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3RD ANNUAL TELEHEALTH SUMMIT

# Overcoming Legal & Regulatory Barriers

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# LEGAL AND REGULATORY ISSUES

## TELEMEDICINE: IT SOUNDS SO SIMPLE . . . .

- ▶ Licensure
- ▶ Physician Patient Relationship
- ▶ Informed Consent
- ▶ Credentialing
- ▶ Standard of Care/Malpractice
- ▶ Patient Confidentiality
- ▶ HIPAA
- ▶ Reimbursement
- ▶ Fraud and Abuse
- ▶ Other:
  - ▶ Corporate Practice of Medicine
  - ▶ Antitrust
  - ▶ FDA
  - ▶ Etc.

# LICENSURE REQUIRED IF PRACTICING MEDICINE

- ▶ Any physician who practices medicine in South Carolina must be licensed in South Carolina.
- ▶ “Practice of Medicine” means:
- ▶ (a) advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in this State;
- ▶ (b) offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person;
- ▶ (c) offering or undertaking to prevent or to diagnose, correct or treat in any manner, or by any means, methods, or devices, disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of a person, including the management or pregnancy and parturition;
- ▶ (d) offering or undertaking to perform any surgical operation upon a person;
- ▶ (e) rendering a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient or the actual rendering of treatment to a patient within this State by a physician located outside the State as a result of transmission of individual patient data by electronic or other means from within a state to such physician or his or her agent;

# LICENSURE REQUIRED IF PRACTICING MEDICINE

- ▶ (f) rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient is the practice of medicine subject to all of the powers provided to the Board of Medical Examiners, except as provided in Section 38-59-25;
- ▶ (g) using the designation Doctor, Doctor of Medicine, Doctor of Osteopathic Medicine, Physician, Surgeon, Physician and Surgeon, Dr., M.D., D.O., or any combination of these in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in this State that is applicable to the clinical setting; and
- ▶ (h) testifying as a physician in an administrative, civil, or criminal proceeding in this State by expressing an expert medical opinion. SC Code Ann. § 40-47-20(36)

# LICENSURE REQUIRED IF PRACTICING MEDICINE

- ▶ Practice of Medicine v. Consulting
- ▶ Practice Tip: Beware of the risks inherent in the “curbside consult” between a distant site physician and a physician practicing medicine in South Carolina.
  - ▶ Could be construed as the distant site physician practicing medicine and the South Carolina physician aiding the unauthorized practice of medicine.
    - ▶ But see S.C. Code Ann. § 40-47-30(a)(10): Nothing [in the Physician Practice Act] prohibits a physician from practicing in actual consultation with a physician licensed in this State concerning an opinion for the South Carolina physician's consideration in managing the care or treatment of a patient in this State.
- ▶ Misconduct: “knowingly performed an act that in any way assists an unlicensed person to practice.” S.C. Code Ann. § 40-47-110(B)(7).

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ When is a physician patient relationship established?
  - ▶ A physician-patient relationship is generally described as “a consensual one wherein the patient knowingly seeks the assistance of a physician and the physician knowingly accepts him as a patient.”
  - ▶ The courts state whether a physician patient relationship exists is generally a question of fact for a jury to determine.
- ▶ When does the relationship arise?
  - ▶ Over the telephone/internet when an appointment is made?
  - ▶ When there is a first “encounter”?
    - ▶ Face-to-Face?
    - ▶ Over the Phone?
    - ▶ Via Telemedicine?

