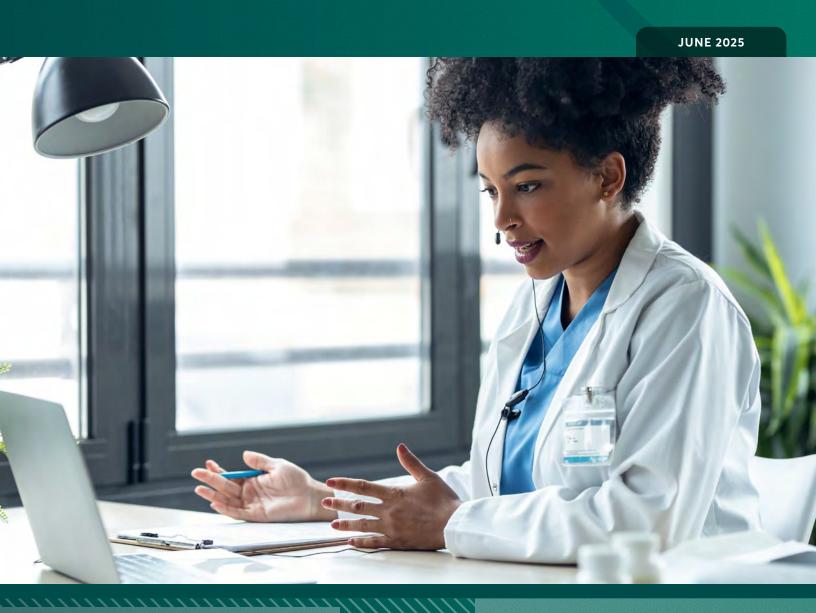


INSIGHT

Navigating the Medical Liability Aspects of Telehealth





Contents

Copic Insight is a specialized resource for individual healthcare providers, practices, and facilities. Drawing on our decades of experience, we provide insight into timely healthcare issues, along with resources to help you navigate them confidently in your own setting.

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Note: Information in this publication is for general educational purposes and is not intended to establish practice guidelines or provide legal advice.

Overview

The use of telehealth has grown rapidly and emerged as a popular and effective option that many medical providers are embracing. The telehealth environment presents many benefits, but there are also challenges and risks that medical providers need to be aware of and manage.

This booklet focuses on telehealth issues from a medical professional liability perspective. It highlights some key considerations for insureds and policyholders. Some important questions when looking at telehealth include:

- Does telehealth impact claims trends or patterns of adverse outcomes?
- What issues need to be considered about how telehealth is used by different medical specialties and/or practice settings?
- · What concerns for patient safety arise from telehealth services?
- How do standards for telehealth practice differ from those for in-person care?
- · How do we manage legal and insurance coverage complications arising from practice across state lines?

These questions and others are being discussed by legislators, regulatory and professional organizations, technology companies, legal scholars, and healthcare experts as they seek to distribute the benefits of new technologies in healthcare while protecting patients and society from hazards, abuses, and errors.

Executive Summary

- The jurisdiction of telemedicine is where the patient is located at the time of treatment, unless it meets the exception for continuity of care for existing patients established in the state of your licensure.
- You might be subject to laws and conditions of the state where the patient is located, even with an existing patient exclusion. Hence, we strongly advise against providing reproductive healthcare, medical terminations, gender affirming therapy, and other issues, as legislative landscapes are ever-evolving and vary widely from state to state. Best practices for providers offering various services are to provide them in person in a state where they are licensed and know the regulations of that state.
 - We make no assurances nor opinions on billing and reimbursement of telehealth services.
 - Enforcement of telehealth is generally "complaint driven." One should anticipate the potential sources of such complaints and act accordingly. An example is prescribing via telehealth to a patient who will present that prescription to a pharmacist in a state where the provider is not licensed. A call to that pharmacy to discuss what you are doing and why can reduce such complaints. Another is website advertising and soliciting of patients solely via telemedicine for therapies that might be considered unusual or profit driven in the state where the provider is not licensed.



Overview

2020 COVID FLEXIBILITIES

At the peak of the COVID-19 pandemic, several factors stimulated a rapid expansion of telehealth services. However, many of these provisions, dating from 2019, have expired or have been significantly adjusted since 2021.

- "Relaxation" of federal and state regulations that previously encumbered telemedicine, including licensure, HIPAA, DEA, and Medicare rules.
- Executive orders by state governors and licensing boards "waiving" restrictions that were impediments.
- Changes to payment policies by Medicare, Medicaid, and commercial carriers that created "parity" or at least attractive levels of reimbursement.
- A variety of effective and aggressively marketed, mature telemedicine platforms, sometimes integrated with existing EHRs.
- Widespread acceptance (though sometimes reluctantly) of remote video conferencing as a "new normal" by schools, businesses, governments, and industries apart from healthcare.

2023 CHANGES

With a few exceptions, many federal and state "flexibilities" expired or returned to their prior status when the federal, COVID-19 Public Health Emergency officially ended on May 11, 2023. (Some provisions were extended to August 9, 2023.)

