Telepsychiatry Resources

In the interest of being of service and support during this critical time, we would like to share the following materials with you:

- Telepsychiatry: Keeping Up With Regulators' Waivers
- Telepsychiatry Checklist
- Telepsychiatry: A Primer

Please remember that we are all operating in uncharted territory and there are very few clear answers. This is a very fluid situation, and recommendations change based upon events and new guidance and actions from federal and state governments.

We will continue to update our Coronavirus Resources and Telepsychiatry pages, and encourage you to check our website often for the latest risk management updates. We hope you find this information useful.

TELEPSYCHIATRY: KEEPING UP WITH YOUR REGULATORS' WAIVERS

FEDERAL REGULATORS

- HHS – OCR enforces HIPAA's Privacy and Security Rules
  - ***Waiver***: Discretionary enforcement when non-HIPAA compliant telemedicine platforms are used.
  - ***Impact***: Allows use of "non-public" facing applications that do not provide Business Associate Agreements to temporarily be used. Note that public-facing apps such as Facebook Live or TikTok cannot be used.
  - ***For more information***: www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html
  - ***When waiver will end***: Once the federal COVID Public Health Emergency (PHE) ends.
  - ***How to know when the waiver ends***: HHS should announce the expiration of the PHE and it will be posted on www.prms.com/faq.
  - ***Significance of the waiver ending***: You will likely have to go back to using a HIPAA-compliant telemedicine platform that will provide a Business Associate Agreement.
  - ***Risk management thoughts***: Given the confidentiality of psychiatric treatment, the advice is to at least consider, if possible, utilizing a HIPAA-compliant platform, rather than relying on the waiver.
  - ***Prediction***: This waiver will not last post-PHE, given the importance of protecting the confidentiality and security of patient information.
- DEA – Regulates the prescription of controlled substances nationwide
  - ***Waiver #1:*** PHE exception to Ryan Haight Act (RHA) requirement of a one in-person visit prior to prescribing controlled substances.
    - ***Impact***: Temporarily allows for the prescribing of controlled substances without first having one in-person visit.
    - ***For more information***: www.deadiversion.usdoj.gov/coronavirus.html
    - ***When waiver will end***: Once the federal COVID PHE ends.
    - ***How to know when the waiver ends***: HHS should announce the expiration of the PHE and it will be posted on www.prms.com/faq.
    - ***Significance of the waiver ending***: You will need to see the patient in-person prior to prescribing controlled substances, unless one of the very limited exceptions under the RHA or under another federal law applies. Also, for those patients you started on controlled substances during the pandemic without an in-person visit under the waiver, you may need to see them once in-person post-PHE.
    - ***Risk management thoughts***: Remember that state law could also, separate and apart from federal law, require in-person visits – see discussion below.
    - ***Prediction***: While many are advocating for this waiver to become permanent after the PHE ends, this is unlikely to occur. In a recent DEA regulation under the RHA, dealing exclusively with online pharmacies (the formal name of the Act is the Ryan Haight Online Pharmacy Consumer Protection Act), the DEA noted in the comments that the in-person requirement is the DEA's way to protect the public from prescriptions based solely on an online questionnaire. The comments also noted the DEA's obligation to have issued a regulation for the telemedicine registration (under which no in-person visit is required) by October 2019, and indicated that more on that would be forthcoming in the future.
  - ***Waiver #2***: DEA registration in patient's state (in addition to the prescriber's state) temporarily not required
    - ***Impact***: No federal DEA registration in the state where the patient is located is required during the pandemic.

- ***For more information***: www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf
- ***When waiver will end***: Once the federal COVID PHE ends.
- ***How to know when the waiver ends***: HHS should announce the expiration of the PHE and it will be posted on www.prms.com/faq.
- ***Significance of the waiver ending***: If the requirement goes back into effect, you will need a DEA registration in the patient's state. However, these historically are issued only to those with a license in the state. You may also need an address in that state to get the state DEA registration.
- ***Risk management thoughts***: Those patients for whom you are currently prescribing controlled substances under this waiver should be made aware of the potential that you will not be able to continue prescribing
- ***Prediction***: This requirement, which came into existence in 2007, is likely to go back into effect post-PHE.

STATE REGULATORS – STATE LICENSING BOARDS

- ***Waiver #1***: State licensure
  - ***Impact***: Many, but not all, states have waived licensure to some degree to allow out-of-state physicians to treat patients in their states without a state license. The impact varies by state – some states require physicians to apply for a temporary license, some only allow if treating COVID directly, some allow this only for established patients, etc. Remember that the federal waiver of state licensure for Medicare reimbursement is relevant only to being paid for services to Medicare patients - state licensure requirements must still be followed.
  - ***For more information***: www.prms.com/faq (first Quick Link is to state licensure waiver information)
  - ***When waiver will end***: Varies by state, and is not necessarily tied to the federal COVID PHE end date.
  - ***How to know when the waiver ends***: You can check with the individual licensing board (it should be on the board's website); we are also monitoring this and updating our state waiver information on www.prms.com/faq.
  - ***Significance of the waiver ending***: You need to avoid the unauthorized practice of medicine. Your professional liability insurance will not cover this, and the jurisdiction(s) where you are licensed could impose discipline.
  - ***Risk management thoughts***: Psychiatrists treating out-of-state patients under a state's waiver of licensure should ensure patients are aware of the temporary nature of the ability to do this, and patients' expectations should be managed accordingly. Once the waiver expires, you can email the state licensing board, and explain the facts (e.g., only one patient, border state, your sub-specialty expertise, etc.) to see if you actually need a license in that state to continue to treat that patient. You may be offered options such as a "registration" (as is available in Florida), or be told that no license is needed (as is true with some states with shared borders), or even possibly be given permission to continue to treat without a license based on your sub-specialty (as was the case for at least one child and adolescent psychiatrist). If you do not receive permission to continue to treat without a full license after the waiver ends, you will need to terminate (give 30 days' notice) your treatment relationship, or have the patient come into your state (or a state where you are licensed) for the telepsychiatry or in-person appointment.
  - ***Prediction***: Historically states have been slow to facilitate telemedicine, but perhaps the pandemic will result in more consideration of telemedicine by the state licensing boards. We hope more states will offer a registration instead of full licensure, as well as expanding other licensure exceptions.
- ***Waiver #2***: State requirements for prescribing controlled substances
  - ***Impact***: In addition to federal law, states can also regulate the prescribing of controlled substances, with different requirements. There is no consistency among the states – a few have a regulatory framework very similar to / exactly the same as the federal framework. But others may require an in-person visit for periodic monitoring, in addition to prior to prescribing. During the pandemic, most states have waived their requirements, some explicitly as New Jersey did in this document - www.njconsumeraffairs.gov/COVID19/Documents/FAQ-Telehealth.pdf. Once the state requirements go back into effect, they will need to be followed. This may result in the need to

terminate treatment with those patients that cannot meet the requirements, such as those related to in-person visits.

- ***For more information***: Check the state's licensing board's website for prescribing requirements and COVID waivers.
- ***When waiver will end***: Varies by state.
- ***How to know when the waiver ends***: Check the state licensing board's website.
- ***Significance of the waiver ending***: You will need to comply with state requirements, in addition to federal requirements, to continue to prescribe controlled substances. This may mean that patients will need to be seen in-person, depending on the state.
- ***Risk management thoughts***: It may be difficult to determine state law on prescribing controlled substances. Your Risk Managers may be able to provide some assistance. In the meantime, be sure to check the Prescription Monitoring Program (PMP) in the patient's state prior to prescribing controlled substances, even if not technically required to do so. The PMP is one of the best patient safety tools. If you do not have access to the PMP in the patient's state, consider asking the pharmacist to review the PMP prior to dispensing your prescription.
- ***Prediction***: Psychiatrists may have to devote considerable time to learning the rules of prescribing controlled substances out-of-state via telemedicine. While some boards have made such information readily available, the majority of boards have not.

