

Telemedicine: Navigating legal issues

Some legal concerns and caveats of using telemedicine, as well as a prediction for the future of virtual health care

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In the first 2 articles of this series, “Telemedicine: A primer for today’s ObGyn” and “Telemedicine: Common hurdles and proper coding for ObGyns,” which appeared in the May and June issues of OBG MANAGEMENT, we discussed caring for patients without face-to-face visits and that virtual visits are an opportunity to provide good care in a world such as that created by COVID-19. We also discussed which patients are the most appropriate candidates for telemedicine, as well as how to properly code virtual visits so that you are paid for your time and service. This third article addresses the legal concerns and caveats of using telemedicine and makes a prediction for the future of virtual health care.

Legal issues surrounding telemedicine

There are numerous legal, regulatory, and compliance issues that existed before the

pandemic that likely will continue to be of concern postpandemic. Although the recent 1135 waiver (allowing Medicare to pay for office, hospital, and other visits furnished via telehealth)¹ and other regulations are now in place for almost every aspect of telemedicine, virtual medicine is not a free-for-all (even though it may seem like it). Practicing ethical telemedicine entails abiding by numerous federal and state-specific laws and requirements. It is important to be aware of the laws in each state in which your patients are located and to practice according to the requirements of these laws. This often requires consultation with an experienced health care attorney who is knowledgeable about the use of telemedicine and who can help you with issues surrounding:

- **Malpractice insurance.** It is an important first step to contact your practice’s malpractice insurance carrier and confirm coverage for telemedicine visits. Telemedicine visits are considered the same as in-person visits when determining scope of practice and malpractice liability. Nevertheless, a best practice is to have written verification from your malpractice carrier about the types of telemedicine services and claims for which your ObGyn practice is covered. Additionally, if you care for patients virtually who live in a state in which you are not licensed, check with your carrier to determine if potential claims will be covered.

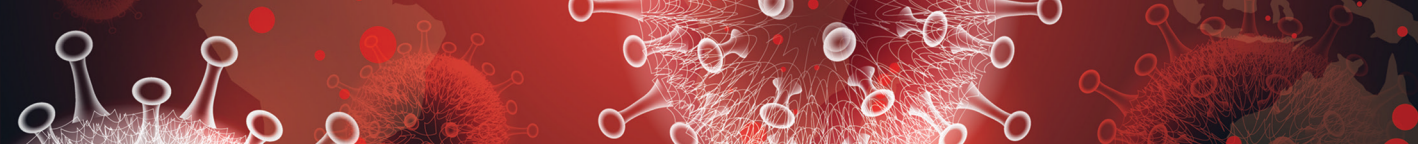
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- **Corporate practice laws.** These laws require that your practice be governed by a health care professional and not someone with a nonmedical background. This becomes important if you are looking to create a virtual practice in another state. States that prohibit the corporate practice of medicine have state-specific mandates that require strict adherence. Consult with a health care attorney before entering into a business arrangement with a nonphysician or corporate entity.
- **Delegation agreement requirements.** These laws require physician collaboration and/or supervision of allied health care workers such as nurse practitioners (NPs) and physician assistants (PAs) and may limit the number of allied health care providers that a physician may supervise. Many states are allowing allied health care workers to practice at the top of their license, but this is still state specific. Thus, it is an important issue to consider, especially for practices that rely heavily on the services of advanced practice registered nurses (APRNs), for example, who have a broad scope of practice and who may be qualified to care for many common ObGyn problems.
- **Informed consent requirements.** Some states have no requirements regarding consent for a virtual visit. Others require either written or verbal consent. In states that do not require informed consent, it is best practice to nevertheless obtain either written or oral consent and to document in the patient's record that consent was obtained before initiating a virtual visit. The consent should follow state-mandated disclosures, as well as the practice's policies regarding billing, scheduling, and cancellations of telemedicine visits.
- **Interstate licensing laws.** Because of the COVID-19 pandemic, federal and state licensure waivers are in place to allow physicians to care for patients outside the physician's home state, but these waivers likely will be lifted postpandemic. Once waivers are lifted, physicians will need to be licensed not only in the state in which they practice but also in the state where the patient is located at the time of treatment. Even physicians who practice in states that belong to the Interstate Medical Licensure Compact² must apply for and obtain a license to practice within Compact member states. Membership in the Interstate Medical Licensure Compact expedites the licensure process, but does not alleviate the need to obtain a license to practice in each member state. To ensure compliance with interstate licensure laws, seek advice from a health care attorney specializing in telemedicine.
- **Drug monitoring laws.** The Ryan Haight Online Pharmacy Consumer Protection Act of 2008³ implemented a requirement that physicians have at least one in-person, face-to-face visit with patients *before* prescribing a controlled substance for the first time. Because state laws may vary, we suggest consulting with a health care attorney to understand your state's requirements for prescribing controlled substances to new patients and when using telemedicine (see "Prescription drugs" at <https://www.cdc.gov/phlp/publications/topic/prescription.html> for more information).
- **Data privacy and security.** From a content perspective, health care data and personally identifiable information are extremely rich, which makes electronic health records (EHRs), or the digital form of patients' medical histories and other data, particularly tempting targets for hackers and cyber criminals. We caution that services such as FaceTime and Skype are not encrypted; they have been granted waivers for telemedicine use, but these waivers are probably not going to be permanent once the COVID-19 crisis passes.
- **HIPAA compliance.** Generally—and certainly under normal circumstances—telemedicine is subject to the same rules governing protected health information (PHI) as any other technology and process used in physician practices. The Health Insurance Portability and Accountability Act (HIPAA) Security Rule includes guidelines on telemedicine and stipulates that only authorized users should have

