

ARIZONA  
TELEMEDICINE  
PROGRAM



# Standards, Guidelines & Telemedicine as Standard of Care

**Elizabeth A. Krupinski, PhD**

# Why Need Guidelines?

- **Supply health care professionals with needed support & information**
- **Improve health care quality & encourage more efficient use of limited health care resources**



# Guidelines & Policy

- **Federal & state government**
  - General healthcare policy
  - Medicare & Medicaid
  - Liability standards
- **FDA (especially medical devices)**
- **Professional societies**
  - Daily practice
- **Funding opportunities**



# TM Guidelines

- **TM rapidly evolving & tech advancements impact scope & extent clinical practice**
- **Rigorous evaluation key to developing guidelines, shaping policy, growing & promoting practice**
- **When research lacking, assessment based on clinical consensus & review existing data performed**

# Guidelines

- ATA practice guidelines
- Professional societies
  - ACR, ASHA, APA, ADA
- Technical requirements (min) often included & standards available as well (HL7, DICOM, FDA)
- Standard guidelines & requirements for medical practice
- Common sense!



Dr. Colton is asking that everyone in the waiting room wear a mask to protect patient privacy."

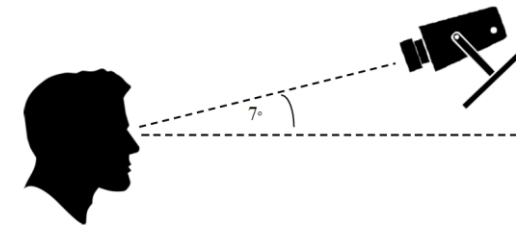
<b>Step 1: Identification of Practice Guideline Subject Area</b>	<ul style="list-style-type: none"> <li>• Topic Identified (Standards &amp; Guidelines Committee or Member request)</li> <li>• Board review/approval</li> </ul>
<b>Step 2: Planning Phase</b>	<ul style="list-style-type: none"> <li>• Appointment of a stakeholder work group</li> <li>• Plan and refine project scope</li> <li>• Assign work group member roles into subgroups: clinical, technical, administrative</li> </ul>
<b>Step 3: Assessment of Validated Outcomes and Best Practices</b>	<ul style="list-style-type: none"> <li>• Develop outline for guidelines sections: clinical, technical and administrative</li> <li>• Develop plan/revise as needed for literature search</li> <li>• Conduct literature search</li> <li>• Filter references</li> <li>• Assemble articles and resources</li> <li>• Conduct assessment</li> <li>• Prepare reports and analyze data</li> </ul>
<b>Step 4: Drafting Guidelines</b>	Subgroups draft guidelines (in-person workshop where funds are available) for clinical, technical, administrative areas
<b>Step 5: Reviews</b>	Draft guidelines reviews/revisions by work group Review 1: Work group Review 2: Chair Standards & Guidelines Committee/ATA staff Review 3: Standards & Guidelines Committee (full) Review 4: Open Public Comment Review 5: Board of Directors
<b>Step 6: Dissemination and Adoption</b>	<ul style="list-style-type: none"> <li>• Promotion</li> <li>• Training</li> <li>• Adoption</li> </ul>
<b>Step 7: Impact Assessment</b>	Evaluate and measure impact of practice guidelines
<b>Step 8: Periodic Updates and Revisions</b>	Periodic review of guidelines to update and revise

# ATA S&G

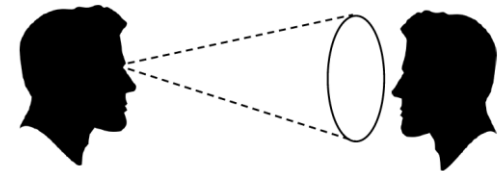
- Telehealth Practice Recommendations for **DR**
- Principles **Telerehabilitation** Delivery
- VC-based **Telepresenting** Expert Consensus Report
- Practice Guidelines VC-based **Telemental Health**
- Evidence-based Practice **Telemental Health**
- Practice Guidelines **Teledermatology & Quick Guides** (SF & VTC)
- Core **Operational** Guidelines Telehealth Services Involving Provider-Patient Interactions
- **Home Telehealth** Clinical Guidelines
- Clinical Guidelines **Telepathology**
- **Video-Based Online Mental Health** Services
- **TeleICU** Operations
- **Live, On-Demand Primary & Urgent Care**
- **Teleburn Care**
- **Telestroke**
- **Telemental Health** Children & Adolescents

# Related Materials

- **Lexicon *Assessment & Outcome Measures* Telemental Health**
- **Quick Guide Eye Contact**
- **Quick Guide for Telemedicine Lighting**
- **ATA State telemedicine Toolkit Medical Board**
- **ATA State Telemedicine Toolkit**
- **ATA State Telemedicine Bill Components**
- **ATA Medical Board Talking Points & FAQ**



Cone of Gaze





# Other S&G

- ACR Standard **Teleradiology**
- AAD Position Statement **Telemedicine**
- APA Statement on Services by **Telephone**
- AMA Guidelines Physician-Patient **Electronic Communications**
- Medem's eRisk Guidelines Physician-Patient **Online Communications**
- Guidelines **Surgical Practice Telemedicine**
- ACR Guidelines Electronic Medical Information **Privacy & Security**
- FDA **Telemedicine Guidance**