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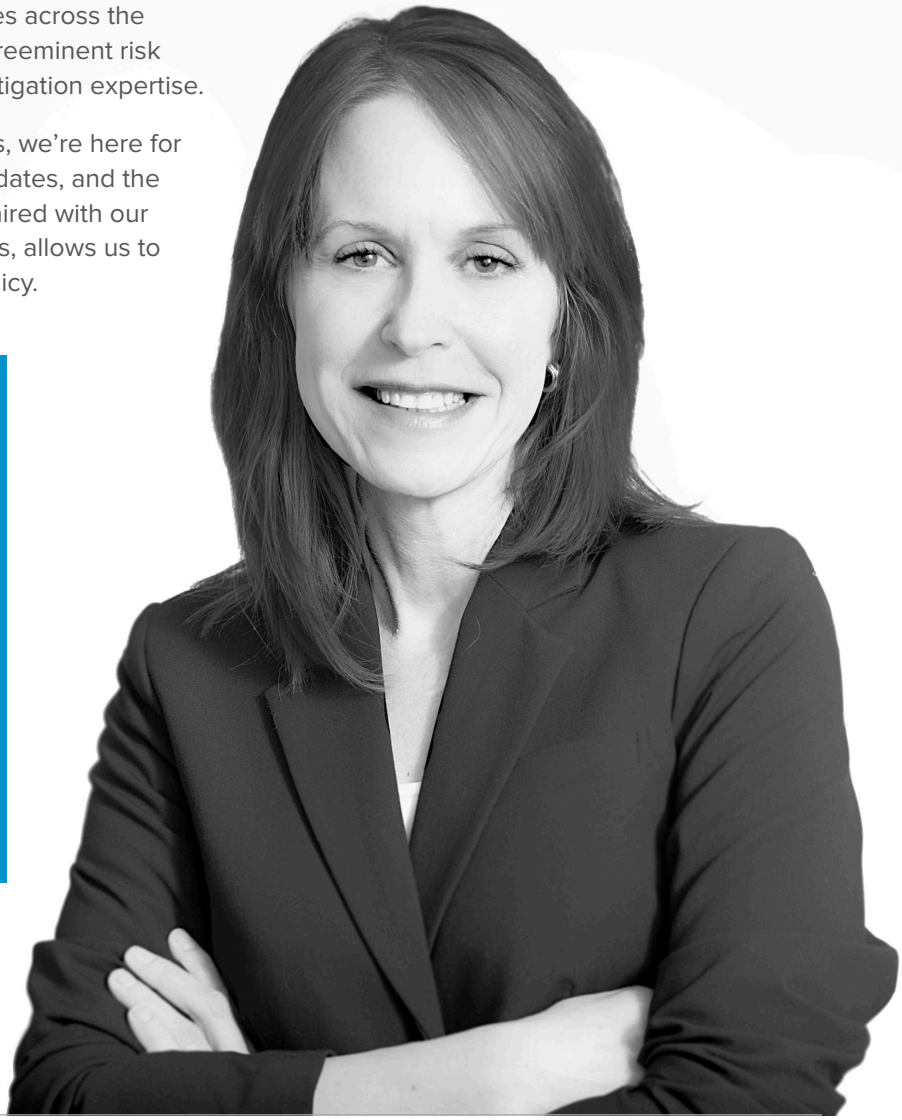

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TELEPSYCHIATRY CHECKLIST – MODIFIED PER CORONAVIRUS UPDATES (8/30/21)

- □ I have reviewed my state's law on telemedicine, including, but not limited to:
  - □ In-person examination requirements
  - □ Prescribing requirements

    9/1/21: States may have waived some of the requirements during their COVID States of Emergency, but these waivers are ending.

- □ If I'm located in a state where I'm not licensed, and I'm not seeing any patients located in that state:
  - □ I have confirmed with that state's licensing board that no license is necessary to treat out-of-state patients.

- □ If a patient will be treated in a different state:
  - □ Licensure
    - □ I am licensed in the patient's state, all state requirements are met (CME requirements, PMP requirements, etc...)
  - □ Law
    - □ I have reviewed the law on telemedicine in the patient's state, including, but not limited to:
      - □ In-person examination requirements
      - □ Prescribing requirements
      - □ Informed Consent

- □ I am using HIPAA-compliant equipment
  - □ If the equipment vendor stores any patient information, I have a Business Associate Agreement from the vendor

  3/19/20: The federal government has exercised "its enforcement discretion and will waive potential penalties against health care providers that serve patients through everyday communication technologies during the COVID-19 nationwide public health emergency. This exercise of discretion applies to widely available communication apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID-19."

  https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html

  The federal COVID Public Health Emergency is expected to continue to be renewed every 90 days through 2021, and we expect to get 60 days notice of its expiration. (9/1/21)

□ I understand that services are considered rendered at the patient's location, not my location

□ I understand that the standard of care for telepsychiatry services is the same as for in-person visits

3/19/20: This is still true. So, for example, just as you need to get a patient in crisis to the hospital from your office, you would need to be able to call emergency services if a remotely treated patient is in crisis. Be sure to know the patient's exact location at the beginning of each session.

□ I understand that this treatment modality is not appropriate for all patients and I engage in careful patient selection

□ I re-evaluate periodically the appropriateness of treatment

□ I require patient identification at the first session

□ I confirm patient location at the start of every session

□ I obtain informed consent to the use of telepsychiatry, in addition to informed consent to treatment

3/19/20: if written informed consent is not possible, at least document consent obtained verbally.

□ If I am prescribing, I am complying with:

- □ State law in my state and, if different, state law in the patient's state
- □ Check the Prescription Monitory Program, as applicable
- □ Federal law, if prescribing controlled substances, by:
  - □ Having a DEA registration in my state as well as each patient's state (if different from my state)

    3/31/20: The DEA has temporarily waived the requirement to have a DEA registration in the patient's state for the duration of the federal COVID Public Health Emergency.

  - □ Seeing patient one time in person prior to prescribing controlled substances

    OR

    - □ Qualifying for one of the DEA's very limited exceptions to the one in-person visit rule

    3/19/20: The DEA has reminded providers of the public health emergency exception to the one in-person visit prior to prescribing controlled substances. www.deadiversion.usdoj.gov/coronavirus/html

- □ I provide appropriate patient monitoring, including follow-up on testing ordered
- □ I provide appropriate follow-up care
- □ I maintain appropriate documentation of all sessions
- □ I have contingency plans for:
  - □ Clinical emergencies – including contact information for local authorities in the event of a crisis
  - □ Technical failures: such as continuing the interrupted video sessions by phone

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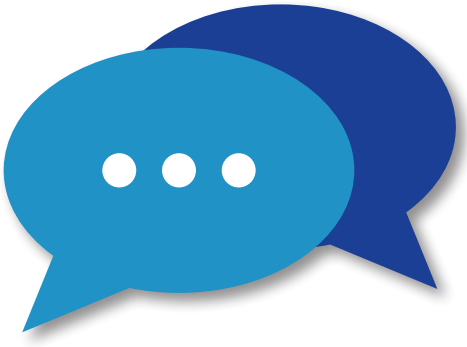
TELEPSYCHIATRY: A PRIMER

INTRODUCTION



Telemedicine, and specifically telepsychiatry, has been practiced in this country since at least the mid-1960s. In 1964, the Nebraska Psychiatric Institute received a grant for the National Institute of Mental Health to link the Institute with Norfolk State Hospital (over 100 miles away) by Closed-Circuit Television. Later the Institute was also linked to the Omaha Veterans Administration (VA) Hospital and other VA hospitals.

Several other telemedicine programs also started in the late 1960s and through the 1970s, mostly to provide services to rural or remote populations, or to provide access to specialists in towns with only general practitioners.[1] As of this publication, the American Telemedicine Association (ATA) estimates that there are about 200 established telemedicine networks involving almost 3,500 sites.[2]

As technology has advanced it has not just been large institutions who have engaged in the use of telemedicine, but also individual practitioners many of whom are psychiatrists. This trend is expected to continue as recent developments and events have brought increased focus to the need for greater access to mental healthcare. This booklet is intended as a guide to assist those psychiatrists contemplating the use of telepsychiatry in their practices in evaluating both the risks of telepsychiatry and their ability to minimize those risks.