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It is best practice to obtain and document informed consent before initiating a virtual visit

access to ePHI, that a system of secure communication must be established to protect the security of ePHI, and that a system to monitor communications must be maintained, among other requirements.⁴ Third parties that provide telemedicine, data storage, and other services, with a few exceptions, must have a business associate agreement (BAA) with a covered entity. Covered entities include health care providers, health plans, and health and health care clearinghouses. Such an agreement should include specific language that ensures that HIPAA requirements will be met and that governs permitted and required uses of PHI, strictly limits other uses of PHI, and establishes appropriate safeguards and steps that must be taken in the event of a breach or disallowed disclosure of PHI. Best practice requires that providers establish robust protocols, policies, and processes for handling sensitive information.

During the COVID-19 pandemic, however, certain HIPAA restrictions relating to telemedicine have been temporarily waived by the US Department of Health and Human Services (HHS). More specifically, HHS Secretary Alex Azar has exercised his authority to waive sanctions against covered hospitals for noncompliance with requirements: to obtain a patient's consent to speak with family members or friends involved in the patient's care, to distribute a notice of privacy practices, to request privacy restrictions, to request confidential communications, and the use of nonpublic fac-ing audio and video communications products, among others.⁵ These are temporary measures only; once the national public health emergency has passed or at the HHS Secretary's discretion based on new developments, this position on discretionary nonenforcement may end.

Crisis creates opportunity: The future of telemedicine

It was just a few years ago when the use of telemedicine was relegated to treating patients in only rural areas or those located a great distance from brick and mortar practices. But the pandemic, along with the coin-

cident relaxation of the Centers for Medicare and Medicaid Services' (CMS) requirements for conducting telemedicine visits has made the technology highly attractive to ObGyns who can now treat many patients 24/7 from their homes using laptops and even mobile devices. In addition, the pandemic has prompted an expansion of current procedural terminology (CPT) codes that makes it possible to bill patients for telemedicine services and be appropriately compensated.

Thus, as awful as COVID-19 is, we can conclude that it has provided us with opportunities. We predict that when the crisis has abated, although the current relaxation of HIPAA guidelines will probably be rescinded, restrictions will not likely return to pre-coronavirus status; changes will certainly be made, and telemedicine will likely become part and parcel of caring for ObGyn patients.