Condition	Telemedicine Appropriate	
	Video	Telephone Only*
<b>Routine Conditions That Are Appropriate For Telemedicine Management</b>		
Acid Reflux	Yes	Yes
Acute Conjunctivitis (e.g., uncomplicated viral or allergic)	No	Yes
Allergic rhinitis	Yes	Yes
Anxiety and Depression	Yes	Yes
Assessment of minor wounds	No	Yes
Burns (e.g., minor, sunburn)	No	Yes
Common rashes (e.g., contact dermatitis, shingles)	No	Yes
Constipation	Yes	Yes
Diabetes management (routine and follow-up)	Yes	Yes
Influenza (uncomplicated)	Yes	Yes
Sinusitis (uncomplicated)	Yes	Yes
Skin Infections	No	Yes
Smoking Cessation	Yes	Yes
Upper Respiratory Infections (uncomplicated)	Yes	Yes
Urinary tract infections (uncomplicated in non-pregnant women and in the absence of vaginitis)	Yes	Yes
Weight management	Yes	Yes

<b>Conditions That May Be Appropriate for Telemedicine Management</b>		
Asthma	No	Yes
Bronchitis (mild symptoms, pneumonia not suspected)	Yes	Yes
Essential Hypertension	Yes	Yes
Migraine headache (diagnosis established, uncomplicated)	Yes	Yes
Musculoskeletal issues muscle strains and joint sprains	No	Yes
Pain control (mild to moderate for known conditions)**	Yes	Yes
Rash (generalized without fever or systemic symptoms)	No	Yes
Viral gastroenteritis (uncomplicated)	Yes	Yes

<b>Conditions That Are NOT Appropriate For Telemedicine Management***</b>		
Acute abdominal pain	No	No
Acute neurologic symptoms	No	No
Altered mental status and inability to communicate history or symptoms	No	No
Anaphylaxis or severe allergic reaction	No	No
Chest pain	No	No
Diarrhea and vomiting (severe and with at least moderate dehydration)	No	No
Immune-compromised patient in which condition poses significant added risk	No	No
Procedure required for treatment	No	No
Rash (disseminated with fever and systemic symptoms)	No	No
Acute, or chronic shortness of breath	No	No
Trauma (moderate to severe of one or multiple sites)	No	No
UTI or kidney stone (complicated)	No	No
Vision disturbance due to eye trauma, peri-orbital infection	No	No

**The practice of medicine is an integration of both the science and art of preventing, diagnosing, and treating diseases. Accordingly, it should be recognized that compliance with these guidelines will not guarantee accurate diagnoses or successful outcomes. The purpose of these standards is to *assist practitioners in pursuing a sound course of action to provide effective and safe medical care that is founded on current information, available resources, and patient needs.* The practice guidelines and technical standards recognize that safe and effective practices require specific training, skills, and techniques, as described in each document.**

If circumstances warrant, a *practitioner may responsibly pursue a course of action different from the guidelines* when, in the reasonable judgment of the practitioner, such action is indicated by the *condition of the patient, restrictions or limits on available resources, or advances in information or technology* subsequent to publication of the guidelines. Nonetheless, a practitioner who uses an approach that is significantly different from these guidelines is strongly advised to provide documentation, in the patient record, that is adequate to explain the approach pursued.

- **Guidelines for practice TM that are required whenever feasible & practical as determined by referring clinician practicing under local conditions identified by *“shall”***
- ***“Should”* indicates an optimal recommended action, one that is particularly suitable, without mentioning or excluding others.**
- **Optional or permissible action are indicated by *“may/attempt to”* to indicate additional points that may be considered to further optimize the tele-consult process.**

# **Best Practices in Videoconferencing-Based Telemental Health April 2018**

- **Administrative Considerations**

- Program Development
- Legal & Regulatory Issues
  - Licensure & Malpractice
  - Scope of Practice
  - Prescribing
  - Informed Consent
  - Billing & Reimbursement
- SOPs
  - Patient-provider Identification
  - Emergencies: *General Considerations, Clinically Supervised Settings, Clinically Unsupervised Settings*
  - Care Coordination



- **Technical Considerations**

- VTC Platform Requirements
- Integration VTC into Other Technology & Systems
  - Privacy, Security & HIPAA
- Physical Location/Room Requirements

- **Clinical Considerations**

- Patient & Setting Selection
- Mngt Hybrid Patient-Provider Relationships
- Ethical Considerations
- Cultural Issues
- Specific Populations & Settings: *child/adolescent, forensic & correctional, geriatric, military/veteran & other federal, substance use disorder treatment, inpatient & residential, primary care, rural*

# Following Guidelines

- **Practice medicine integration science & art preventing, diagnosing, treating diseases**
- **Compliance alone will not guarantee accurate diagnoses/successful outcomes**
- **Circumstances warrant may responsibly pursue alternate course action**
- **Divergence indicated when, in reasonable judgment practitioner, condition patient, restrictions/limits on available resources, advances info/tech occur**
- **If use approach sig different strongly advised document it**