# PHYSICIAN PATIENT RELATIONSHIP: IN THE CONTEXT OF PRESCRIBING DRUGS

- ▶ It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. S.C. Code Ann. § 40-47-113(A)
- ▶ “A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee’s training and experience and that the licensee:
  - ▶ (1) *personally perform and document an appropriate history and physical examination*, make a diagnosis, and formulate a therapeutic plan;
  - ▶ (2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and
  - ▶ (3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.” S.C. Code Ann. §40-47-113(A)



# PHYSICIAN PATIENT RELATIONSHIP

- ▶ (B) Notwithstanding subsection (A), a licensee may prescribe for a patient whom the licensee has not personally examined under certain circumstances including, but not limited to,
  - ▶ writing admission orders for a newly hospitalized patient,
  - ▶ prescribing for a patient of another licensee for whom the prescriber is taking call [ See BoME Policy on the Est. of Phys/Pt Relationship as Prerequisite to Prescribing Drugs: An “on call” physician: “available to physically attend, if necessary, to urgent and follow up care needs of a patient for whom he has temporarily assumed responsibility with the acknowledgment of the patient’s primary care provider.”]
  - ▶ prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or
  - ▶ continuing medication on a short-term basis for a new patient prior to the patient's first appointment. S.C. Code Ann. §40-47-113(B)
- ▶ (C) Prescribing drugs to individuals the licensee has never personally examined based solely on answers to a set of questions is unprofessional. S.C. Code Ann. §40-47-113(C)

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ What does “**personally perform** and document **an appropriate history and physical examination**, make a diagnosis, and formulate a therapeutic plan” mean?
- ▶ Traditional model: In person/hands on physical examination (and historical interpretation of the language).
- ▶ \*\* None of the bills discussed (S290; H.3779; H.4901) passed: discussed for illustration only.
- ▶ Variation in interpretation: “Teleconsulting Model”:
  - ▶ S.290: Required that a “referring health care provider” who has evaluated the patient and determined the need for the services of a “consulting health care provider” via telemedicine.
  - ▶ Specifically does not require (for payment to be made by the State Health Plan) a “face to face” contact between the patient and the consulting health care provider for covered services appropriately provided through telemedicine in accordance with generally accepted health care practices and standards at the time the telemedicine service was rendered.

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ S.290: Defines Telemedicine as “the delivery of health care, including diagnosis, treatment, or transfer of medical data, by means of bi-directional, real-time, interactive, secured and HIPAA compliant, electronic audio and video telecommunications systems by a consulting health care provider to a patient of a referring health care provider, at a referring site. HIPAA compliant electronic audio and video telecommunications systems must be used between the consultant site and referring site. Standard telephone, facsimile transmissions, unsecured electronic mail, or a combination of them do not constitute telemedicine services.”

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ H.3779 – Similar to S.290 as it requires a referring health care provider and a consulting health care provider.
  - ▶ BUT defines Telemedicine differently:
  - ▶ “Telemedicine' means the delivery of health care, including diagnosis, treatment, or transfer of medical data, by means on interactive audio, video, or data communications by a consulting health care provider to a patient at a referring site. Interactive audio and video telecommunications must be used between the consultant site and referring site. Standard telephone, facsimile transmissions, unsecured electronic mail, or a combination of them do not constitute telemedicine services.”

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ Variation in interpretation:
  - ▶ H.4901: Allows the practice of medicine via telemedicine **without** the need for a referring or consulting health care provider.
  - ▶ “If the health care practitioner is a physician as defined in Section 40-47-20(35), the examination and diagnosis services provided through telemedicine to the patient must meet the requirements to establish a physician-patient relationship as defined in Section 40-47-113 if the services are provided in accordance with generally accepted health care practices and standards at the time the telemedicine service was provided.”
  - ▶ Requires “insurers” (any accident or health insurance company) to provide coverage for telemedicine services to the same extent that the services would be covered through an in-person consultation.

# PHYSICIAN PATIENT RELATIONSHIP

- ▶ H.4901 - "Telemedicine' means the delivery of health care services, including diagnosis, treatment, or transfer of medical data by means audio telecommunications systems and video telecommunications systems that are bidirectional, real-time, interactive, secured, and HIPAA compliant. Standard telephone, facsimile transmissions, unsecured electronic mail, or a combination of them do not constitute telemedicine services.