- Congress extended some payment considerations for Medicare and Medicaid through September 30, 2025.
- The DEA extended certain waivers pertaining to prescribing controlled substances until December 31, 2025, with specific restrictions.
- Medicare has made permanent certain payment rules and coverage policies; others it has extended until September 30, 2025.
- State telehealth rules—particularly licensure requirements—are positioning themselves across a spectrum from quite welcoming to quite restrictive. State laws should be considered potentially volatile for the near future. Telehealth regulations should remain favorable for providers licensed in the state where the patient is physically located at the time of service. However, for providers delivering services where they are not licensed, restrictions vary widely and need to be closely monitored.

TERMINOLOGY

We have chosen to use the terms "telehealth," "telemedicine," and "telecare" interchangeably. Some authorities define them differently based on nuances about platforms, scope, beneficiaries, technologies, clinical applications, etc. However, statutes, regulations, and legal and clinical literature use these words inconsistently, which makes settling on a standard definition potentially confusing.

Telehealth service (or telemedicine, telecare) is typically delivered in real time via a teleconferencing platform. It may include data channels for physiologic monitoring or record review. In some states, audio-only encounters (e.g., telephone) may fall under the definition of telehealth. This includes telephone calls, which for decades occurred entirely under the radar. "Store and forward" services (e.g., teleradiology or remote monitoring, where a clinical recording is reviewed after an interval) are also considered forms of telehealth. In addition, there are beginning to be discussions around whether email or portal messages to out-of-state patients might constitute "practicing" in those jurisdictions.

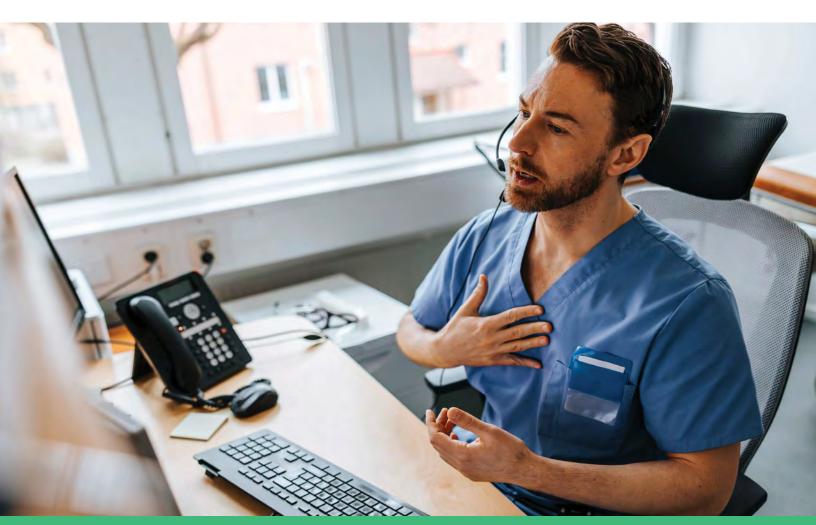
THE "CONTINUITY OF CARE EXCEPTION"

The longstanding practice of some states allowing limited telephone care and prescribing by out-of-state providers to their established patients who are temporarily visiting (the "continuity of care exception") remains essentially intact. But ironically, telehealth has increased scrutiny over every type of service by unlicensed practitioners. A few states have even looked more closely at telephonic (audio only) care, which some are considering a subset of telemedicine.

Each of these considerations is discussed in greater detail in the Coverage Considerations section.

LIABILITY COVERAGE FOR TELEHEALTH

With respect to insurance for professional liability, it is an open question whether a surge in new claims is pending in the pipeline, or whether, for reasons not entirely clear, telehealth may entail lower risk than in-person care. Copic has taken the position of welcoming and supporting appropriate telehealth practice as a valuable enhancement to the care delivery system. We see a future in which patients' access to care is meaningfully enhanced by this technology, lowering longstanding barriers of geography, logistics, economics, and other factors. We also expect continuing evolution in legal, regulatory, clinical, and organizational processes to accompany the shifts brought about by telehealth and its expanded use.





Coverage Considerations

As telemedicine becomes more commonplace, it's important to be familiar with how medical liability insurance coverage applies and the issues that may differ from face-to-face care. In general, Copic's policies do provide coverage for telemedicine, however, important areas to consider in determining the scope of coverage are highlighted in this section. Changes in services offered and/or other significant practice changes should be discussed with your agent and/or Copic underwriter to confirm an understanding of coverage. This is particularly important if you provide services in more than one state.

POLICY DEFINITIONS

Copic's policy includes definitions of "medical incident," "medical services," and "telehealth/telemedicine" as defined below:

- Medical incident means any alleged act or omission in furnishing or delivery of medical services, by the insured or any person under the insured's control and supervision. Multiple acts or omission related to the provision, furnishing or delivery of medical services in a continuing course of care that result in an injury or damages will be considered one medical incident only.
- Medical services means the provision of professional services within the limits of the insured's professional license, certification, or registration, including telemedicine, medical treatment and diagnoses and rendering medical opinions or medical advice.
- **Telemedicine** means the provision of medical services to a patient in another location through the use of technology, with or without an intervening healthcare provider.

Based upon these definitions, Copic's professional liability coverage includes telemedicine practice, under appropriate conditions.

The scope of coverage may be narrowed by an endorsement to the policy. Copic is continually reviewing our coverage for telemedicine services as this form of medical care is evolving. Copic is considering whether telemedicine may be higher risk for certain specialties or practice areas.