# Following Guidelines

- **Do not purport to establish binding legal standards for TM interactions**
- **Result of accumulated knowledge & expertise leading experts in field**
- **Aspects may vary depending on individual circumstances (e.g., location parties, resources, nature interaction)**
- **Not designed to be “how to”**

**THIS IS NOT  
LEGAL ADVICE**

**IF YOU HAVE QUESTIONS OR NEED LEGAL ADVICE  
PLEASE CONTACT A LAWYER**

# Educating & Informing

- **Structure & timing services, records, scheduling, privacy, security, potential risks, confidentiality, billing, VTC info, emergency plan, potential technical failure, coordination care others; contact between visits, conditions termination & refer in-person care**
- **Provided language easily understood**
- **Provided orally or in writing**
- **Set appropriate expectations**
  - **Prescribing, scope services, follow-up**



# Providers Shall

- **Conduct care consistent jurisdictional regulatory, licensing, credentialing & privileging, malpractice & insurance, rules profession jurisdiction practicing**
- **Ensure compliance required by appropriate regulatory & accrediting agencies**
- **Be cognizant provider-patient relationship**
- **Have necessary ed, training, orientation, licensure, etc.**
- **Ensure workspaces secure, private, reasonably soundproof, lockable door**
- **Ensure privacy & make patient aware other persons & agree to presence**

**Table 1. Lexicon of Assessment and Outcome Measures for Telemental Health (TMH)**

Item No.	Item	Definition	Measurement	Considerations
2.1.1	Patient satisfaction	Patient's subjective satisfaction and experience with the TMH service provided.	The perception of the patient's satisfaction during the TMH visit with usability of the technology, patient-provider communication, and convenience of receiving care via this approach. Does the patient believe that the service met her/his health needs? Would patient do this again? Would patient refer others to this service?	There may be overlap with other constructs such as "Satisfaction with Usability of Technology." Satisfaction does not necessarily require in-person comparison. It could be compared to no care (i.e., non-inferiority testing). Use of validated measures of TMH satisfaction because measures exist. Measure satisfaction with experience as well as with technology.
2.1.2	Provider Satisfaction	The extent to which the provider values telehealth when interacting with patients.	The following metrics may serve as surrogate markers: retention and recruitment of providers, ease of transition in technical competency, ease of integration into clinical workflow, perceived value of better diagnosis, treatment and disease management.	Satisfaction metric must be considered longitudinally. Include both referring PCMs and consulting provider satisfaction surveys.
2.1.3	Coordination of care	Care coordination is the development and implementation of a shared plan to support patient wellness.	Care coordination measurement consists of both the number of telehealth encounters and the number of different participants involved in the shared plan (e.g., consultant-primary care provider, consultant-teacher, etc.) and the type of telehealth interaction (asynchronous and synchronous).	The nature of the communication, external technologies such as electronic health records and quality of encounters can all impact care coordination.
2.1.3	Integration of care	Integration of care is the efficient assimilation of multiple components within a health system in order to decrease redundancy, delay, and cost.	Measurement of the integration of care includes the type of the telehealth interactions assessed on standardized questionnaires of care coordination or other measures of communication (i.e., participant A to participant B).	The nature of the communication, external technologies such as electronic health records and quality of encounters can all impact integration of care.
2.1.4	Usability	1) The ease (preference, comfort, fit, readiness) of patients to communicate digitally with their providers. 2) Includes technology availability, simplicity of use, service availability, technology native vs. non-facile.	Measurement should include: provider retention rate, patient drop out and rationale, support staff required, technology ease of use, technology down time, and subjective ratings of comfort.	Subjective and objective measurements from both the patient and provider perspective. Part of the evaluation should include how "seamless" the interaction was between people/technology, to include latency and failure of technology. This can be used as both a process/acceptability and an access measure, but definition should remain the same. Patient/provider preferences should also be included.
2.1.5	Rapport	When two or more people feel	Self-reported level of direct and/or indi-	Transcends cultural, racial, ethnic, religious, gender, age,