# PHYSICIAN PATIENT RELATIONSHIP: PRACTICAL TIPS

- ▶ For distant site examinations:
  - ▶ Document the method/medium of examination
  - ▶ Verify and authenticate: Know and document “who is who”:
    - ▶ The patient’s location and identity
    - ▶ The provider’s location and identity/credentials
  - ▶ Obtain appropriate informed consent (Next slides!)
  - ▶ Provide for appropriate follow up services
  - ▶ § 40-47-113(A): Interpretation? Scope?

# INFORMED CONSENT

- ▶ Basis of doctrine of informed consent is patient's right to exercise control over his or her body by deciding intelligently for himself or herself whether or not to submit to a particular procedure/treatment.
- ▶ The patient consent to treat is typically obtained at the first encounter.
- ▶ Specific informed consent is typically required for specialized procedures and services.
- ▶ The doctrine of informed consent: A physician has a duty to disclose “(1) the diagnosis, (2) the general nature of the contemplated procedure, (3) the material risks involved in the procedure, (4) the probability of success associated with the procedure, (5) the prognosis if the procedure is not carried out, and (6) the existence of any alternatives to the procedure.” Hook v. Rothstein, 281 S.C. 541, 547, 316 S.E.2d 690, 694–95 (Ct.App.1984).



# INFORMED CONSENT

- ▶ Should the patient consent to the telehealth encounter?
- ▶ What risks / benefits / alternatives should be disclosed to the patient?
- ▶ Practice Tips:
  - ▶ Use clear and understandable language.
  - ▶ Clearly define the telehealth service to be provided.
  - ▶ Clearly state the patient's right to revoke consent (subject to the providers reliance on the consent prior to revocation).
  - ▶ Clearly state the alternatives.
  - ▶ Clearly describe the benefits.
  - ▶ But also . . .

# INFORMED CONSENT

- ▶ Be comprehensive in describing the potential risks:
  - ▶ Risks in the use of telemedicine technology:
    - ▶ Equipment/technology failure resulting in errors in diagnosis;
    - ▶ Security failures (will get to HIPAA!);
    - ▶ Potential for poor data quality;
    - ▶ Limited ability to for the distant provider to examine and provide emergent treatment;
    - ▶ Limited access to information.
- ▶ Always ask yourself if the patient has the information the patient needs to make an informed decision.

# CREDENTIALING

- ▶ The process by which institutions determine whether providers are qualified to practice at that institution.
- ▶ Typically required to be “credentialed” at the originating site (where the patient is located) as well as the distant site.
- ▶ Typically requires an application for appointment/request for specific privileges and a review of the competencies of the provider.
- ▶ Typically requires reappointment every 2 years.

# CREDENTIALING: TELEMEDICINE CoPS

- ▶ On May 5, 2011, CMS issued its final rule on credentialing telemedicine physicians and practitioners to allow for a streamlined process of credentialing, reducing the burden of credentialing and privileging telemedicine providers.
- ▶ Background:
  - ▶ TJC standards provided for a mechanism whereby a hospital could rely on a distant TJC hospital's credentialing processes to grant telemedicine privileges.
  - ▶ Effective July 15, 2010, TJC is no longer specifically referenced under the Medicare/Medicaid "deeming" statute and, because CMS does not approve TJC's standards, hospitals can no longer rely on the TJC's processes.

# CREDENTIALING: TELEMEDICINE CoPS

- ▶ CMS defines telemedicine in the preamble to the final rule as: “the provision of clinical services to patients by practitioners from a distance via electronic communications.”
- ▶ CMS defines telemedicine entity as one that “(1) provides telemedicine services; (2) is not a Medicare-participating hospital (therefore, a non-Medicare participating hospital that provides telemedicine services would be considered a distant-site telemedicine entity also); and (3) provides contracted services in a manner that enables a hospital or CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital or CAH.”

