platform space, the government could adequately protect privacy and PHI by dictating technology and privacy standards that all developers in the space must meet, as opposed to burdening healthcare providers with the necessity of entering in to BAAs with these developers as a means of ensuring HIPAA compliance by the telemedicine platform.

Global crises almost by definition spark change, innovation and enormous shifts in the way we lead out lives. As the New York Times quoted a physician in London as saying about telemedicine, “[w]e’re basically witnessing 10 years of change in one week;” and that change is here to stay.

¹ The Centers for Medicare and Medicaid Services, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers* <<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>> (accessed July 9, 2020).

² CMS has also temporarily expanded the types of services that, if provided via phone without an visual connection, may also be reimbursable, but that list is not identical to the telehealth services expansion. The Centers for Medicare and Medicaid Services, *Telehealth: List of Telehealth Services* <<https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>> (accessed July 9, 2020).

³ The Centers for Medicare and Medicaid Services, *Interim Final Rule, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*, at 13 <<https://www.cms.gov/files/document/covid-final-ifc.pdf>> (accessed July 9, 2020).

⁴ *Id.* at 14.

⁵ *Id.* at 15.

⁶ The Centers for Medicare and Medicaid Services, Medicare Telehealth Frequently Asked Questions (FAQs), March 17, 2020 <<https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>> (accessed July 9, 2020).

⁷ The Centers for Medicare and Medicaid Services, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, at 30 <<https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>> (accessed July 9, 2020).

⁸ United States Drug Enforcement Administration, *COVID-19 Information Page* <<https://www.deadiversion.usdoj.gov/coronavirus.html#TELE>> (accessed May 26, 2020).

⁹ Michigan Executive Order 2020-86, *Encouraging the use of telehealth services during the COVID-19 emergency* (May 15, 2020) <https://content.govdelivery.com/attachments/MIEOG/2020/05/14/file_attachments/1451862/E_O%202020-86%20Emerg%20order%20-%20telehealth.pdf> (accessed July 9, 2020).

¹⁰ Emily Klatt and Paul Hilliard, Michigan Bar Health Care Law Section, *Michigan Controlled Substances Regulation in Response to the Opioid Epidemic* <<https://connect.michbar.org/healthcare/publications/sectionpublications>> (accessed July 9, 2020).

¹¹ Mich. Comp. Laws 30.411(4) <[http://www.legislature.mi.gov/\(S\(lpt4y30geywbzl0wltoj5l3e\)\)/mileg.aspx?page=getObject&objectName=mcl-30-411](http://www.legislature.mi.gov/(S(lpt4y30geywbzl0wltoj5l3e))/mileg.aspx?page=getObject&objectName=mcl-30-411)> (accessed July 19, 2020).

¹² Notably, the legality of the protection afforded by Executive Order 2020-30 (and Executive Order 2020-61) was called into question by a lawsuit against Governor Whitmer questioning her authority under the Emergency Powers of the Governor Act of 1945 and the Emergency Management Act of 1976. While the lawsuit does not specifically relate to the immunity provisions, it does call into question her underlying authority to grant such immunity.

¹³ Michigan Legislature, Senate Bill 0899 (2020) <<http://legislature.mi.gov/doc.aspx?2020-SB-0899>> (accessed July 9, 2020).

¹⁴ Dep't of Health and Human Services, *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency* <<https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>> (accessed July 9, 2020).

¹⁵ Dep't of Health and Human Services, *FAQ 3011* <<https://www.hhs.gov/hipaa/for-professionals/faq/3011/where-an-individual-directs-a-covered-entity-to-send-epi-to-a-designated-app-does-a-covered-entits-ehr-system-developer-bear-liability.html>> (accessed July 9, 2020).

¹⁶ ONC Health IT Certification Program: Enhanced Oversight and Accountability: A Rule by the Health and Human Services Department on 10/19/2016 <<https://www.federalregister.gov/documents/2016/10/19/2016-24908/onc-health-it-certification-program-enhanced-oversight-and-accountability>> (accessed July 9, 2020).