		that they are connected and understand one another.	rect evidence that the condition of rapport is present between the patient(s) and the professional(s).	geographic, etc. differences and experiences. Try to link clinical outcomes which could be related to rapport.
2.1.6	Stigma	Preconceived, often negative, association with an illness, diagnosis, therapy, technique etc. that may interfere with the provision and/or acceptance of care.	Measures should evaluate stigma among health care providers/staff, patients, and social networks and include, at minimum, the following concepts: Stereotyping/discrimination such as beliefs about mental illness, mental health treatment, TMH and the use of technology to deliver care. Labeling/disclosure such as acceptance of diagnosis, willingness to diagnose appropriately, help seeking and delivering behaviors, willingness to use or conduct TMH sessions.	Perceived stigma should not simply focus on the recipient of care but the providers of care and those giving support. Concerns about stigma should focus on both mental illnesses in general and on the type of delivery (e.g., TMH). From a research and programmatic perspective this is best evaluated pre/post introduction of a TMH service. This can be related to both general access to care and readiness.
2.1.7	Motivational readiness	Assessment of an individual's or organization's willingness to change and adopt TMH services. This is different from preparedness, which is an assessment of individual and organizational ability to adopt TMH services.	Includes: stage of change for individuals and organizations, situational self-efficacy (confidence), trans theoretical model-based measures (pros & cons of change, processes/strategies for change, situational self-efficacy).	Defining criteria for moving into the action stage. Relationship between individuals and institutional readiness and motivation. How interrelated are individuals and institutional motivation? Self-report can be inaccurate, but necessary.
2.2.1	No shows	A patient or clinician who does not attend session, or is more than 15 minutes late.	Percent of no shows as compared to a disease-state specific comparisons in-person group. No shows defined as 15 minutes late or more to appointment. No shows need to be identified as either clinically related or a systems issue (scheduling, time zones, etc.).	Determine cause of no show, i.e., was it lack of transportation, lack of ability to maintain a schedule, did they show up late and have to reschedule, dissatisfaction with treatment. Examine the reasons for the no shows i.e. technology failed or could not be used, the use of technology (vs. travel) made it easier to keep the appointment, etc.
2.2.2	Accuracy of assessment	How well the modality of TMH impacts the reliability and validity of the assessment when compared with the traditional behavioral health care standards for the construct in question.	Comparison of standard measures of assessment (reliability, validity) of TMH vs. in-person (national standard) vs. other telehealth modalities. Measurement should also include session time and number of sessions needed for specific assessments comparing TMH with in-person services at patient site.	Proxy measures to track providers comfort with reliability of assessment through tracking utilization of tests and consults comparing TMH with in-person services at patient site.
2.2.3	Symptom outcomes	Change in identified clinical symptoms over time.	Use of measures of symptom change that are appropriate and psychometrically sound (validity, reliability data published in the literature). Need to be appropriate for the population being treated/assessed	How is this information documented so it is meaningful? Include measure used, cutoff criteria, inclusion/exclusion, what they are comparing outcome to, effect size of intervention. Symptom outcomes are part of a larger universe of outcome metrics that need to be considered. Consider adding

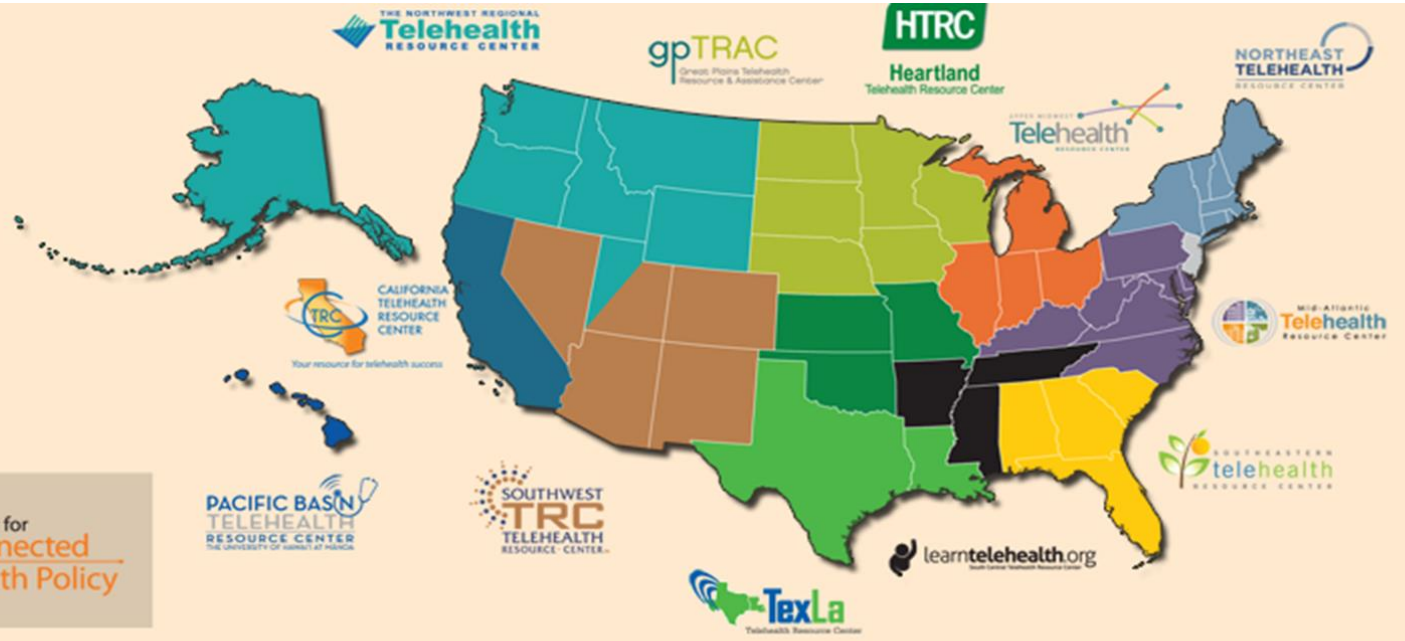
			to include accepted gold standards.	intervention/treatment outcomes with symptom outcomes as a subset as well as other outcomes such as Quality of Life, work attendance/absenteeism, compliance/adherence or psychosocial measures (unit cohesiveness, social isolation).
2.2.4	Completion of Treatment	Degree to which appointments, treatments and completion of treatment plans occurred within the prescribed time frame.	Average number of visits according to treatment plan, average number of visits in given time period, duration of treatment, number/percentage of modules completed; percentage of patients who completed treatment; pre/post functional measures	Third party payers use Axis 5 (Global Assessment of Functioning) to evaluate progress and completion, although this will evolve with the conversion to DSM-V criteria.
2.2.5	Quality of Care	Quality of care represents the process of delivering services and includes both the technical and interpersonal aspects of treatment. Technical quality includes concordance with treatment guidelines, fidelity to evidence based protocols, and system performance measures (e.g., HEDIS). Interpersonal quality includes patient rapport, therapeutic alliance, and cultural competence.	Performance measures (e.g., timely outpatient visit follow hospital discharge) can sometimes be measured from administrative data. Concordance with treatment guidelines and fidelity to evidence based protocols can be measured from chart review. Interpersonal quality should be measured from patient self-report (e.g., therapeutic alliance can be measured using the working alliance inventory).	Quality is defined as the process rather than the outcome of care, because clinical outcomes are measured using other metrics and because high quality care does not necessarily lead to good outcomes. Quality of TMH services should be measured against benchmarks rather than the quality of in-person services which is often sub-optimal. When TMH services are compared to in-person services, it will be critical to choose a similar clinical setting and patient population.
2.2.6	Treatment Utilization	Use of TMH services compared with all other health services related to specific disease processes.	Measurements on number of TMH and non-TMH visits within a health care system to include data on visit duration, frequency, and problem addressed. Measurements on system resources (labs, medications, system funded travel, devices, consultation, number of referrals made and utilized) of TMH vs. non-TMH. Utilization should be correlated with symptom reduction of specific disease processes.	Comparison of digital contacts (mobile phone, e-mail, Web) and its impact on service utilization in non-telemental healthcare. Recommend healthcare systems systematize data on digital contacts. Collect data on both internal utilizations within a system but as possible external service utilizations from outside agencies and providers. As possible during implementation of TMH services collect compare data on pre and post implementation service utilization data.
2.3.1	Number of Services	Degree of access to additional services which are derived from enrollment in telehealth.	The number of clinical care options and auxiliary services offered (e.g., medication management, social services, labs, cardiac care, group therapy); frequency in the use of clinical care options and auxiliary services.	Used for program evaluation, ROI for program expansion, quality, patient/provider satisfaction.
2.3.2	Numbers Served (also referred to as	The workload credit given for the TMH encounter that is	Types of services; complexity of services; time spent with patients; number of	Coding accuracy. Coding training and follow up to ensure coding is being done correctly, i.e., no under or over coding.