# CREDENTIALING: TELEMEDICINE CoPS

- ▶ 42 C.F.R. § 482.12: Governing body
  - ▶ (a)(8) requires that the governing body ensures that there is an agreement with the distant hospital that the provisions of 42 C.F.R. § 482.22(a)(1) – (7) are met for physicians providing telemedicine services.
  - ▶ (a)(8) further allows the governing body to, in accordance with 42 C.F.R. § 482.22(a)(3), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.
  - ▶ (a)(9) requires that the governing body ensures that there is an agreement with the distant site telemedicine entity that the provisions of 42 C.F.R. § 482.22(a)(1) – (7) are met for physicians providing telemedicine services.
  - ▶ (a)(9) further allows the governing body to, in accordance with 42 C.F.R. § 482.22(a)(4), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site telemedicine entity.

# CREDENTIALING: TELEMEDICINE CoPS

- ▶ 42 C.F.R. § 482.22 Medical Staff:
  - ▶ (a)(3) in lieu of traditional credentialing (482.22(a)(1) & (2)), the medical staff may rely on the credentialing and privileging decisions of the distant site hospital when making recommendations on privileges if the hospital's governing body ensures, through its written agreement the following:
    - ▶ The distant-site hospital is a Medicare participating hospital
    - ▶ The individual distant-site physician or practitioner is privileged at the distant-site hospital and provides a current list of the distant-site physician or practitioner's privileges at the distant-site hospital.
    - ▶ The individual distant-site physician or practitioner is licensed in the state in which the hospital whose patients are receiving the telemedicine services is located.
    - ▶ As to the individual distant-site physician or practitioner, the hospital has evidence of an internal performance review and the distant-site hospital sends the hospital the review for periodic appraisal (must include adverse events and complaints).

# CREDENTIALING: TELEMEDICINE CoPS

- ▶ (a)(4) in lieu of traditional credentialing (482.22(a)(1) & (2)), the medical staff may rely on the credentialing and privileging decisions of the distant site telemedicine entity when making recommendations on privileges if the hospital's governing body ensures, through its written agreement:
  - ▶ the distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at 482.12(a)(1) – (7) and 482.22(a)(1) – (2).
  - ▶ The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity and provides a current list of the distant-site physician or practitioner's privileges at the distant-site telemedicine entity.
  - ▶ The individual distant-site physician or practitioner is licensed in the state in which the hospital whose patients are receiving the telemedicine services is located.
  - ▶ As to the individual distant-site physician or practitioner, the hospital has evidence of an internal performance review and the distant-site telemedicine entity sends the hospital the review for periodic appraisal (must include adverse events and complaints)



# CREDENTIALING: TELEMEDICINE CoPS

- ▶ § 482.22(c)(6): Requires that the hospital's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges.
- ▶ Nearly identical provisions are added to 485.616 related to CAHS.
  - ▶ One additional provision exists for CAHs: CAH's are required to contract only with "one or more Medicare-participating providers in order to furnish other services to its patients. § 485.635(c)(5) provides an exception to this requirement to allow CAHs to contract with non-Medicare participating telemedicine providers.

# TELEMEDICINE CoPS: “TO DO” LIST

- ▶ The Medical Staff Bylaws must be amended to include:
  - ▶ criteria for determining telemedicine privileges; and
  - ▶ a procedure for applying the criteria to individuals requesting privileges. See § 482.22(c)(6).
- ▶ Need to develop/enter into agreements with telemedicine providers.

# CREDENTIALING: TELEMEDICINE CoPS: PRACTICAL QUESTIONS AND OPEN ISSUES

- ▶ Distinguishes the “curbside consult” between distant physicians and practitioners . . . But this could create confusion.
- ▶ What if the distant-site has significantly different privileges lists than the hospital?
- ▶ What if there are significantly different Medical Staff privileging requirements? (e.g., Board Certification requirements; malpractice coverage limits)
- ▶ Should you ask for a copy of the distant-site Medical Staff Bylaws?
- ▶ Should the hospital agree to provide peer review information to the distant-site hospital/telemedicine provider?
- ▶ Consider risk management issues: how would this “play” in light of an allegation of negligent credentialing?