TERRITORIAL RESTRICTIONS/STATE CONSIDERATIONS

Most policies define the territory in which a claim will be covered, or where it must be filed for coverage to be available. While some policies may limit the insurance coverage to the state where the policy is issued (i.e., a single state), others may include worldwide coverage which would apply to claims arising from any location where the provider is appropriately licensed, as long as the claim/suit is brought within the United States.

Copic's policies have the following territorial restriction language: This policy provides coverage only for any covered claim made and filed in the United States of America, its territories or possessions.

When working outside of your principal state and providing telemedicine services to patients in other states, it is important to be aware of any state-mandated or optional Patient Compensation Funds (PCFs) that are available. As of December 2024, states having these are Indiana, Kansas, Louisiana, Nebraska, New Mexico, New York, Pennsylvania, South Carolina, and Wisconsin. An insured medical provider who is providing patient care in these states may be required to enroll in the PCF and premium surcharges may apply.

EXCLUSIONARY LANGUAGE



Review of policy exclusions should be completed to determine how any exclusions might apply to telemedicine services. Standard policy exclusions will generally continue to apply, such as those that are considered business and employment-related activities, criminal or intentional acts, disputes on fees, etc.

Copic's policies include the following exclusion, which would apply if a provider were not considered properly licensed, certified, registered, etc., in the state in which they are providing telemedicine services:

• Exclusion—Any act or omission when the provider is not properly licensed, certified or registered to provide the medical services, or when the provider was violating the terms of any denial, restriction, reduction, suspension or revocation of his or her license, certification, registration or hospital or clinical practice privileges, except for a temporary restriction due to incomplete medical records.

LIMITS OF LIABILITY

Given that each state develops its own rules/laws, there may be changes in financial responsibility requirements depending on the state in which medical care is considered to be practiced and delivered. Therefore, it is important that you make sure that your policy complies with the laws of the states where you may be practicing telemedicine. In some cases, the limits you maintain may need to be adjusted based upon state-specific requirements.

OTHER COPIC COVERAGE RELATED TO TELEMEDICINE

With respect to insurance for professional liability, it is an open question whether a surge in new claims is pending in the pipeline, or whether, for reasons not entirely clear, telehealth may entail lower risk than in-person care.

- Breach Response Coverage—Copic's policies include limited embedded breach response coverage. We encourage policyholders to review this to understand what it covers. This added level of protection includes coverage for not only cyber-related events like phishing or ransomware, but also HIPAA breaches resulting from human error or inadequate policies and procedures. Some examples where cyber coverage may apply to telemedicine include unauthorized access to IT systems, data breach response costs, damages to network assets, business interruption expenses, and cyber extortion expenses. We recommend reviewing the liability limits available for purchase to ensure they align with your practice needs. Please review the separate Copic Breach Response Coverage endorsement for more details.
- Covered Proceedings Coverage—Copic's policy provides limited defense-only coverage for covered proceedings events that may include incidents arising from telemedicine situations. This includes coverage for billing fraud and abuse investigations, disciplinary proceedings (i.e., responding to a patient complaint to the medical board), a governmental investigation

patient complaint to the medical board), a governmental investigation or peer review proceeding. See coverage specifics in your policy for additional details.

Policyholders are encouraged to contact their agent or Copic if they are embarking upon a telemedicine practice, particularly when providing care outside of their principal state, so that an assessment can be made with respect to the adequacy of their policy.



Legal and Regulatory Issues

Providing healthcare services through telemedicine is regulated by myriad federal and state laws that are subject to frequent updates. The complexity of governmental requirements begins with what is considered telemedicine—an evolving concept that differs across licensing jurisdictions.

A practitioner's telemedicine services will generally require compliance with federal and state laws as if the practitioner provides the services in an in-person setting, but may include additional requirements related to telehealth. This section focuses on three areas: licensure, prescribing authority, and privacy/security. Certainly, other legal considerations apply, such as establishing a practitioner-patient relationship, scope of practice, supervision of advanced practice providers and other staff, informed consent, and more. Several of these are discussed in the section, Patient Safety/Risk Management Guidelines for Telemedicine.

LICENSURE

There is no nationwide license for telemedicine. As with all professional healthcare services, state laws primarily govern. With limited exceptions, states require healthcare practitioners that treat patients through telemedicine to be licensed in the state of the physical location of the patient at the time of service. A licensed professional practicing in a state through telehealth is subject to the state's medical practice act and all medical board regulations and policies, and should be familiar with these.

During the declared COVID-19 Emergency, a number of states waived some licensure provisions through executive orders. By May 2023, all such waivers expired. Most states have reverted to requiring full state licensure for practitioners who deliver telehealth services to patients located within their borders.

However, at least a dozen states have created limited licenses or registries that allow telehealth services by out-of-state providers. Application processes can be found on state medical board sites.

Telehealth providers who wish to offer services in jurisdictions where they are not licensed are advised to contact each relevant regulatory agency to understand its requirements. This is understandably burdensome. Hopefully mechanisms to make interstate telemedicine easier will be implemented in coming years.