	RVUs, relative value units)	related to the complexity of services provided and the time spent with patients which equates to the level of financial reimbursement.	patients seen.	
2.3.3	Wait Times	Wait time is a temporal dimension of access that represents the delay between when the patient wants to receive services and when they can actually receive services.	Operationally, time to next available appointment, when scheduling, and when the patient actually presents for care. For TMH requiring a referral, wait time could be measured as the difference in the referral date and the date the patient was seen. May want to measure wait time separately to see the preferred provider versus any provider.	It is important to realize that improving other dimensions of access (e.g., lowering costs or de-stigmatizing TMH services) could result in increasing wait times due to increased demand. Health systems should measure wait times to all clinics (not just TMH clinics) to determine how resources could best be reallocated to minimize variability in wait times across clinics. Other important measures of temporal access include wait time in clinic and convenience of office hours.
2.3.4	Length of session	How much time the patient spends receiving care. This could include time spent with the provider.	Average/total clinical encounter time, average/total administrative time (set-up time, out-of session contact such as email, text, phone, letters).	Needs to be clinician, patient, staff, and system viewpoint. Needs to accommodate emerging platforms such as mobile health. Length of sessions may interact with frequency of appointments. Efficiencies with telehealth solution create opportunities for novel session duration (e.g., 10-minute check-in)
2.3.5	Distance to Service	Geographic separation or functional barriers between patients and providers.	Distance, time zones, time to appointment.	This includes structural barriers, weather.
2.3.6	Likelihood to access vs. traditional care	Likelihood to use TMH.	Measurement should include the following concepts: familiarity (past use), acceptability (cultural and technical), associations with stigma, willingness, and perceived benefit. Measurement should not focus on satisfaction but rather broad willingness to use.	When possible this should include baseline comparisons against both available and unavailable treatment as usual (e.g., in-person) Most likely this is assessed through self-report questionnaires.
2.3.8	Cultural access	Access to healthcare services that align with cultural expectations.	The degree to which an individual perceives the mode of delivery and related processes to align with cultural beliefs and expectations.	This should include cultural understanding of technology and expectations of interpersonal communication. It should also consider how technology may better connect cultural expectations, e.g., providing access to same culture providers or allowing for communication with a provider outside of one's in-group.
2.4.1	Economic evaluation that incorporates standard economic models			In general, clear definitions do not exist for many of the cost structures. This may be appropriate as costs are derived and perceived differently. There are several costs factors that were identified as important to measure objectively. Until final definitions are set, each cost factor should be operationalized and reported. Consideration should also be given to what is sunk or similar cost of care as usual (provider time).