# STANDARD OF CARE/MALPRACTICE

- ▶ To establish a cause of action for medical malpractice, the plaintiff must prove the following facts by a preponderance of the evidence:
- ▶ (1) The presence of a doctor-patient relationship between the parties;
- ▶ (2) Recognized and *generally accepted standards, practices, and procedures* which are exercised by competent physicians in the same branch of medicine under similar circumstances;
- ▶ (3) The medical or health professional's negligence, *deviating from generally accepted standards, practices, and procedures*;
- ▶ (4) Such negligence being a proximate cause of the plaintiff's injury; and
- ▶ (5) An injury to the plaintiff. Brouwer v. Sisters of Charity Providence Hospitals, --- S.E.2d ----, 2014 WL 3844059, (S.C. 2014).

# STANDARD OF CARE/MALPRACTICE

- ▶ Local v. National standard of care
- ▶ In South Carolina, “[t]he degree of care which must be observed is . . . that of an average, competent practitioner acting in the same or similar circumstances.” King v. Williams, 279 S.E.2d 618 (S.C. 1981). Abandoned the locality rule.
- ▶ What is the standard of care for telemedicine/telehealth?
- ▶ Varies:
  - ▶ From state to state;
  - ▶ By type of medical practice;
  - ▶ Dicta: “The best philosophy and approach to telemedicine is that the same standards of care and protocols applicable to more traditional forms of medicine exist with telemedicine. The physician-patient relationship and interaction are the same. The process should be the same as if the patient were in the room with the doctor.” U.S. v. Rodriguez, 532 F.Supp. 2<sup>nd</sup> 316, 327 (2007).

# STANDARD OF CARE/MALPRACTICE

- ▶ April 26, 2014: Federation of State Medical Boards adopted policy guidelines for safe practice of telemedicine.
- ▶ Key provisions:
  - ▶ “Standards of care that protect patients during in-person medical interactions apply equally to medical care delivered electronically.
  - ▶ Providers using telemedicine should establish a credible ‘patient-physician relationship’ and ensure that their patients are properly evaluated and treated.
  - ▶ Providers should adhere to well-established principles guiding privacy and security of records, informed consent, safe prescribing and other key areas of medical practice.”
- ▶ Advise that you review the guidelines at:

[http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB\\_Telemedicine\\_Policy.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf)

# STANDARD OF CARE/MALPRACTICE

- ▶ Recommendations:
  - ▶ Understand the standard of care for your type of practice;
  - ▶ Consult your specific professional board;
  - ▶ Consult your certification boards;
  - ▶ Consult your national associations;
  - ▶ Consult AHRQ standards:

<http://www.innovations.ahrq.gov/content.aspx?id=2847>

- ▶ Consult your accreditation bodies (TJC; DNV; etc.);
- ▶ Consult the American Telemedicine Association:

<http://www.americantelemed.org/resources/standards/ata-standards-guidelines>

# PATIENT CONFIDENTIALITY/HIPAA

- ▶ Every State and Federal law that protects the confidentiality, privacy and security of protected health information that is created in a face-to-face encounter apply to virtual encounters.
- ▶ Most notable:
  - ▶ Privacy Rule: A Covered Entity is required to provide administrative, physical and technical safeguards to protect the privacy of PHI. 45 C.F.R. §164.530
  - ▶ Security Rule: A Covered Entity is required to implement policies and procedures to protect the integrity, confidentiality, and availability of e-PHI. 45 C.F.R. Part 164, Subpart C.