Becoming licensed in several states to perform telemedicine is an arduous application process that is somewhat mitigated by the Interstate Medical Licensure Compact (IMLC)—adopted by 42 states, D.C., and Guam that seek to streamline the application process (www.imlcc.org). However, please note that the IMLC process still requires a practitioner to obtain licensure from each state's medical board in which the practitioner seeks to provide telemedicine services and to pay the applicable licensing fee. If a practitioner provides healthcare services in a state without that state's license, the practitioner can be subject to disciplinary action. Additionally, any negative complaint against a practitioner is required to be reported to each state participating in the IMLC.

PRIVACY AND SECURITY

Practitioners must also comply with all privacy and security laws (state and federal, such as HIPAA) in a telemedicine setting to generally the same extent that apply when examining or treating a patient in person. A few states have additional disclosure requirements, such as risks of electronic communication. The telemedicine technology platform and all patient records and information must be stored, preserved, and secured in compliance with all applicable requirements as in any other setting. Covered healthcare providers that seek additional privacy protections for telehealth while using video communication products should provide such services through technology

vendors that are HIPAA-compliant and will enter into HIPAA business associate agreements with providers using their video communication products. Additionally, patient records originating from a telemedicine setting must adhere to ONC's Cures Act Final Rule requirements (the "Information Blocking Rules") that give patients the right to immediate access to their medical information.

Telemedicine technology platforms should be HIPAA-compliant and medical records must adhere to ONC's Cures Act Final Rule requirements that give patients the right to immediate access to their records.

PRESCRIBING

Another consideration for telemedicine services is compliance with regulations governing prescribing controlled substances. This area is currently undergoing active legislative and regulatory review. DEA rules significantly changed in 2023 and more changes are planned for 2025. It is imperative to monitor federal and other notices in this regard. The authority to prescribe originates from the practitioner's state of licensure regardless of the clinical setting.

Before COVID-19, prescriptions for a controlled substance issued by means of telemedicine were predicated on an in-person medical evaluation (21 U.S.C. 829(e)). During the designated public health emergency, DEA-registered practitioners were permitted to issue prescriptions for all schedule II-V controlled substances to patients for whom they had not conducted an in-person medical evaluation, provided all of the following conditions were met:

- The prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine visit with the patient was conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner was acting in accordance with applicable federal and state laws. Practitioners were
 required to be registered with the DEA in at least one state and have permission under state law to
 practice using controlled substances in the state where the dispensing occurred.

This waiver of DEA regulations was extended for the third time through December 31, 2025, as long as the criteria set forth above are met. It is not clear what the final rules will become after December 31, 2025, but the DEA has proposed three new telemedicine rules which will make permanent some temporary telemedicine flexibilities established during the COVID-19 public health emergency while also establishing new patient protections. More detail about these proposed changes for 2025 may be found at www.dea.gov/press-releases/2025/01/16/dea-announces-three-new-telemedicine-rules-continue-open-access.

Regardless of whether a public health emergency exists, if the prescribing practitioner previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, as long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his or her professional practice.



PRESCRIBING (Continued)

In addition, for the prescription to be valid, the practitioner must comply with applicable federal and state laws. The prescribing practitioner should also determine the possible requirement to register and maintain an account with the state's prescription drug monitoring program (PDMP), and consult with the PDMP when prescribing controlled substances. It is expected that some states will continue the longstanding practice of allowing out-of-state providers to order prescriptions (controlled substances and otherwise) for established patients who are temporarily visiting, under certain conditions. Providers should communicate with the local pharmacist about whether a local database search is required and how it should be done.

All other prescribing requirements will apply, such as issuing a prescription either electronically (for schedules II-V) or by calling in an emergency schedule II prescription to the pharmacy, or by calling in a schedule III-V prescription to the pharmacy.



COPIC'S PERSPECTIVE

Practitioners who provide services through telemedicine should seek legal counsel with respect to the applicable requirements and monitor these closely.



MEDICALLY ASSISTED THERAPY (MAT) FOR OPIOID USE DISORDER

On February 1, 2024, the Substance Abuse and Mental Health Services Administration (SAMHSA) announced a final rule updating the regulations regarding Opioid Treatment Programs (OTPs). Compliance with this new final rule was required as of October 2, 2024. These include relaxing requirements for in-person physical exams, expanding the types of practitioners eligible to prescribe buprenorphine, and allowing for the dispensing of take-home methadone doses. This final rule allows an OTP practitioner to initiate treatment of methadone or buprenorphine via telehealth without an initial in-person exam. The final rule states that if certain practitioners, including the OTP physician, primary care physician, or other authorized healthcare professional under the supervision of program physician determines that an evaluation of the patient can be accomplished via audio visual technology, then a licensed OTP practitioner may prescribe and dispense methadone or buprenorphine to the patient.

Importantly, the rule does not extend the use of audio-only telehealth technology to methadone, except under very limited circumstances, because methadone holds a higher risk profile for sedation and does not authorize the prescription of methadone via telehealth outside the OTP context. The final rule expands the definition of practitioner, which was modified to include any "health care professional who is appropriately licensed by the state to prescribe and/or dispense medications for opioid use disorder." This means, subject to state laws, more non-physician practitioners such as nurse practitioners or physician assistants may prescribe or order medication. However, some states may not allow non-physician practitioners such as certified nurse-midwives, nurse practitioners, physician assistants, or pharmacists to prescribe these medications.