DEFINITIONS

Although different agencies and organizations use slightly different definitions, "**telehealth**" essentially encompasses all applications of technology to the healthcare field. This includes but is not limited to providing distance medical education, certain public health endeavors, health administration, and long-distance clinical care.[3]

"**Telemedicine**" is now generally thought of as one component of telehealth and is generally defined as being limited to the use of technology to facilitate clinical care at a distance. For example the Centers for Medicare and Medicaid Services (CMS) define telemedicine as "... the use of medical information exchanged from one site to another via electronic communications to improve a patient's health."[4] Similarly, the American Telemedicine Association defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology."[2]

"**Telepsychiatry**" is a subset of telemedicine. The practice of telepsychiatry encompasses tools used in telemedicine for the purpose of addressing a patient's psychiatric needs.

More important than general definitions will be the definition of telemedicine used by the specific state(s) in which you intend to practice. This is true because, depending upon what state you are in (or connecting to), the activity you're planning may or may not be deemed to be the practice of telemedicine. This in turn, may impact whether there are specific laws or regulations with which you must comply. For example, in California, the Medical Board has stated,

> "Telehealth is not a telephone conversation, email/instant messaging conversation, or fax; it typically involves the application of videoconferencing or store and forward technology to provide or support health care delivery."[5]

And in New York:

> "Telemedicine means the delivery of clinical health care services by means of real time two-way electronic audio-visual communications with facilitate the assessment, diagnosis, consultation, treatment, education, care management and self-management of a patient's health care while such patient is at the originating site and the health care provider is at a distant site."[6]

> "The term "telehealth" means the use of electronic information and communication technologies by telehealth providers to deliver health care services, which shall include the assessment, diagnosis, consultation, treatment, education, care management and/or self-management of a patient. Telehealth shall not include delivery of health care services by means of audio-only telephone communication, facsimile machines, or electronic messaging alone, though use of these technologies is not precluded if used in conjunction with telemedicine, store and forward technology or remote patient monitoring.
>
> Telemedicine means the use of synchronous, two-way electronic audio visual communications to deliver clinical health care services, which shall include the assessment, diagnosis, and treatment of a patient, while such a patient is at the originating site and a telehealth provider is at a distant site."[7]

By contrast is Ohio's statute:

> "...the practice of telemedicine means the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication, by a physician located outside this state."[8]

TELEPSYCHIATRY: GETTING STARTED

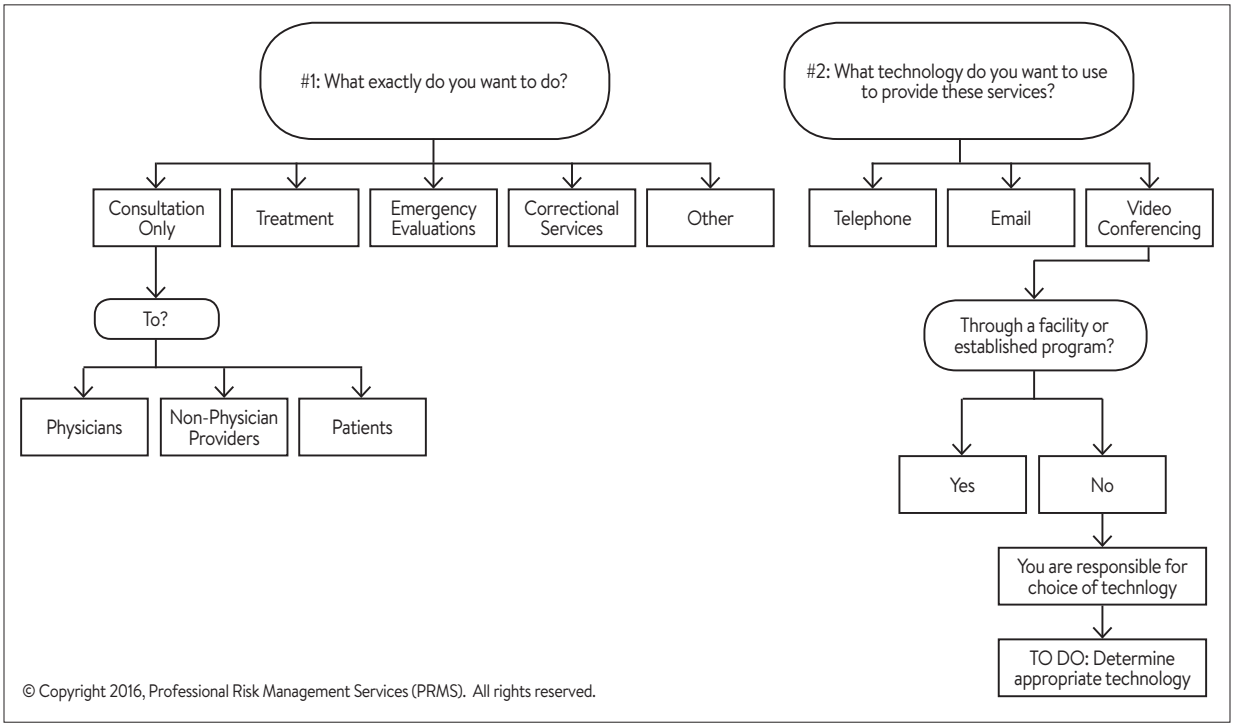
Psychiatrists who contact our Risk Management department with questions on the use of telepsychiatry fall into two major categories: those who have a particular patient (or patients) whom they wish to treat remotely, and those who are contemplating the use of telepsychiatry as a way to expand their practices either by affiliating with a company that provides telepsychiatry or by setting up as a service within their own offices. Regardless of whether your intent is to use telepsychiatry once or to make it a routine part of your practice, your initial considerations are the same.

STEP ONE: Determine what exactly you want to do

When contemplating the use of telepsychiatry, the first questions to ask yourself are, what activities do I wish to engage in and what services do I want to perform? Do I want to offer consultation to other healthcare providers? Treat patients directly? Perform emergency evaluations? Provide service to a specific population such as inmates at a correctional facility? Will I be prescribing medication?

Once you have answered the question of what it is you want to do, you must then think about how you want to do it. Do you want to provide services directly on your own or do you want to collaborate with others such as an internal medicine group or through an established telemedicine program at a facility? Perhaps you want to contract as a provider with a company that offers telemedicine services. What technology will be used?

Figure 1



The following is one example of how telemedicine has been used in psychiatry and also of the unpredictability of the courts as this area of law develops.