# PATIENT CONFIDENTIALITY/HIPAA

- ▶ Examples of issues with Telemedicine/Telehealth can create increased risk exposure:
  - ▶ Interoperability in cooperating locations' systems could increase risks (breach; medical errors);
  - ▶ Interruptions in connectivity mid-examination/procedure;
  - ▶ Differences in operational procedures and technology implementations could increase risk exposure
  - ▶ Treatment could be viewed by unauthorized individuals without patient knowledge or permission
  - ▶ Electronic communications could be hacked by unauthorized individuals
  - ▶ Locally stored PHI could be accessed or altered by people with system-level privileges.

# PATIENT CONFIDENTIALITY/HIPAA

- ▶ Recommendations:
  - ▶ Foster a strong culture related to the privacy & security of PHI;
  - ▶ Be sure your cooperative providers also have similar cultures;
  - ▶ Encrypt (data in transmission and at rest);
  - ▶ Work with your cooperative providers to address interoperability issues up front;
  - ▶ Coordinate operational policies and procedures with your cooperative providers;
  - ▶ Conduct a thorough risk assessment to identify vulnerabilities, both internal and external threats to the system;
  - ▶ Conduct a review of your HIPAA Privacy and Security Standards to address new issues;
  - ▶ Be sure your insurance carriers (GL & Cyber) cover telemedicine practice; and
  - ▶ Distant site providers: Remember to provide the patient with your Notice of Privacy Practices!!

# REIMBURSEMENT: MEDICARE

- ▶ “The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1395x(r) of this title) or a practitioner (described in section 1395u(b)(18)(C) of this title) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary.” 42 U.S.C.A. § 1395m(m)
- ▶ Payment:
  - ▶ Distant site: The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this subchapter had such service been furnished without the use of a telecommunications system.

# REIMBURSEMENT: MEDICARE

- ▶ Payment:
  - ▶ Facility fee for the originating site:
    - ▶ With respect to a telehealth service, subject to section 1395l(a)(1)(U) of this title, [be 80 percent of the lesser of the actual charge or the amounts specified in such section] there shall be paid to the originating site a facility fee equal to— after 2002, the facility fee for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) [%age increase in the Medicare economic index applicable for that year] for such year.
  - ▶ No requirement for there to be a physician at the originating site (see next slides for limits on what can be an “originating site”).

# REIMBURSEMENT: MEDICARE

- ▶ Limits on:
  - ▶ Location of the patient (rural primarily);
  - ▶ Type of provider (physician or practitioner [PA, NP, CNS, CRNA, CNMW, Clinical SW, Clinical Psychologist; RD]);
  - ▶ Type of facility (Physician office; CAH; RHC; FQHC; Hospital; Hospital based renal dialysis center; SNF; Community Mental Health Center);
  - ▶ Type of services (updated annually).
- ▶ See also:
  - ▶ 42 C.F.R. § 410.78 - Telehealth Services
  - ▶ 42 C.F.R. § 414.65 - Payment for Telehealth Services

# REIMBURSEMENT: MEDICAID

- ▶ South Carolina Medicaid does reimburse for telemedicine:
- ▶ Physicians, Laboratories, and Other Medical Professionals Provider Manual :
- ▶ Telemedicine includes consultation, diagnostic, and treatment services. Telemedicine as a service delivery option, in some cases, can provide beneficiaries with increased access to specialists, better continuity of care, and eliminate the hardship of traveling extended distances.
- ▶ Covered referring sites (where the patient is located)
  - ▶ The office of a physician or practitioner; Hospital (Inpatient and Outpatient); RHC; FQHC; Community Mental Health Centers.
- ▶ Providers: Physicians and NPs.
- ▶ Covered services include consultation, office visits, individual psychotherapy, pharmacologic management, and psychiatric diagnostic interview examinations and testing, delivered via a telecommunication system.
- ▶ A licensed physician and/or nurse practitioner are the only providers of telepsychiatry services.