Patient Safety/Risk Management Guidelines for Telemedicine —



The guiding assumption about telemedicine liability claims is that they will be fundamentally the same as claims seen with in-person care, despite the novelty of the medium, the nature of medical treatment, and the variables that create uncertainty and adverse outcomes. Copic has been monitoring the legal and clinical literature for reports of new risks related to telemedicine. So far, these have been rare and largely foreseeable. Copic's risk management attention generally falls into two categories:

Familiar Patient Safety Risks That Require Special Mitigation Strategies for Telemedicine

· A sudden patient emergency.

- · A language or communication barrier.
- · Performance of many aspects of the physical examination.
- · Identification and management of patients, visitors, minors, assistants, and caregivers in the session.

Novel Patient Safety Risks Arising from Electronic Communication Technology

Technology hazards that may impact telemedicine risk:

- Interrupted or inconsistent connection; poor quality audio or video; distortion.
- Intrusion or interception; unauthorized participants.
- Unintended or surreptitious recording.
- Impersonation, misrepresentation, spamming, hijacking, or diverting a session.
- · Loss, distortion, or breach of data collected during the session.
- · Malfunction of monitoring devices or data streams.

KEY FACTORS THAT INFLUENCE RISK

When we look at specific telehealth interactions with patients, risk should also be evaluated based on factors including: the acuity of the situation, the expectations of the patient, and the involvement of other clinicians or a pre-existing provider/patient relationship. These factors can either increase or decrease the risk. How each factor affects the risk and some strategies to reduce that risk is outlined as follows.

Acuity

In primary care, acute care, and non-procedural medicine, the majority of claims involve an allegation of failure or delay in diagnosis. When that failure or delay leads to a preventable or alterable adverse outcome, also known as "missing the window of opportunity," then liability claims of significance can arise.

Acute diagnoses with narrow windows of opportunity include:

- Acute neurologic conditions, such as cerebral vascular accident, intracranial hemorrhage, encephalitis/meningitis, space occupying lesions, and spinal cord conditions such as spinal epidural abscess, hematoma, or disc compression of the cord;
- Chest pain including acute coronary syndrome /myocardial infarction, pulmonary embolism, and aortic dissection;
- Acute serious infectious disease, including sepsis, pneumonia, septic arthritis, necrotizing fasciitis, and deep abscesses; and
- Acute intraabdominal conditions, including appendicitis, perforated viscus, abscess, ischemic bowel, and ectopic pregnancy.



Patient Safety/Risk Management Guidelines for Telemedicine —

Careful consideration for these diagnoses coupled with a low threshold for escalation to a higher level of care, including in-person care, referral, or consultation can be a strategy to reduce these "narrow window of opportunity" risks. Documentation that you considered these risks, had a plan to escalate or rule them out, and that plan was consistent with the timeliness necessary to prevent an adverse outcome is also important.

For procedural physicians the highest risks outside of the actual performance of the procedure include:

- · Correct patient selection and indications for the procedure, pre-procedure, and;
- Recognition and rescue of patients with complications, post-procedure.

While telemedicine can be used as an adjunct to both pre- and post-procedure care, excellent documentation pre-procedure and a low threshold for escalating to in-person evaluation are excellent risk management considerations.

Patient Expectations

Patients who use telehealth in order to avoid hospitalization or medical interventions can be at higher risk. Liberal use of well-documented informed refusal can protect you when adverse outcomes occur due to non-compliance with medical advice. Informed refusal documentation can range from a chart note describing your discussion of the risk and benefits to a more comprehensive informed refusal document that the patient affirms their understanding of by signature or remote confirmation.

Copic has a sample informed refusal form that can be downloaded at www.copic.com/consent-forms. It is available in a Word document format that can be edited or incorporated into your specific documentation system.





Provider Relationships

Provider/patient or provider/provider relationships fall into three categories, which correspond to different levels of risk.

Low Risk

Clinician-to-clinician consultation:

This has been common historically via telephone. Telehealth modalities can improve the consultation. Improved access to information and even the ability to interview or examine the patient remotely can be superior to the limitations of a simple phone call. In remote areas or locations with less access to specialty and subspecialty consultation, telehealth consultative services can improve clinical care and outcomes.

Out-of-state consultants have historically not needed a local license for recommendations for which an in-state licensed practitioner will be making final decisions. However, some states may consider consultation to represent the "practice of medicine," particularly when the in-state provider is relying on the expertise of the consultant. In all cases, thorough documentation of assumptions and expectations is warranted. Providers who regularly offer this type of service are advised to obtain legal counsel.

Existing patient-provider relationship:

Telehealth where the provider is delivering enhanced access to their patients via telehealth modalities is also an improvement over simple phone calls and screening. From the patient's perspective, there is greater satisfaction from connecting with the physician who knows their history and diagnoses, and who can reduce duplication of services and urgent or emergent visits compared to providers who have no previous knowledge of the patient.

When failing to communicate with an established patient would constitute "abandonment," the provider should always engage, regardless of the patient's location. If the provider is not licensed in the patient's location, this should be disclosed and the patient should collaborate with a local source of care. Ongoing treatment of patients who are out-of-state is discussed below.