CASE EXAMPLE

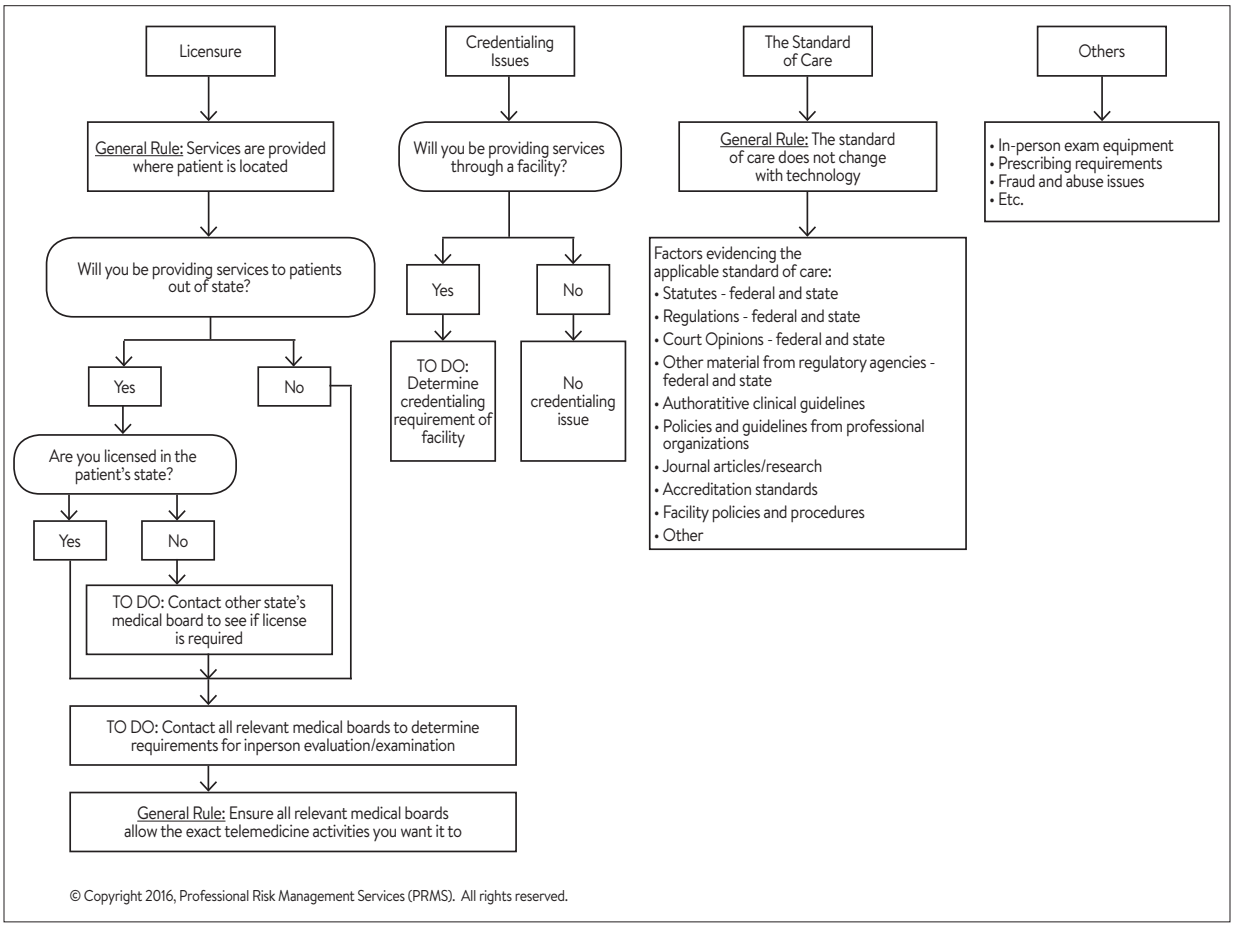
Doctor was conducting a telepsychiatry research study in which a 14-year old female patient participated at the suggestion of her case manager. As part of the study, the patient and her parents completed pre-assessment documentation which was followed by a 90-minute consultation with the psychiatrist via telemedicine. Afterward, patient and her family completed a survey about their reaction to the use of telemedicine. The psychiatrist subsequently provided them with his consult report setting forth his diagnostic impressions and his recommendations for an initial treatment plan. It was specifically stated that there would be no follow-up, no medications would be prescribed and that the patient's treatment team was to decide upon the course of treatment. No further contact occurred. Ten months later, the

patient suicided by a variety of medications, none of which had been recommended by the psychiatrist. The patient's family subsequently brought suit naming the psychiatrist as one of the defendants. The psychiatrist was initially dismissed from the case by the trial court who found that no duty existed on the part of the psychiatrist at the time of the death; however, the patient's family appealed. The state Supreme Court reversed the trial court, ruling that a limited doctor-patient relationship was established, and therefore the psychiatrist assumed a duty to act in a manner consistent with the standard of care and to not harm the patient. The Court noted that it was too early in the case to determine the scope of the psychiatrist's duty and the standard of care, and left it to the trial court to continue with the case against the psychiatrist and the other defendants.[9]

STEP TWO: Overcoming legal hurdles

Depending upon the type of activity you have chosen to perform and the technology you want to utilize, there may be legal requirements that must be met. Among these are licensure, credentialing, standard of care, and other state-specific requirements.

Figure 2



Licensure

After you have defined the scope of your telepsychiatry practice, the next step is ensuring that you can meet all of the legal requirements; the first of which is licensure. Many psychiatrists erroneously believe that because they are licensed in the state in which they will be located during the patient encounter, they have met the legal requirements. In fact, a physician is deemed to be practicing medicine in the state in which the patient is physically located at the time of treatment and thus he or she must meet the licensure requirements of that state. Currently each state has its own rules and whether a license is required may vary depending on several factors including: type and frequency of the encounter, duration of treatment, whether another local psychiatrist is also involved in care, etc. Some states have limited telemedicine certificates that may be obtained by out-of-state physicians for the sole purpose of practicing telemedicine within their states.

SAMPLE STATE LAWS

> *"A physician who uses telemedicine in the diagnosis and treatment of a patient located in Iowa shall hold an active Iowa medical license consistent with state and federal laws." Iowa Administrative Code 653-1311*

> *"The practice of medicine is deemed to occur in the state in which the patient is located. Therefore, any licenses using telemedicine to regularly provide medical service to patients located in North Carolina should be license to practice medicine in North Carolina."*[10]

> *"Physicians and physician assistants who practice or hold out to practice or engage in any physician-patient relationship in New York must be licensed and currently registered in New York...The practice of medicine through telemedicine in New York State by someone not authorized to practice in New York State may constitute the illegal practice of a profession, subject to investigation by the New York State Education Department and prosecution by the New York State Attorney General."*[11]

If you are contemplating treating a patient who will be located in a state in which you do not hold a current medical license, the following steps should be taken:

- Contact the remote state's licensing board and explain your intended activities
- Ask whether a state license is required
- Contact your own licensing board to ensure its requirements have been met
- Contact should ideally be in writing or via email to allow for a written record of the board's answer

- Alternatively, note the number called, the date, time, with whom you spoke, the question posed, and the answer given

The Federation of State Medical Boards, in an effort to promote telemedicine and allow greater access to care, has proposed a licensure compact to make it easier for physicians to obtain licenses in other states . As of the date of this publication 12 states have adopted this compact. While adoption of the compact by states may ease the process of obtaining a license in that state, it will not negate the need for individual state licenses.

Understand also that although what you plan on doing (e.g., telephone consultation) may not fit your state's (or that of the patient) definition of "telemedicine," that does not mean that the issue of licensure is moot. If you are tempted to proceed without requisite licensure consider this. In many states the practice of medicine without a license is considered a criminal act. Should you be involved in a claim or a lawsuit, coverage may be denied as criminal acts are an exclusion under malpractice insurance policies. In a worst case scenario, you might find yourself subjected to criminal prosecution, licensing board actions, and a malpractice lawsuit all without defense coverage.

CASE EXAMPLE

A Colorado psychiatrist was charged with a single felony count of practicing medicine without a valid California license after he prescribed an antidepressant over the internet to a 19-year old California college student. Following the student's suicide, the medical examiner found the prescribed medications in the patient's system. Although the doctor initially argued the California court lacked jurisdiction to prosecute him, after the California appellate court ruled that California did in fact have jurisdiction, he pled no contest and was sentenced to nine months in jail.[13]

Credentialing

If you intend to provide telepsychiatry services through a hospital, you will need to consider the issue of credentialing which may be a lengthy process. The Centers for Medicare and Medicaid and The Joint Commission do allow credentialing by proxy where the governing body of the hospital whose patients are receiving telemedicine services may choose to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services.[14]

The Standard of Care

The Standard of Care is a legal concept but is based upon clinical standards determined by the medical profession. The actual definition varies by jurisdiction but a good general definition is the degree of skill, care, and diligence exercised by members of the same profession/specialty practicing in light of the present state of medical science. What care meets the standard of care ultimately depends upon the particular patient and his or her unique needs; however, there are certain documents that could potentially be used in court as evidence of what care meets the standard of care. Examples of these are:

- Statutes – state and federal
- Regulations – state and federal
- Case law – state and federal
- Rules, guidelines, and policy statements from state and federal regulatory agencies and state medical boards
- Authoritative clinical guidelines
  - *AACAP's Practice Parameter for Telepsychiatry With Children and Adolescents.*
  - APA's Resource Document on Telepsychiatry and Related Technologies in Clinical Psychiatry
- Policies and guidelines from professional organizations
  - *Federation of State Medical Boards' Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*
  - American Telemedicine Association
    - *Evidence-Based Practice for Telemental Health*
    - *Practice Guidelines for Videoconferencing-Based Telemental Health*
    - *Practice Guidelines for Video-Based Online Mental Health Services*
- Learned treatises
- Journal articles
- Research reports
- Accreditation standards
- Facility's own policy and procedures
- PDR recommendations

- Drug manufacturer recommendations

When practicing telemedicine, one must consider not only meeting the standard of care from a *clinical* perspective but also meeting the standards required for the practice of *telemedicine*. Many states have very specific regulations for telemedicine practices that must be complied with. In addition to licensure requirements, be aware of other rules and regulations your state (and that of the patient) may have regarding telemedicine practice as you will be required to comply with both sets of rules. These may include requirements for such things as:

- Documentation
- Obtaining informed consent for the use of telemedicine
- Establishing a treatment relationship
- The need for a face-to-face visit prior to prescribing
- Type of equipment used
- Etc.