# REIMBURSEMENT: MEDICAID

- ▶ Services not covered:
  - ▶ Telephone conversations
  - ▶ E-mail messages
  - ▶ Video cell phone interactions
  - ▶ Facsimile transmissions
  - ▶ Services provided by allied health professionals
- ▶ Referring site fee (RHCs & FQHCs): \$14.96 per encounter
- ▶ Hospital Providers: Receive a facility fee only when operating as a referring site.

# REIMBURSEMENT: MEDICAID

- ▶ Community Mental Health Services Providers
  - ▶ Reimbursement requires “real time” presence of the client
  - ▶ Telepsychiatry can be used to assess and monitor the client’s psychiatric and/or physiological status for one or more of the following purposes:
    - ▶ Assess the mental status of a client and provide a psychiatric diagnostic evaluation, including the evaluation of concurrent substance use disorders
    - ▶ Provide specialized medical, psychiatric, and/or substance use disorder assessment
    - ▶ Assess the appropriateness of initiating or continuing the use of medications, including medications treating concurrent substance use disorders (more)



# REIMBURSEMENT: MEDICAID

- ▶ Provide or review information on which to base a psychiatric evaluation and establish the medical necessity for care
- ▶ Assess or monitor a client's status in relation to treatment
- ▶ Assess the need for a referral to another health care, substance abuse, and/or social service provider
- ▶ Diagnose, treat, and monitor chronic and acute health problems. This may include completing annual physicals and other health maintenance care activities such as ordering, performing, and interpreting diagnostic studies such as lab work and x-rays.
- ▶ Plan treatment and assess the need for continued treatment.

# REIMBURSEMENT: MEDICAID

- ▶ Beginning 8/1/2014 BlueChoice Health Plan Medicaid members have access to ISelectMD.
  - ▶ An effort to decrease inappropriate ED use.
- ▶ Board certified physicians are available 24 hours a day to triage non-emergent, no life-threatening illnesses.
- ▶ Members speak directly with the physician who then advises the member and may order prescriptions.
- ▶ Comply with §40-47-113?

# REIMBURSEMENT: MEDICAID

- ▶ Proviso 33.26
- ▶ (E)(3)DHHS contracts with MUSC in the amount of \$14Mil to lead in the development of a telemedicine network.
- ▶ Requires that MUSC coordinate Palmetto Care Connections.
- ▶ REACH MUSC Program: Provides urgent stroke-care consultations to network hospitals.

# REIMBURSEMENT: PRIVATE

- ▶ Varies from payor to payor.
- ▶ Legislation: (All proposed – none passed)
  - ▶ H3779: No insurer shall require face-to-face contact between a consulting health care provider and a patient as a prerequisite for payment appropriately provided through telemedicine in accordance with generally accepted health care practices and standards at the time the telemedicine service was rendered.
  - ▶ H4901: An insurer must provide coverage for telemedicine services to the same extent that the services would be covered if provided to an insured individual through in-person consultation.

# REIMBURSEMENT: PRIVATE

- ▶ S290: The State Health Plan shall not require face-to-face contact between a consulting health care provider and a patient as a prerequisite for payment for covered services appropriately provided through telemedicine in accordance with generally accepted health care practices and standards at the time the telemedicine service was rendered.

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ **Anti-kickback Statute** - The federal health care program anti-kickback statute (the “Anti-Kickback Statute”) provides criminal and civil penalties for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business for which payment may be made under a federal health care program. 42 U.S.C. § 1320a-7b(b)
  - ▶ Due to the potential breadth of the Anti-kickback Statute, there are numerous safe harbors to protect certain transactions from liability.
- ▶ **Stark Law** - The federal physician self-referral statute (“Stark Law”) prohibits a physician or his family from referring Medicare (and to some extent Medicaid) patients to entities providing designated health services if that physician or his family has a financial (ownership, compensation or investment) interest in the entity. 42 U.S.C. § 1395nn.
  - ▶ There are exceptions that provide protection from liability for certain financial relationships a physician may have with an entity.