High Risk

No pre-existing patient-provider relationship:

Telehealth where there is no pre-existing relationship is a higher risk category. While verification of the identity, experience, and credentials of the provider is important, so too is identification and verification of the authenticity of the patient's complaints and motivations for the telehealth interaction. Profit motives, maximal coding capture, and high-volume remote practices are more likely in this setting.

Engaging with—and particularly soliciting—new patients located in a state where the provider does not have a license can create legal jeopardy. Practitioners may communicate with prospective patients (e.g., give general information about a diagnosis, treatment or medication) without crossing the threshold of formally "practicing medicine." What must be avoided are diagnosing, prescribing or providing individual medical advice; and should not involve a fee for the service.



Patient Safety/Risk Management Guidelines for Telemedicine —

SCOPE OF SERVICES

Telehealth services must be consistent with the scope of practice and privileges otherwise provided in an in-person manner.

Telemedicine implies that the provider's scope of practice and expertise for a given clinical situation are equal to that of an in-person traditional encounter. When that is not possible to achieve in a telemedicine setting, escalation to a clinical setting equipped to deliver that level of care is necessary. Except in extraordinary circumstances, it will be insufficient as an excuse to claim a different standard or that the limitations of the medium was the reason for the failure or delay in performance.

Regardless of initial screening or triage, there should be a process by which the patient can be referred to the next available provider who has the requisite scope of practice, training, and experience. There should be a backup/contact plan for the rare possibility that a patient experiences an emergency during a telehealth session or the session is interrupted. This is particularly important if the provider is not licensed in the jurisdiction where the patient is located.

INFORMED CONSENT

Practitioners will be held to the requirements of the state where the patient is physically located, whether informed consent for telehealth services needs to be done verbally and/or in writing. The memorialization of that process is not a simple signature, but involves documentation of how it occurred. Several important elements to record include the patient's understanding of the technical aspects of the visit, the limitations of the service, and their acknowledgment that the clinician may deem it necessary to escalate the service to a different setting.

DOCUMENTATION

There are some unique aspects of telehealth documentation. A good practice is to note the medium used (e.g., teleconference, phone, telemetry data review, etc.). If any technical issue prevented optimal communication, that should be noted (e.g., "Exam limited by capabilities of the patient's cell phone"). It's required by some states to record the fact that the patient was aware of the limits of the technology and that there was a backup plan if it failed. Extra steps need to be taken to document consent for recording or photography.

You should identify and document any additional parties at either end, such as assistants, scribes, translators, or relatives. If an in-person visit would have been preferable but was not possible or advisable due to circumstances (e.g., weather, COVID, etc.), this needs to be documented in the disclosure and consent.

The following elements are the minimum necessary for the documentation of a telemedicine visit:

- · A statement of technical modality used for the encounter;
- A statement of verbal and/or written consent:
- The customary documentation of the clinical visit. Great care should be exercised to not use templates that imply levels of examination that are impossible to conduct via the telemedicine modality;
- The medical decision making process and working diagnosis;
- The treatment plan, including how it was conveyed to the patient and some statement of the patient's understanding and willingness to comply with it;
- In circumstances where escalation to a more clinically intensive service is recommended, there needs to be discussion of that understanding and the patient's intent to comply. It would be ideal if the provider would close the communication loop with the subsequent provider by direct communication with them, explaining the medical decision making and why the next service was recommended.



SUPERVISION AND CONSIDERATIONS FOR ADVANCED PRACTICE PROVIDERS (APPs)

APPs are subject to the same considerations about scope of services described previously. In states where supervision is implied or required for APPs, their supervising physician must have the necessary experience, training, and scope of practice to include the clinical management APPs are providing. Simply put, "Supervisors cannot oversee what they themselves don't have the experience and training to do." Some states even mandate the "active performance of a service" to be qualified to supervise that service. Both physicians and APPs have a responsibility to ensure they are practicing appropriately and within the guidelines that may be established by their state and licensure.

MEDICATION/PRESCRIBING

Prescribing medications over telehealth when the physician and the patient are in the same state and have a pre-existing relationship has the lowest risk and is essentially equivalent to prescribing for traditional in-person visits. In some states there may be special considerations when prescribing controlled substances after a telehealth encounter. The risk increases when there is no previous relationship or the patient is located in a different state at the time of the telehealth visit and will need to access follow-up, imaging, consults, referrals, and additional prescriptions in the other state.

State pharmacy laws have traditionally accepted out-of-state prescriptions for established patients. Prescriptions are subject to both federal and state laws. Most states give pharmacists discretion whether to fill or deny a prescription from a provider who is not licensed in that state, on a case-specific basis. It is much more likely to trigger licensing inquiries and complaints if you do not have a pre-existing relationship (and a history of in-person visits) with the patient in a state in which you are licensed. That doesn't mean every prescription will be accepted or rejected; it means you can usually rely on the local pharmacist to know whether they are allowed to cooperate. It is best to contact the pharmacist directly if there is any question about a prescription in a state where you do not hold a license.

High patient dissatisfaction and even adverse patient outcomes can arise from delays in dispensing medications. And pharmacists who believe that the prescriptions were generated out-of-state and are not in compliance with the local state regulations might feel a need to generate complaints to local licensing boards.