Failure to follow these requirements could subject you to a licensing board action. In addition, there are various professional organizations and associations (such as the Federation of State Medical Boards and American Telemedicine Association) that have issued guidelines for the practice of telemedicine that may also inform the standard of care. Evidence of failure to comply with various rules and guidelines could potentially be used to establish that the standard of care was not met in the event of a lawsuit. (For more information regarding the standard of care, see Clinical Hurdles below.)

It is important to remember that the standard of care for treatment via telemedicine is *exactly* the same as it would be were the patient seen in a face-to-face encounter. Many states have issued policy statements to this effect two examples of which are set forth below:

New York:

> "All the current standards of care regarding the practice of medicine apply. The fact that an electronic medium is utilized for contact between parties or as a substitute for face-to-face consultation does not change the standards of care."[11]

Texas:

> "Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of acceptable medical practices as those in tradition in-person clinical settings."[15]

OTHER CONSIDERATIONS

HIPAA Compliance

If you are practicing telepsychiatry through a program at a facility or an established telemedicine provider, presumably the issue of HIPAA compliance will have already been addressed. If, however, you are going it alone and contemplating the use of an online platform, you personally will be responsible for ensuring that the chosen platform complies with HIPAA and relevant state laws.

HIPAA privacy and security protections represent the *minimum* of what is required in terms of confidentiality standards. This is true regardless of whether you are a covered entity under HIPAA as several courts have recently allowed HIPAA rules to be used as evidence of the standard of care.[16]

If you utilize a system wherein patient-identifying information is created, received, maintained, or transmitted, you must have in place a Business Associate Agreement with the system vendor. If the information is not stored and the system merely acts as a conduit then the vendor is not a Business Associate under HIPAA.[17] Take note, however, that the conduit exception applies to *very few* situations and thus, if your system vendor is unwilling to provide a Business Associate Agreement, you must closely scrutinize their privacy policy to confirm that they are not Business Associates. Remember, it is *your* responsibility to ensure HIPAA compliance.

CASE EXAMPLE

An Oklahoma psychiatrist who was disciplined by his licensing board after it received three complaints stemming from his telepsychiatry practice. Two complaints were in regard to his prescribing practices and another, from the state Medicaid program, alleged that he was treating Medicaid patients via telemedicine using Skype which was not a Medicaid approved network. The Medicaid complaint also alleged that he had prescribed controlled substances without and in-person evaluation and that he had failed to get patient's consent for the use of telemedicine. The state Medicaid program provided for reimbursement of telemedicine visits if, among other things, HIPAA and state privacy requirements were maintained and followed at all times, and the network used was on the list of Medicaid-approved telemedicine networks. Additionally, the Oklahoma Board of Medical Licensure and Supervision had a telemedicine policy that required the use of a telemedicine network that met all technical and confidentiality standards as required by state and federal law, as well as the patient's written consent to participate in telemedicine. The doctor was

found guilty of nine counts of unprofessional conduct; however, these did not include the inappropriate use of technology. Subsequently, the Oklahoma medical board issued rules stating that internet contact such as web-based video does not meet the equipment requirements thus necessitating an actual face-to-face encounter between physician and patient, and stating that technology used must be HIPAA compliant.[17]

Prescribing

If part of your treatment plan includes prescribing medication, you should be aware of relevant federal and state laws regarding the internet prescribing of controlled and non-controlled medications. (To clarify, internet prescribing should not be confused with ePrescribing where a physician sends a prescription electronically to a pharmacy.) Prior to prescribing any medications, most states require that a physician-patient relationship exist between the patient and prescribing physician. Other requirements many include the need for a physical examination before a prescription may be written. What constitutes a valid physical examination varies greatly from state to state. Several states do allow for these examinations to take place via telehealth technologies; however many also uniformly prohibit "prescribing based solely on information about a patient that the physician has gathered from an online questionnaire."[18]

SAMPLE STATE LAWS AND POLICIES

Maryland Regulation 10.32.05.05

A. A physician shall perform a patient evaluation to establish diagnoses and identify underlying conditions or contraindications to recommend treatment options before providing treatment or prescribing medication.

B. A Maryland-licensed physician may rely on a patient evaluation performed by another Maryland-licensed physician if one physician is providing coverage for the other physician

C. If a physician-patient relationship does not include prior in-person, face-to-face interaction with a patient, the physician shall incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation.

Arizona Medical Board Substantive Policy Statement #12 – Internet Prescribing

Prior to prescribing any medication or device a physician must obtain a reliable medical history, conduct an appropriate physical examination, and establish a proper diagnosis for the medication or device being prescribed. A physician cannot rely on a questionnaire submitted over the internet to meet these requirements.

CASE EXAMPLE

An Idaho-licensed physician was disciplined by the state board of medicine after she ordered an antibiotic prescription for a patient she had not seen following a telephone consult. The doctor was working for a telemedicine company called "Consult-A-Doctor" who would refer calls to her for consults in one of the nine states in which she was licensed. In its opinion, the Board stated that a telephone patient encounter is telemedicine. The physician was disciplined for, among other things, failure to do an appropriate physical examination of a patient complaining of a respiratory tract infection.[17]

Prescribers must also bear in mind federal law, specifically the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 which amends the Controlled Substances Act. Ryan Haight was a 17 year-old who overdosed and died after taking prescription drugs he had received from an online website. He had been able to obtain them simply by completing an online questionnaire which was then forwarded to a physician who wrote a prescription without ever seeing him with the drugs delivered to his home. Following to the Act, no controlled substance may be delivered, distributed or dispensed by means of the Internet without a valid prescription. Whether a prescription is valid is based upon whether the patient was examined in-person by the physician writing the prescription. The Act does, however, provide exceptions for certain telemedicine activities such as when the patient is located in a hospital or other facility registered with the DEA and the remote physician/prescriber possesses a DEA license in the patient's state.

While the intent of the Ryan Haight Act was well-reasoned, the wording of the law has proved to be troublesome for the advancement of telemedicine – particularly telepsychiatry. In an effort to remedy this, on October 15, 2015, the American Telemedicine Association (ATA) sent a letter to the DEA advocating a "structured yet flexible framework for appropriate online prescribing that recognizes long-standing practices by legitimate, licensed providers who offer needed medical services to a highly targeted group of patients" that would recognize a distinction between telepsychiatry and other forms of telemedicine.[19] Stay tuned.

CLINICAL HURDLES

Assuming you are able to satisfy licensure requirements and other state and federal regulations, you are by no means home free. Once you have determined that you can legally practice telemedicine, the next thing to ask yourself is whether you should?

As a psychiatrist, you have spent many years evaluating patients and assessing their current needs. No doubt you have patients whose status you can determine just by the way they walk into your office. But what happens when that's taken away and what you have instead is a two-dimensional view of your patient on screen? Are you absolutely certain that you can meet the standard of care?

When providing care via telepsychiatry, you must be cognizant of the problems of lost abilities; in other words, the inability to use (or fully use) certain senses to examine the patient. For example, if you are treating a patient with an alcohol abuse problem, being able to smell the patient's breath or to determine whether he or she had a hand tremor or unsteady gait might be important. Less easy to articulate is the sixth sense that most psychiatrists have with regard to their patients that lets them know immediately if a patient is not doing well. This ability is often lost in telemedicine. All of this becomes very important because, as previously stated, the standard of care does not change when you are treating a patient remotely. You are expected to be able to render the exact same level of care you would provide were the patient in your office.