Telemedicine has been used successfully for years to improve patient access to medical care while reducing health care costs. In 2016, an estimated 61% of US health care institutions and 40% to 50% of US hospitals used telemedicine.⁶ And according to the results of a survey of America's physicians conducted in April 2020, almost half (48%) are treating patients through telemedicine, which is up from just 18% 2 years ago.⁷

Letting loose the genie in the bottle

Widespread use of telemedicine traditionally has been limited by low reimbursement rates and interstate licensing and practice issues, but we predict that the use of telemedicine is going to significantly increase in the future. Here's why:⁸ Disruptive innovation was defined by Professor Clayton Christensen of the Harvard Business School in 1997.⁹ Disruptive innovation explains the process by which a disruptive force spurs the development of simple, convenient, and affordable solutions that then replace processes that are expensive and complicated. According to Christensen, a critical element of the process is a technology that makes a product or

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Services such as Facetime and Skype have been granted waivers for telemedicine use, but these waivers will probably end after the COVID-19 crisis

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A look at one company's use of telemedicine: CVS Pharmacy

CVS is using telemedicine to complement the company's retail "Minute Clinic," which offers routine preventive and clinical services, such as vaccine administration, disease screenings, treatment for minor illnesses and injuries, and monitoring of chronic conditions—services that traditionally were provided in physician's offices only. These clinics are open 7 days per week, providing services on a walk-in basis at an affordable price—about \$60 per visit compared with an average of \$150 for an uninsured patient to see a primary care physician in his/her office.¹ While this seems to be fulfilling an unmet need for patients, the service may prove disruptive to traditional health care delivery by removing a lucrative source of income from physicians.

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service more accessible to a larger number of people while reducing cost and increasing ease of use. For example, innovations making equipment for dialysis cheaper and simpler helped make it possible to administer the treatment in neighborhood clinics, rather than in centralized hospitals, thus disrupting the hospital's share of the dialysis business.

The concept of telemedicine and the technology for its implementation have been available for more than 15 years. However, it was the coronavirus that released the genie from the bottle, serving as the disruptive force to release the innovation. Telemedicine has demonstrated that the technology offers solutions that address patients' urgent, unmet needs for access to care at an affordable price and that enhances the productivity of the ObGyn. The result is simple, convenient, and affordable; patients can readily access the medical care they need to effectively maintain their health or manage conditions that arise.

Telemedicine has reached a level of critical mass. Data suggest that patients, especially younger ones, have accepted and appreciate the use of this technology.¹⁰ It gives patients more opportunities to receive health care in their homes or at work where they feel more comfortable and less anxious than they do in physicians' offices.

Several other health care issues may be altered by telemedicine.

The physician shortage. If the data are to be believed, there will be a significant short-

age of physicians—and perhaps ObGyns—in the near future.¹¹ Telemedicine can help the problem by making it possible to provide medical care not only in rural areas where there are no ObGyns but also in urban areas where a shortage may be looming.

Continuing medical education (CME). CME is moving from large, expensive, in-person conferences to virtual conferences and online learning.

The American health care budget is bloated with expenses exceeding \$3 trillion.¹² Telemedicine can help reduce health care costs by facilitating patient appointments that do not require office staff or many of the overhead expenses associated with brick and mortar operations. Telemedicine reduces the financial impact of patient no-shows. Because patients are keen on participating, the use of telemedicine likely will improve patient engagement and clinical outcomes. Telemedicine already has a reputation of reducing unnecessary office and emergency room visits and hospital admissions.¹³

Clinical trials. One of the obstacles to overcome in the early stages of a clinical trial is finding participants. Telemedicine will make patient recruitment more straightforward. And because telemedicine makes distance from the office a nonissue, recruiters will be less restricted by geographic boundaries.

In addition, telemedicine allows for the participants of the trial to stay in their homes most of the time while wearing remote moni-

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Telemedicine can help to address physician shortages in rural and urban areas alike

toring devices. Such devices would enable trial researchers to spot deviations from patients' baseline readings.

The bottom line

COVID-19 has provided the opportunity for us to see how telemedicine can contribute to reducing the spread of infectious diseases by

protecting physicians, their staff, and patients themselves. Once the COVID-19 crisis has passed, it is likely that telemedicine will continue to move health care delivery from the hospital or clinic into the home. The growth and integration of information and communication technologies into health care delivery holds great potential for patients, providers, and payers in health systems of the future. ●

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