For more information on legal/regulatory considerations when prescribing controlled substances, please see the Prescribing section on page 8.

SHIPPING AND TRANSPORTING MEDICATIONS

Prescribers should be aware, and patients should be cautioned that it is illegal to ship prescription drugs by either the U.S. Postal Service or private carriers such as UPS and FedEx. Penalties can be severe, especially for controlled substances.

In some circumstances, it is legal for a household member to pick up a prescription and transport it to the patient. Anyone considering traveling across state lines with a medication that is not prescribed for them personally should seek advice from an attorney about exactly what they propose to do. Drugs of any kind that are not clearly labeled for use by the person in possession should never be carried across international borders.

Some pharmacies with national networks have arrangements with the DEA that allow them to dispense medications (including controlled substances) in states where the prescriber is not licensed. Telehealth providers are encouraged to explore the legal processes for doing this, if it applies to their practice.



Patient Safety/Risk Management **Guidelines for Telemedicine**

INTERPRETATION SERVICES

The ADA and Limited English Proficiency rules (LEP) apply to telehealth encounters. There are services available that enable the integration and use of remote, qualified interpreters with telehealth platforms. Providers should be familiar with restrictions on the use of "informal" translators or family members.

INTEGRATION WITH EHRs

Being able to generate a unique patient identifier, gather the necessary background information, and access previous records, studies, images, consults, etc. are all challenges in telehealth. It is not a given that an EHR will integrate smoothly with the telehealth application. The pre-visit registration that goes into preparing a patient for an in-person visit remains necessary in the telehealth environment. Collateral record sources such as text and portal messages and email also need to be captured in the EHR. Efforts should be taken to make sure that telehealth providers have access to existing patient data in real-time.

INTERSTATE "EDUCATIONAL SERVICES" THAT DO NOT **CONSTITUTE "PRACTICE OF MEDICINE"**

Some providers offer health education services in states where they are not licensed. (This is similar to publishing general medical advice on a website or in a blog.) This is a legitimate professional activity that does not constitute "practicing medicine" when done properly. Typically, an interaction will be considered "medical practice" if a professional "diagnoses, treats or prescribes." Providing personalized medical advice to an individual may cross the line between general information and making a clinical recommendation.

Publishing a book or an article, posting health tips on a public website, giving health or condition-related advice in a seminar or answering general questions when no provider-patient relationship is established are not normally considered practicing medicine. It is even possible to charge a fee for such activities, as long as it is clear that a provider-patient relationship is not being created (particularly in the mind of the audience), and that the fee does not cover any service that could be construed as making a diagnosis,

recommending a treatment or prescribing a remedy for a specific individual.

Copic Resources for Telehealth:

- 24/7 Risk Management Hotline: Contact a Copic physician for urgent, after-hours guidance at 720.858.6396.
- Copic seminars/on-demand courses: Visit www.copic.com/education for a current listing of education activities.
- Medical Guidelines and Tools: Our website also features downloadable resources such as consent forms (www.copic.com/consent-forms) and practice management resources (www.copic.com/tools-and-resources).

Such activities, when conducted via teleconferencing in an individual or group setting, fall outside the definition of telemedicine." However, other legal considerations may still apply, even if the activity does not comprise the of medicine" (for example, regulations on advertising and commerce). Advice from an attorney should be sought to guide any online commercial activity, including associated products, materials, and documentation.

Cyber Risk



Copic provides a basic level of breach response coverage (embedded in policies) to insureds. It became apparent several years ago that health information technology presented a new category of liabilities for practitioners.

Telemedicine—as an extension of health information technology—is vulnerable to inadvertent risks like power outages and human error, as well as intentional and malicious risks that arise from its offering an additional "attack surface" for malware, hacking, and fraud.

So far, telemedicine has not produced similar high impact disasters that security and privacy breaches have caused for email, EHRs, financial systems, patient registration, and clinical data. This may be partly because video conferencing technology is newer, narrower, and better designed; and because the volume of telemedicine transactions is magnitudes lower than other healthcare activities.

However, scrupulous attention must be given to securing and managing telemedicine platforms and their accompanying data. The advent of "Generative Language Models" (e.g., ChatGPT) has increased these risks substantially. The most vulnerable points where intrusions penetrate healthcare are where workers interact with external correspondents through email, document exchange, database connectivity, etc. The main cyber risks for telemedicine today are probably:

- Impersonation (of either party)
- Phishing, fraud, and malware encountered during data exchange
- Data loss, corruption, and theft

Privacy breach is perhaps the most sensitive risk in the perception of the public and some regulators. However, the potential use of telemedicine platforms to covertly invade other systems is probably a more serious threat. Intrusions into telemedicine systems are more likely to enter through connections from clinical, administrative, and other primary systems, rather than by direct interception.

In principle, cyber safeguards for telemedicine are the same as for all information systems. Areas specific to the platform that should be considered are:

- Risk assessment
- · Policies, procedures, and training
- · Data flow, connectivity, and backup



Copic recommends reviewing your cyber risk coverage with your agent or Copic underwriter to clarify what it entails, and to evaluate whether current limits are appropriate for your needs.