Figure 3

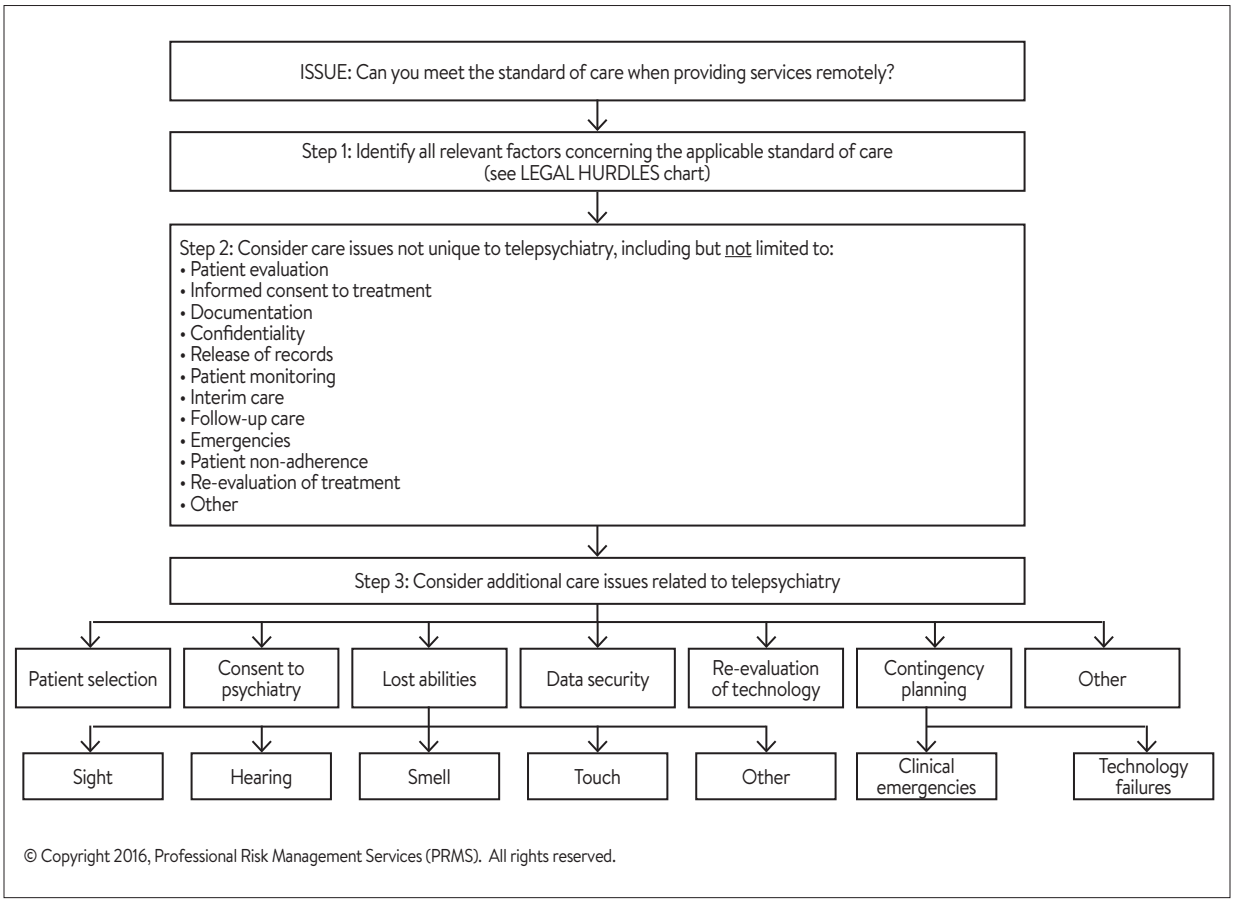


Figure 3 sets forth those issues a psychiatrist must routinely deal with when treating patients in an office setting. By now handling each of these is likely second nature to you but stop for a moment and consider whether the processes you currently have in place will work when seeing the patient via telemedicine.

- How will you monitor your patient remotely?
- Will you be able to spot patient non-adherence?
- How will interim care be provided?
- How will prescriptions be handled?

None of these issues are insurmountable; however, it is important to determine how they will be handled *before* you begin seeing patients via telemedicine.

In addition to possibly modifying your procedures to fit with remote providing care at a distance, you must also consider the additional care issues that are related to telepsychiatry.

ADDITIONAL CARE ISSUES

Patient Selection

Psychiatrists routinely engage in patient selection by using initial and ongoing evaluations to identify patients who are and who are not a good fit for the psychiatrist's particular practice. In the context of telepsychiatry, it may be helpful to first define a general patient population for whom telepsychiatry would be an appropriate method of delivering care.

Begin by thinking about what conditions you routinely treat and which of these might reasonably be managed remotely, taking into consideration the problem of lost abilities. Whether a condition may be managed remotely will be affected by the model of telepsychiatry you have chosen. For example, if you are treating a patient who will be in the presence of another healthcare provider, that person may be able to compensate for your lost abilities, but if the patient is not in the presence of another, the problem of lost abilities may make optimal care difficult.

There are other considerations:

- Is your patient stable?
- Is your patient tech-savvy enough to handle the equipment and possible tech glitches?
- Do you trust your patient?
- Will your patient be truthful about his or her location during the session?
- Where will your patient be located at the time of treatment?
  - > Will your patient have sufficient privacy to communicate freely?
- Has this patient been a reliable reporter in the past?
- How will the use of telemedicine impact this particular patient?
  - > Will it create an uncomfortable distance between the two of you or will it actually make the patient feel more at ease and more likely to disclose important information?
  - > How will such a setting impact progression toward treatment goals?

Additionally, in its Practice Guidelines for Video-Based Online Mental Health Services, the ATA recommends the following:

- Geographic distance to nearest emergency medical facility
- Efficacy of patient's support system
- Current medical status
- Patient's general level of competence upon technology
- Patient's ability to arrange appropriate setting for receiving videoconferencing
- Patient's continued cooperativeness regarding managing safety issues
- Cognitive capacity
- History regarding cooperation with treatment professionals
- Past difficulties with substance abuse
- History of violence or self-injurious behavior

Even if your patient appears to be a good candidate for the use of telepsychiatry initially, these questions must continually be re-asked during the course of treatment to ascertain whether your patient continues to be a good candidate and is truly benefitting from its use.

CASE STUDY

Dr. Jones, a New York psychiatrist, has been treating Mr. Smith for schizophrenia with an antipsychotic for about a year, and the medication has successfully controlled the psychotic features that were present when treatment began. Now Mr. Smith is planning to move to Texas but because of the success of treatment with Dr. Jones and the strong working relationship they have developed, Mr. Smith wishes to continue having Dr. Jones prescribe medication and monitor his treatment.

Because Dr. Jones is also licensed to practice medicine in Texas, he is considering telepsychiatry options. Among the available options are telephone sessions, e-mail exchanges, webcam chat sessions, and the telemedicine facility at an academic medical center near where Mr. Smith will be living. Presumably, Dr. Jones will need to continue monitoring for early signs of movement disorders. How will Dr. Jones accomplish this?

If Dr. Jones uses only phone or e-mail exchanges, it will be impossible for him to visually observe Mr. Smith, and he will be relying on self-reports only. Webcam chat sessions may partially restore Dr. Jones's ability to see Mr. Smith, but can Dr. Jones

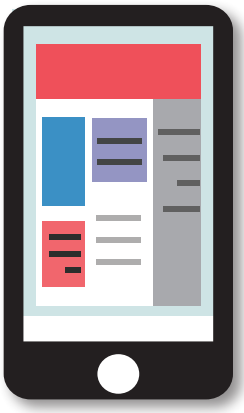
be confident that the video stream will always be smooth enough that small tics or muscle twitches will be as evident as they would be to the naked eye? Will his field of vision be wide enough, and the image large enough, to adequately observe Mr. Smith's gait for any abnormalities?

It is crucial that Dr. Jones examine how his choice of telepsychiatry impacts his ability to adequately monitor Mr. Smith, as well as his ability to treat him. A good way to approach this is by examining lost and restored abilities in the context of evaluation and intervention.

In the most basic and broad sense, the standard of care in any situation comprises two elements – what the psychiatrist is expected to do to evaluate the patient, and what he is expected to do to intervene with the patient.

When a patient is not physically present with the psychiatrist, all ability to evaluate and intervene has been lost. In telemedicine, technology is used as a tool for restoring some lost abilities. However, technology will not always be able to restore all abilities, nor will it always completely restore any ability. In the example of Dr. Jones, various forms of technology may restore his basic abilities to communicate with, hear, and/or see the patient – but the limitations of the technology used may still prevent him from being able to adequately monitor for early signs of a movement disorder.