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ Issue – A telemedicine provider and its customers (i.e., participating distant sites) are potential sources of referrals of Federal health care program business to one another. As such, the exchange of anything of value between them potentially implicates the Anti-kickback Statute and Stark Law.
  - ▶ Most fraud and abuse issues unique to telemedicine relate to the infrastructure, equipment, and support needed to operate a telemedicine service.
  - ▶ Example: Provision of free telemedicine equipment to originating locations.
- ▶ The OIG’s “longstanding and clear” position on free or below-market items or services to actual or potential referral sources is that such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. OIG Advisory Opinion No. 11-12 (Aug. 6, 2011).

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ However, the OIG distinguishes between free or below-market services that are **integrally related** to a provider's service and those that are not. OIG Advisory Opinion No. 12-19 (Nov. 30, 2012).
- ▶ This means that the item or service offered (e.g., telemedicine equipment) can be *used only as part of the underlying service* being provided (e.g., telemedicine), such that the free or below-market items or services appear to have **no independent value** apart from the underlying service. *Id.*
- ▶ Where the item or service has no independent value apart from the services being provided, the preamble to the 1991 safe harbor states, its purpose is not to induce any act prohibited by the anti-kickback statute. Fed. Reg. 35,952, 35,978 (July 29, 1991).
- ▶ Accordingly, in such circumstances, the OIG has determined that the arrangement between a provider and customer is not likely to result in fraud or abuse under the anti-kickback statute.



# FRAUD AND ABUSE CONSIDERATIONS

- ▶ The preamble to the Anti-kickback Statute's safe harbors, however, makes clear that in determining whether a free item or service constitutes illegal remuneration, **the substance—not the form—of the transaction** controls and any **reasonably foreseeable misuse** of the equipment implicates the provider as well as the customer in potential liability. Fed. Reg. 35,952, 35,978 (July 29, 1991).
- ▶ Thus, OIG will view with skepticism any arrangements involving general purpose, multi-use equipment (such as computers) to determine if it is *integrally related* to the provider's service. *Id.*
- ▶ In making its determination, the OIG will examine:
  - ▶ The criteria used by the provider to determine which customers receive the equipment;
  - ▶ The ownership of the equipment
  - ▶ The location and access to the equipment at the customer's place of business
  - ▶ The procedures used by the customer and provider to police unauthorized use of the equipment
  - ▶ The value added to the core service being provided by the additional equipment
  - ▶ The number and extent of similar arrangements with other parties

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ Additionally, the following is a compilation of safeguards that should be put in place that are aimed at reducing the risk of improper payments for referrals of Federal health care program business and derived from OIG opinions on telemedicine or arrangements analogous to telemedicine:
  - ▶ **No obligation for local site to refer to distant site**
  - ▶ **No additional payment, beyond a consultation fee, for physicians to provide telemedicine services**
  - ▶ **No referral restrictions on physicians at distant site**
  - ▶ **Customers targeted based upon need and access, not referrals**
  - ▶ **Each party covers its own marketing costs**
  - ▶ **Cost of the equipment is not billed to any patient or third party payor**
  - ▶ **Equipment is**
    - ▶ **used exclusively for the telemedicine service, and**
    - ▶ **an integral part of the physician's use of the service**
  - ▶ **Expectation of less cost to the Federal health care programs**

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ If a transaction's health care fraud and abuse concerns have not been resolved by the foregoing considerations, it is very likely that the equipment must be provided at fair market value and meet the requirements of:
  - ▶ Equipment Rental Safe Harbor/Exception
- ▶ Other potentially applicable safe harbors/exceptions to Telemedicine:
  - ▶ Space Rental Safe Harbor/Exception
  - ▶ Personal Services and Management Contracts Safe Harbor/Exception
  - ▶ Bona Fide Employees' Safe Harbor/Exception
  - ▶ Electronic Prescribing or Health Records Safe Harbor/Exception

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NEXT CHALLENGE. NEXT LEVEL.

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