				Baseline assessments help to identify cost outcomes.
2.4.2	Value proposition	Comparison of clinical and other health service outcomes by overall resources allocated.	Standardized and reported taxonomy of resources allocated and outcomes measured.	There is no consensus yet on the best determinations for economic evaluations in TMH.
2.4.3	Travel direct	Direct cost associated with provider and/or patient travel to care site	All direct costs should be identified, operationalized, and reported for comparison.	Should be included within the broad category of costs. Precise definition may not be possible given differing perspectives but all components should be identified, operationalized, and reported.
2.4.4	Travel indirect	Indirect costs associated with provider and/or patient travel to care site	All indirect costs should be identified, operationalized, and reported for comparison.	Should be conceptualized as comparison to normal care, e.g., loss of work productivity is comparable given 1 hr away regardless of mode of delivery. Indirect costs are both inputs to a cost model as well as potential positive outcomes of telehealth (reduction). Evaluators should determine and report up-front whether indirect costs are inputs to a cost model or expected outcomes.
2.4.5	Technology direct	Direct patient and provider costs associated with the technology utilized to deliver telehealth services.	All direct costs should be identified, operationalized, and reported for comparison.	Need to determine upfront whether costs are as a whole or divided between provider- and patient-associated. Inputs to consider include: hardware and depreciation, software and licensing, infrastructure, network, and maintenance costs.
2.4.6	Technology indirect	Indirect patient and provider costs associated with the technology utilized to deliver telehealth services.	Indirect costs include expenses incurred as a result of technology downtimes, specialized licenses, and administration.	There is cross-over between direct and indirect technology costs. Direct costs should focus on tangible assets while indirect costs are often intangible resources allocated based on the need for tangible assets.
2.4.7	Public vs. private	Payer Perspective.	Whether a project, program, or system utilizes public or private funding.	This is not an outcome measure but rather a perspective. Outcomes measures should be evaluated based upon the financial perspective under which a program operates.
2.4.8	Cost avoidance	Current or future direct costs avoided due to a specific intervention or program.	There are currently no industry standards for cost avoidance measures.	Consideration should be given to measuring items such as hospitalizations, visits, and other costs. These should be operationalized and reported as possible.
2.4.9	Missed obligations	Indirect Cost: Missed obligations	Should be measured as part of overall indirect costs.	Where possible a baseline assessment should be conducted against care as usual. As an outcome measure the assumption is that TMH impacts indirect costs/burden, thus requiring a comparison.
2.4.10	Burden on social network	Societal resources associated with either the provision of or inadequate access to TMH services.		Burden on social network should include direct burden to support resources and broad burden to societal infrastructure. When conducting research a positive or negative directional association should be identified <i>a priori</i> .
2.4.11	Personnel (administrative, provider, provider extender, presenter)	Personnel costs associated with the provision of TMH services.		
2.4.12	Supplies	Direct cost of auxiliary supplies required for TMH ser-		

		vices.		
2.4.1 3	Training	Process by which an individual attains the knowledge and skills required to demonstrate predetermined competencies.	A TMH competency set is required.	May be included as an indirect provider cost. Training is not truly an outcome unless the program is development of a training program
2.4.1 4	Facilities and maintenance	Direct costs associated with the facilities and maintenance necessary to support tele-health technologies.	Measurement includes cost of physical facilities, facilities maintenance, and systems such as HVAC. Should also include cost to maintain equipment including servers and individual patient/provider technologies.	Should be included with technology direct costs.
2.4.1 5	Broad resource utilization	Resource utilization is the total allotment of resources necessary to provide tele-health services.	Resource utilization is driven by the numbers of encounters. It encompasses personnel and infrastructure resources necessary to provide each health care service.	Baseline comparisons need to be considered to differentiate resources from treatment as usual and TMH.
Pa- tient safe- ty	Patient safety	Safety of patients and others during the course of treatment (i.e. during sessions and after).	Times had to use safety procedures. Number of times needing to contact collateral/ 911 calls/emergency services calls. Number of psychiatric hospitalizations related to clinic services. Number of times unable to invoke safety plan (tried but could not), hand off to higher level of care from clinic due to safety issues. Problems causing patient transfer to another provider.	Consider Targsoff, other measures of adverse events (or potential ones e.g. increased suicide indication, etc.); response times of all events, etc. including emergency services.



2 National Resource Centers

12 Regional Resource Centers

[www.southwesttrc.org](http://www.southwesttrc.org)

<https://www.telehealthresourcecenter.org/>

# HIPAA & Telehealth

## A Stepwise Guide to Compliance

### Should I Be Concerned?

STEP  
1



**DOES HIPAA APPLY TO ME AND MY TELEHEALTH PRACTICE?** HIPAA applies to you if you are a healthcare provider that transmits personal health information (PHI) in electronic form. If you do, you ARE a covered entity (CE).

STEP  
2



**IS THE INFORMATION I AM TRANSMITTING CONSIDERED PHI?** Anything that can be used to identify an individual is potentially PHI. There are 18 types of identifiers considered PHI. Examples related to telehealth include names, phone numbers, birthdates, IP addresses, email addresses, device identifiers, and photos/images.