Consent to Telepsychiatry



In some states, e.g., California,[20] consent to the use of telepsychiatry is mandated. Even where this is not the case, psychiatrists should obtain their patients' consent to the use of telepsychiatry *in addition* to obtaining consent to treatment. Patients who are familiar and comfortable with a wide range of technologies may not understand some aspects of telepsychiatry, and psychiatrists should obtain informed consent to the use of telepsychiatry in delivering care. Part of this conversation should include discussing the limitations of telepsychiatry. Patients should be made aware of the issue of lost abilities and the potential that conditions that could be diagnosed with an in-person visit may go undetected in a remote encounter.

The chosen telepsychiatry method may present privacy considerations not present in traditional office-based practice. If so, these should be incorporated into the informed consent discussions as well. Psychiatrists should also be aware of any laws, regulations, or rules in their states related to specific requirements for informed consent in telemedicine.

In its *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, the FSMB recommends the following:

"Evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following terms:

- Identification of the patient, the physician and the physician's credentials;
- Types of transmissions permitted using telemedicine technologies (e.g., prescription refills, appointment scheduling, patient education, etc.);
- The patient agrees that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- Hold harmless clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party."[12]

In their *Practice Guidelines for Video-Based Online Mental Health Services*, the ATA recommends that the following key topics be reviewed with patients during the consent process:

- Confidentiality and the limits of confidentiality in electronic communication;
- An agreed upon emergency plan, particularly for patients in settings without clinical staff immediately available;
- The process by which patient information will be documented and stored;
- The potential for technical failures;
- Procedures for coordination of care with other professionals;
- A protocol for contact between sessions;
- And conditions under which telemental health services may be terminated and a referral made to in-person care.[21]

Contingency Planning

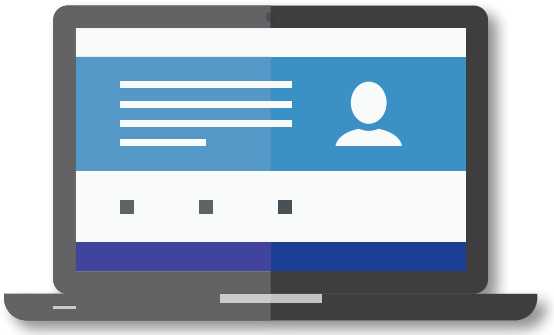
Even though your patient may be very stable you must still have a plan for handling emergencies just as you would were the emergency to occur in your own office. As you are expected to provide the same level of care to a patient being seen via telepsychiatry, you should be as familiar with the resources available at the patient's location as you would be with the resources available to patients seen in-office. Consider the following:

- What would you do if a patient were to become actively suicidal or suffer a seizure or a heart attack during a session?
- You know generally that a patient is located in a specific city during your sessions but do you know the precise address of his location?
- Do you know the telephone number for the local police?
- Do you know how to have your patient involuntarily hospitalized?
  - Can you do so if you are not local?
- Do you have an alternative plan?
- How would you handle a technology failure?
  - Do you have another way to continue the session offline?

Technology allows patients to communicate with physicians from anywhere they can find a signal, whether using cable, closed-circuit television, phone lines, cellular phone towers, wireless internet, or satellite. Therefore, it is important for you to have some confidence about where your patient is actually located during the telepsychiatry session. A patient who uses his laptop with built-in webcam to connect for live video chat could just as easily be at home in Connecticut as at a hotel in Montana. Uncertainty about patient location can pose challenges for reacting to emergencies.

It is also important to be familiar with the non-emergency medical resources available to the patient. For example, a psychiatrist in New York City may not have as many consultative resources available when treating a patient in rural Mississippi, and should be aware of what resources are and are not available both during patient selection and throughout the treatment relationship.

Optimizing the Encounter



If you've never communicated with anyone via video-teleconferencing, you might be surprised at how different the interaction is. It might actually be a good idea to practice with someone before you "see" patients. How to you appear on screen? Think about things like background lighting, whether you are wearing a pattern that "vibrates." Are you sitting close enough to the camera but not too close? Are you making certain that you enunciate clearly and take into consideration the delays in transmission? You may find that you need to accentuate your speech as you may come across as flat on camera. Is there any background noise that might be heard by the other party? Remember also that if you are looking at the screen when you speak, you may not be looking into the camera and it will appear that you are looking down rather than at the patient. These same suggestions will be beneficial to your patient for the best presentation from his end. Consider the following:[22]

Backdrop

- Neutral hues (beige, tan, pale gray, light blue) enhance your picture whereas vibrant colors can reflect light and case hues onto your face
- Avoid striped or patterned walls as these can distort images

Eliminate distracting background noise

- How loud is the HVAC system?
- Can you hear traffic noise?
- Is music playing in the background that might interfere with hearing or distract your patient?
- Do your lights hum?
- Avoid shuffling papers during session
- Do not tap fingers or toes

Lighting

- Ensure that the room is well-lit preferably using light sources as close to daylight as possible

- Lighting should be placed so that psychiatrist and patient are able to see each other's faces without shadows such as behind the camera as opposed to overhead[23]

Camera Position

- Aim to create the illusion of eye contact by placing your patient's image as close to the camera as possible
- Position yourself/the camera so that your eyes appear to be 1/3 down from the top of the screen thus appearing as would a television newscaster[23]

Communication

- Communication should be more deliberate and animated
- Hand gestures should occur at mid-chest and be broader than usual
- Avoid too rapid gestures that may result in pixilation[24]

Documentation

In addition to your usual documentation for a patient appointment, if treating the patient via telemedicine, you should also add the following to your documentation:

- Your location and that of the patient at the time of the encounter
- Technology used
- Name and role of anyone else present for the encounter, e.g., a presenter at a remote site
- The patient's continued agreement and satisfaction with the use of the chosen technology
- Any technical problems that occurred during the encounter