Healthcare's dependence on electronic data puts hardware, software, and infrastructure at risk of environmental, technical, and human mishaps. Health information systems are also subject to attack by hostile actors, including some who are highly skilled and heavily financed. Privacy breaches and misuse of information are widespread and involve significant expenses for mitigation. Costs from cyber losses have become a serious concern for insurers.

Cyber and Security Resources

- · Guide to Privacy and Security of Health Information: www.HealthIT.gov
- U.S. Department of Health and Human Services: Guidance on Risk Analysis (HIPAA): www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html
- Basic information can be obtained from: www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html
- The U.S. Department of Health and Human Services has created a useful "Security Risk Assessment Tool," which can be downloaded at: www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool



Cyber Risk

TELEHEALTH RESOURCES

Agency for Healthcare Research and Quality (AHRQ) Telehealth

>>www.ahrq.gov/topics/telehealth.html

Resources include a mix of tools, research, and listing of funding opportunities; AHRQ offers a sample telehealth consent form that you can download and customize for your needs.

American Medical Association (AMA) Telehealth Guide

>>www.ama-assn.org/practice-management/digital/ama-telehealth-quick-guide

- The AMA Digital Health Implementation Playbook series offers comprehensive step-by-step guides to
 implementing digital health solutions, specifically telemedicine, in practice based on insights from across the
 medical community. Each Playbook offers key steps, best practices, and resources to support an efficient and
 clear path to implementation and scale.
- The AMA, in collaboration with Manatt Health, developed a "Return on Health" framework to show the value of telehealth programs can increase the overall health and generate positive impact for patients, clinicians, payors and society.
- The Telehealth Immersion Program is the AMA's newest offering to guide physicians, practices and health systems in optimizing and sustaining telehealth at their organizations.

American Hospital Association—Telehealth

>>www.aha.org/telehealth

A variety of resources designed for hospitals and their staff.

American Telemedicine Association

>>www.americantelemed.org

Resources include a quick-start guide to telehealth, practice guidelines, webinars, news/updates, and other resources.

Center for Connected Health Policy (CCHP)

>>www.cchpca.org

CCHP tracks telehealth-related laws and regulations across all 50 states and the District of Columbia, as well as at the federal level. Click on a jurisdiction to see all current laws, and pending legislation.

CMS Telehealth Resources

>>www.cms.gov/Medicare/Medicare-General-Information/Telehealth

Includes access to a list of telehealth services, physician fee schedule, and other resources.

Federation of State Medical Boards (FSMB) Telehealth Requirements

>>www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf

A PDF document that is updated regularly and offers details on states and their modifying requirements for telehealth (e.g., out-of-state physicians; pre-existing provider-patient relationships; audio-only requirements; etc.)

HealthIT.gov Telemedicine and Telehealth Resources

>>www.healthit.gov/topic/health-it-health-care-settings/telemedicine-and-telehealth

Resources include a telehealth start-up and resource guide.

Health Resources & Services Administration (HRSA)

>>www.hrsa.gov/rural-health/telehealth/index.html

Information on resources including specific telehealth programs overseen by HRSA.



HHS Telehealth Resources for Providers

>>telehealth.hhs.gov/providers

Resources with a focus on getting started with telehealth, planning your telehealth workflow, health equity in telehealth, preparing patients for telehealth, legal considerations, and best practice guides.

Interstate Medical Licensure Compact (IMLC)

>>www.imlcc.org

The IMLC is an agreement among participating U.S. states to work together to significantly streamline the licensing process for physicians who want to practice in multiple states.

National Committee for Quality Assurance (NCQA) Telehealth Education Resources

>>www.ncqa.org/programs/data-and-information-technology/telehealth/ taskforce-on-telehealth-policy/educational-resources/

A comprehensive guide of educational resources from various healthcare organizations.

National Consortium of Telehealth Resource Centers

>>https://telehealthresourcecenter.org

Offers resources including links to regional telehealth resource centers.

Rural Health Information Hub: Telehealth Use in Rural Care

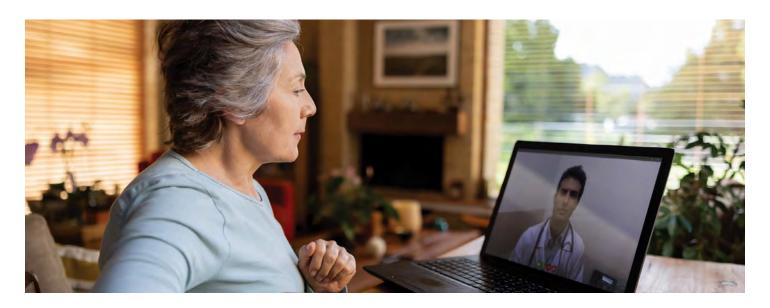
>>www.ruralhealthinfo.org/topics/telehealth

Specific guidance and resources for rural health facilities and providers.

PATIENT EDUCATION RESOURCES

- www.telehealth.hhs.gov/patients/
- www.cms.gov/medicare/coverage/telehealth
- www.medicare.gov/coverage/telehealth

National medical specialty organizations and state medical societies are also great resources for telehealth information that relates to your specific specialty and its unique practice considerations.





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