STEP  
3



**DO I HAVE BUSINESS ASSOCIATES?** A business associate is anyone who creates, receives, maintains or transmits PHI on your behalf; or has the ability to come in contact with PHI in your practice. See PHI examples above.

OK, NOW I'M WORRIED!

Keep Reading To Find Out What You Can Do!

### Did You Know?

#1

If you are sharing any type of PHI with Business Associates, any mistakes they make in protecting the security and privacy of your data are yours too. YOU are still responsible.

#2

Your compliance is now dependent on their practices.

#3

You can protect yourself by having formal Business Associates Agreements (BAAs) documenting how they are protecting your PHI and by performing reasonable due diligence to verify their security practices.



Do not disclose PHI to any Business Associate unwilling to sign a BAA.

### Complying With HIPAA

HIPAA compliance is a combination of physical, administrative and technical safeguards. Technology alone cannot be HIPAA compliant or make you HIPAA compliant. Here are the things you and your Business Associate(s) should do and document:

**RISK ASSESSMENT:** Conduct a comprehensive review of where you store or access PHI and how secure it is in each case. Take appropriate steps to secure it in a way that fits for your organization. Establish and document your security policies and procedures. Train your employees regularly and consistently.

**INFORMATION SYSTEMS ACTIVITY REVIEW:** Conduct and document periodic reviews of access logs or other records for unauthorized activity. It might be bad news if you find some, but YOU want to be the first one to find it. Report the breach and implement a fix immediately. Confer with counsel about what to do next.

You might also want to consider ways to configure your system so that PHI is not stored or shared.

## 4 Questions to Ask a Potential Business Associate

...but they all say they are HIPAA compliant...



### Question 1:

Which of the 18 identifiers of PHI would your company be CAPABLE of accessing?



### Question 2:

May I view the results of your last HIPAA compliance audit?



### Question 3:

What administrative, physical and technical safeguards do you have in place?



### Question 4:

Would you be willing to sign OUR BAA?



Compare these measures among vendors!



Encryption alone is not compliance, and processes that are compliant in a clinic-to-clinic encounter may not be compliant in a clinic-to-consumer encounter. Context matters.

## Things to Keep In Mind WHEN (not IF) You Have a Breach...

### What is At Stake?

UNKNOWING VIOLATIONS  
"But I Didn't Know"

\$50,000  
maximum per  
violation

\$100  
minimum per  
violation



**STAY CALM**  
First time  
infringement  
corrected within 30  
days may avoid  
penalties

### WILLFUL NEGLIGENCE VIOLATIONS "But You Did Know"

Corrected  
in required  
time period

Uncorrected

\$10,000+  
per violation

\$50,000+  
per violation

\*Requires only knowledge of the actions that constitute an offense. Specific knowledge that a particular action violates the HIPAA statute is not required.

### Financial Penalties

### Fines + Criminal + Civil Penalties

The Maximum Penalty is \$1.5 Million Per Year Per Violation

## Learn More About HIPAA

- \* HHS Office for Civil Rights
- \* Center for Connected Health Policy
- \* Electronic Code of Federal Regulations
- \* HIPAA.com
- \* UMTRC HIPAA Clarifications
- \* NIST HIPAA Security Rule Toolkit
- \* American Medical Association and HIPAA

## Have questions? Contact a Telehealth Resource Center!

Disclaimer: This document contains general information solely for the purpose of education. The information herein is not intended to and does not constitute legal advice, nor is it complete, and should not be treated as such. If you have specific questions about any legal matter, you should seek legal counsel. Additional privacy and security requirements may also exist based on jurisdiction (e.g., state law) and type of practice (e.g., behavioral health, school health).

# The Basics: mHealth

## AND THE FDA

### What is a regulated medical device?



Healthcare products intended for diagnosis, cure mitigation, treatment, or prevention of a medical condition intended to affect the structure or any function of the body.

### Not all devices are created equal!

#### Class I

Low risk and subject to less regulatory control

#### Class II

Requires greater regulatory controls to provide reasonable assurance of safety and effectiveness

#### Class III

Highest risk and subject to highest regulatory control

### Are there exceptions?

Certain persons are exempt from needing to register medical devices with the FDA, including licensed practitioners who manufacture or alter devices solely for use in their own practice.



Some states may have more stringent requirements over medical devices!



### What about mobile apps?

Apps are subject to FDA regulatory oversight if they:



- \* Are extensions of a medical device for the purposes of controlling the device or displaying, storing, analyzing or transmitting patient specific medical device data.

- \* Transforms mobile platform into a regulated device by using attachments, display screens or sensors or by including functionalities similar to those of current medical devices.
- \* Uses patient specific information to analyze, diagnose and/or treat a patient.
- \* Involved in active patient monitoring.

The FDA will exercise "enforcement discretion" on mobile medical apps that pose a low risk to patients. This means that the FDA retains the right to enforce requirements on these apps, but are not doing so at this time. The FDA is not the only federal agency that may have applicable laws impacting mobile app development. Visit the Mobile Health Apps Interactive Tool for more information!

#### Examples of Apps Subject to Enforcement Discretion

- \* Used for self-management.
- \* Used to track medication usage or drug-drug interactions.
- \* Used to perform calculations used in clinical practice.
- \* Used as medical device data systems.