TELEPSYCHIATRY: PUTTING IT ALL INTO PRACTICE

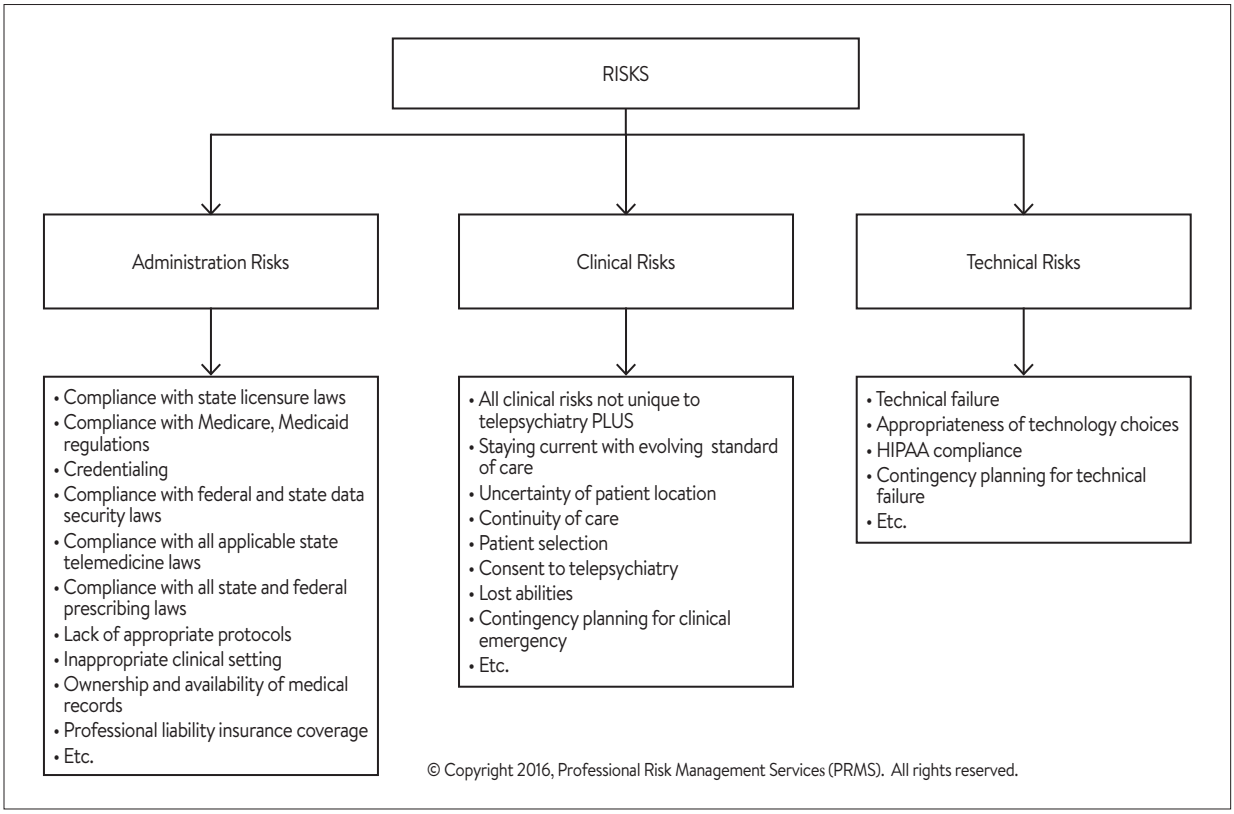
Summary

- Determine your telepsychiatry endeavor
  - > What do you want to do?
  - > What technology do you want to use?
- Determine all relevant laws and other standard of care factors
- Evaluate your ability to comply with legal requirements
  - > E.g., ensure all relevant licensing boards allow you to do the exact telepsychiatry activities you want to do and with the technology you want to use
    - – Licensure requirements
    - – Physical examination requirements
    - – Etc.
- Understand the importance of the location of the patient, both for legal and clinical purposes
- Understand the standard of care does not change with technology
- Evaluate the impact of your proposed telepsychiatry endeavor on your ability to meet the normal standard of care
  - > In addition to meeting all care issues not unique to psychiatry there are additional care issues related to telepsychiatry that must also be met
  - > Understand that technology is a tool that can partially restore lost abilities to evaluate and treat patients at a distance, but technology itself cannot completely restore all lost abilities
  - > Formulate strategies to
    - – Comply will all applicable laws
    - – Restore lost abilities where possible

    - Avoid situations where needed abilities cannot be restored
- Consider what will be lost when treating individual patients re:
    - Communication
    - Ability to diagnose and treat
- Ensure the ability to treat individual patients within the standard of care
    - Carefully evaluate whether a particular form of telepsychiatry is appropriate for a given patient
        - At the beginning of treatment
        - And at clinically significant events
        - And periodically as treatment progresses
    - Determine whether and how the particular form and method of treatment will help the patient progress toward legitimate treatment goals
- Ensure patients have a basic understanding of the technology being used and appreciate its limitations
- Prepare for possible emergencies by having patient addresses and local emergency services numbers available
- Utilize a consent form wherein the patient acknowledges
    - The possibility of a privacy/security breach
    - The possibility that medical conditions may not be able to be observed remotely
- Include in documentation of session
    - That session was conducted via telepsychiatry
    - Location of patient during session
    - Why this method was chosen for this patient
    - Why it continues to be an appropriate treatment option
- Continually re-evaluate physician and patient level of satisfaction

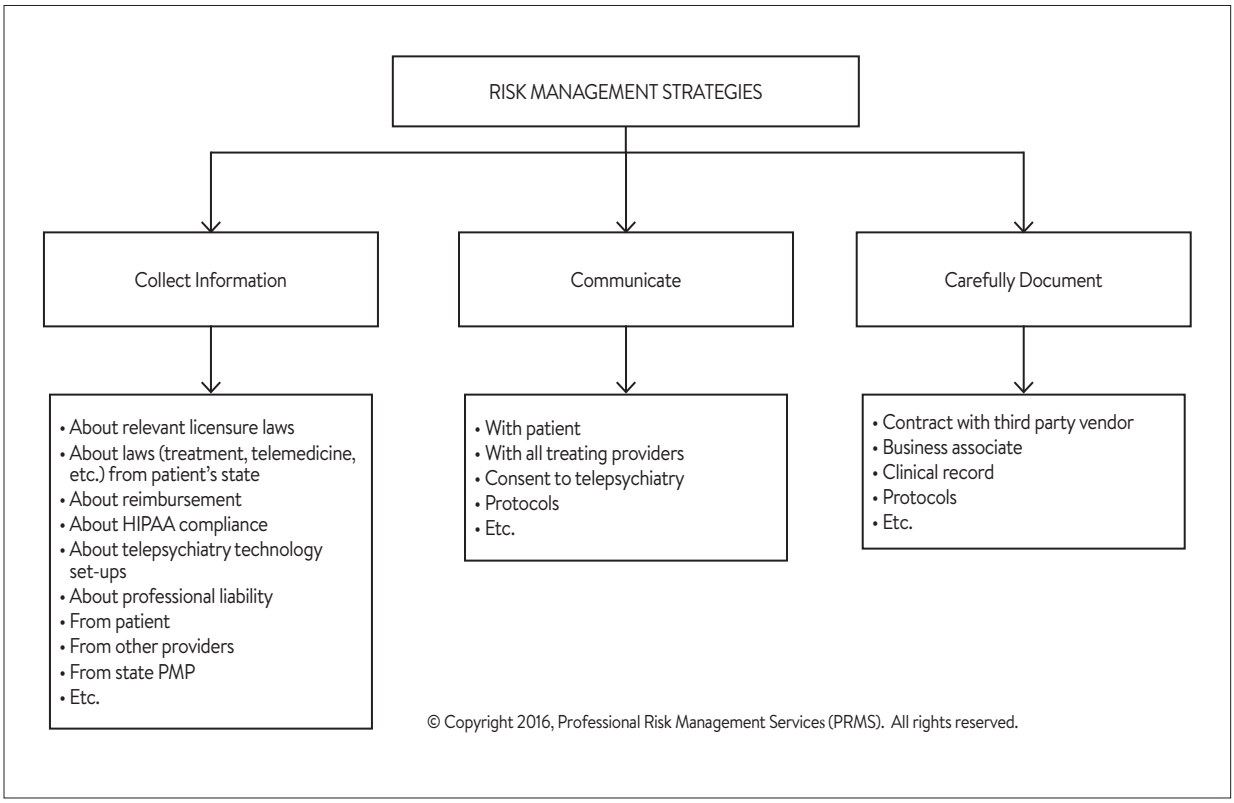
The two charts below summarize the risks associated with the use of telepsychiatry and risk management suggestions for minimizing those risks.

Figure 4



As you have by now realized, treating patients via telepsychiatry carries with it two sets of risks: those related to the usual practice of psychiatry and those related to the use of the technology. Fortunately, the standard risk management strategies you have been taught to use in regular practice may also be used in telepsychiatry: collecting information, communication, and careful documentation.

Figure 5



CONCLUSION

Telemedicine is a rapidly-expanding field and, given the greater focus being placed on access to mental healthcare and the continued shortage of mental health providers, psychiatrists can expect to be a part of that expansion. Because the field is still developing, it is incumbent upon physicians to carefully analyze the implications of any telemedicine activities they wish to undertake. However, with proper preparation and thoughtful risk management, telemedicine can be an invaluable tool for allowing greater access to patients who would otherwise not be able to access their services.

1 Brown, WB. Rural telepsychiatry. Psychiatr Serv. 1998 July 1:49(7):963-4. 1995

2 American telemedicine association. http://www.americantelemed.org

3 See, for example, definitions from the Health Resources and Services Administration (http://www.hrsa.gov/telehealth) and the Center for Telehealth and eHealth Law (http://www.ctel.org)

4 http://www.cms.gov/Telehealth

5 http://www.mbc.ca.gov/Licensees/Telehealth.aspx

6 NY Public Health Law §2805-u

7 http://cchpca.org/ny-state-law-telemedicinetelehealth-definition

8 OH ST § 4731.296

9 White v. Harris 190 Vt 637, 36 A.3d 203 (2011)

10 http://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/telemedicine

11 http://www.health.ny.gov/professionals/doctors/conduct/telemedicine.htm

12 http://www.fsmb.org

13 Hageseth v. Superior Court, 150 Cal.App.4th 1339 (2007).

14 42 CFR 482.22

15 Texas Administrative Code Rule §174.8

16 Vanderpool, D. (2015). Legal aspects of teleanalysis in the United States In J. S. Scharff (Ed.), Psychoanalysis online 2 (pp. 93-104). London: Karnac

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21 American Telemedicine Association. Practice Guidelines for Video-Based Online Mental Health Services ATA. May 2013

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