#### Examples of Apps Not Considered Medical Devices



Medical Flash Cards



Find Closest Medical Facility



Track and Review Medical Bills



Medical Textbooks and Education Materials

#### Sources:

1. Sec 201(h) of the Federal Food, Drug and Cosmetic Act.
2. CFR Section 807.65
3. CFR Section 808
4. Mobile Health Apps Interactive Tool

Have questions? Contact a Telehealth Resource Center!  
[TelehealthResourceCenter.org](http://TelehealthResourceCenter.org)



# Virtual Healthcare

Quality, cost-effective care and education delivered via smartphones, tablets, desktop computers, kiosks, portals, remote monitoring devices and other new and emerging technologies.



## What Should I Know?

May include instant access to a health care provider, personal health information, lab results, prescription refills, appointment scheduling, care reminders and other resources to help you manage your health.

### 3 Reasons For its Growing Popularity

Care when and where you need it, offered through your employer, health system, health plan, primary care provider and others...



**1. More Convenient**



**2. Better Patient Experience**



**3. Lower Cost**

Why It Is Awesome:  
1. No waiting rooms  
2. No long waits  
3. No travel costs and hassles  
4. No need to re-arrange my schedule



## Who Pays for Virtual Visits?



Many insurance companies and employer sponsored health plans will pay



Patients often choose to pay out-of-pocket



In some situations, Medicaid and Medicare may pay

## What Technology Is Needed?



Desktop/laptop computer, tablet, or smartphone



Internet connection with at least 384 Kbps down and up



A Wired Connection is Preferred to WiFi

Good quality camera and microphone



To Improve Image Quality Reduce Lighting from Windows and From Behind You

You will find that more and more payors are deciding that it is worth their while to pay for virtual visits because it lowers the cost of care! Don't be surprised if your health plan or employer has a contract with a virtual visit provider!

You are responsible for establishing a private space, controlling the lighting, letting the provider know if others are in the room with you, checking your image on the camera to ensure clarity and making sure you have updated anti-virus software..

## Should I Use a Virtual Care Provider?

Virtual Care may not be the best option for everyone. Here are some things to consider when deciding whether Virtual Care is the right fit for you.

### Potential Challenges/Risks

Your virtual care provider may not know you, your medical history or have access to your medical record. If there is something important for your provider to know, it becomes your responsibility to share it. However, you may not know what is/isn't important for your virtual care provider to know.

You may experience connectivity and/or other technology challenges. If the quality of the video/audio is insufficient, your virtual care provider may miss some subtle cues. You and/or your provider may choose to discontinue the visit if there are video and/or audio quality issues.

Your virtual visit is often disconnected from your medical record. Therefore, you are responsible for reporting your virtual care visit to your primary care provider (PCP) to make sure there is coordination of care.

### Other Considerations

Virtual care providers may not be able to order lab tests to confirm your diagnosis/condition.

Virtual care providers may choose not to file insurance claims through your insurance company, so you will need to pay for the services up front and submit the claim yourself.

In some states, virtual care providers may not be able to prescribe medications. If they do prescribe, it is your responsibility to notify your PCP.

You may or may not get the same virtual care provider each time you request a virtual visit.

If the alternative to virtual care is getting no care at all, then by all means, get care virtually!

## How Can I Be Prepared for a Virtual Visit?



If you've decided that Virtual Care might be a good option for you, here are some things to help you be prepared for your first visit!

### Consider asking your provider:

- ❓ What city and state are you located in? (you may need this information if you will be submitting for reimbursement)
- ❓ What is your name and what are your credentials (type of license, area of specialty/subspecialty, state of license)
- ❓ Will there be any kind of follow-up visit, and if so, what is the process for that? How and how often may I contact you if it is needed?
- ❓ What should I do if there is an emergency?
- ❓ Will you be communicating with my PCP? If not, what would be most important for me to tell my PCP about this visit?

### Be ready for your provider to tell/ask you:

- 🗂️ How to comply with privacy and confidentiality laws, including computer security arrangements and limitations
- 🗂️ If/how personal healthcare information will be used, stored and shared
- 🗂️ If the encounter will be recorded, whether you consent to being recorded, and if those recordings would be available to you upon request
- 🗂️ To verify your name, contact information, location and show a government issued photo ID
- 🗂️ To provide the name and contact information for someone in case of emergency

## Have Questions or Need More Information?

Telehealth Resource Centers



<http://www.TelehealthResourceCenter.org/>

# TM Standard of Care

- Millions of people are able to **see a doctor on their smartphones** or laptops **for everyday ailments** as nation's largest drugstore chains & major insurers expand into virtual health care
- Patients increasingly demanding telemedicine option
- Need to acknowledge differences between TM & IP care; make decisions based on patient needs conditions & environments; train & educate all involved; integrate TM into everyday workflow – may require some redesign; use common sense



# THANK YOU!

For more information

[swtrc@telemedicine.arizona.edu](mailto:swtrc@telemedicine.arizona.edu)

<https://southwesttrc.org/contact>

[ekrupin@emory.edu](mailto:ekrupin@emory.edu)

