

Telemedicine Survey Guidelines and Department of Health Survey Policy

General statement

Telemedicine is an evolving and developing care strategy, the full impact of which, in most medical disciplines, is not fully understood and in many cases is currently under study. As a general concept, telemedicine has the potential to aid diagnosis and treatment when a visual image is more helpful than an audio description. When smell and tactical examination are necessary, telemedicine unaided is not an appropriate care strategy.

This policy incorporates the optimal standard of care based on current knowledge about telemedicine technology and provides guidelines that will help to formalize the current regulatory process in Pennsylvania. Pennsylvania's current healthcare facility regulations do not specifically address telemedicine services, but the federal Centers for Medicaid and Medicare Services (CMS) Conditions of Participation (CoP) have recently been amended to provide the requirements for telemedicine for hospitals that participate in the Medicare and Medicaid programs. The surveyor guidance contained herein is based on the CMS CoP and relevant state law.¹

This policy is applicable to hospitals licensed by the PA Department of Health, Division of Acute and Ambulatory Care(DAAC). It does not apply to facilities in other states nor to physicians' offices, industrial sites, urgent care centers, and other types of care settings where telemedicine services may be in place. It is not within the Department's purview to regulate individuals who may be involved in telemedicine services, such as physicians, nurses and other licensed or unlicensed health care practitioners.

For the purposes of this paper, the following definitions are used:

Telemedicine: The provision of clinical services to patients by practitioners from a distance via electronic communications. The telemedicine services can be provided simultaneously (in real time) or non-simultaneously (after-the-fact assessment of the patient's condition).

Originating site: the location of a patient at the time the service being furnished via a telecommunications system occurs.

Distant site: Site at which the physician or other licensed practitioner delivering the service is located at the time the service is provided via telecommunications system.

Distant site provider: facility or practitioner furnishing telemedicine services. A distant-site telemedicine physician or practitioner provides clinical services to the hospital or CAH patient

¹References to the related CMS State Operations Manual specific section and standard are included in [brackets]. State law references are included in {parentheses}.

either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services.²

PA hospitals are currently locations of both distant site and originating site telemedicine services.

Consult or Consultation: a telehealth assessment or consultation whereby a patient and attending provider discuss the care of the patient with a specialist at a distant site. The care of the patient remains the responsibility of the patient's attending provider and never transfers to the distant site provider. The patient may or may not be present in real time for the assessment or consult. The relationship must be delineated before the encounter.

Current Policy

A new telemedicine service is subject to all appropriate regulations under state law and the CMS Conditions of Participation. (See 28 PA Code § 51.3, et. seq. for requirements for a new service. Therefore, the Department's Division of Acute and Ambulatory Care (DAAC) is required to perform an occupancy survey before a facility can start to use a telemedicine process. This applies when a hospital initiates any new telemedicine service with another facility and also when a hospital initiates a new telemedicine service "in house" (between and among hospitals or other medical facilities owned or operated by the same entity). However, a facility that is expanding an existing "approved" telemedicine service into other areas of practice that currently exist at the facility is exempt from an occupancy survey for this expanded telemedicine service. A facility that is expanding telemedicine services into an area not currently under its hospital license or is changing the purpose of a physical area of the facility (i.e. office area to patient care area), must notify DAAC and request an occupancy survey for the area to be served by the expanded telemedicine services.

Once the initial occupancy survey is completed and the service is approved by the Department, the telemedicine service is included in the hospital's licensure survey. A facility that contracts with a distant-site hospital to provide telemedicine services, as the *originating site*, must notify DAAC of the new telemedicine service and request an occupancy survey for review of policies, equipment, credentialing, contract, etc. in accordance with the above guidance.

Below are interpretations of the current PA facility licensing requirements as they apply to new telemedicine services.

² Centers for Medicare & Medicaid Services, 42 CFR Part 482 and 485. Final Rule. Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging. May 5, 2011.

Proposed Elements for New Telemedicine Services During Onsite Survey by the DOH³

The following requirements apply to new telemedicine services.

Initiation of a new telemedicine program:

Letter to Pa DOH 60 days in advance of the intended day for the initial provision of a new service. {28 PA Code §51.31}

On-site survey. (See below for details.)

On-site survey obligations:

Written agreements, memoranda of understanding, or contracts for telemedicine services documenting the nature, scope and application of the telemedicine services offered, including all applicable administrative, clinical, and technical requirements. [See 482.12(a)(8) and (9) of the CMS Standards for details required in the agreement.

List of all participating physicians and other practitioners covered by the telemedicine agreement, and privileges of each. [§482.12 and 482.22]

Description of services to be rendered, including but not limited to location of practitioners, location of patients to be served, and type of service, such as store-forward⁴ or interactive⁵. [§482.12]

Policies outlining responsibilities of attending physician in relation to practitioners providing telemedicine services, in particular addressing authority and responsibility for medical treatment decisions, admission/discharge or transfer of patient to a facility that is capable of providing a higher level of care for the specific telemedicine services being provided.

Quality Improvement Program

There must be a quality improvement program for the telemedicine service that is shared between originating and distant sites, including periodic (at least yearly) evidence of an internal review of the distant-site physician's or practitioner's performance, including information on all adverse events that result from the telemedicine services and all complaints the hospital has received about the distant-site physician or practitioner. (see CMS Final Telemedicine Credentialing Rule)

³ Citations relevant to CAHs are not provided. Other general state law or CMS conditions of participation continue to apply.

⁴ Refers to the timing between the provision of the service and the time of collection. Store-forward= Asynchronous – the services are rendered at different time than collected from the patient.

⁵ Refers to the timing between the provision of the service and the time of collection. Interactive = Synchronous – the services are rendered in real time while the patient is present.

Practitioner Credentials and Privileges

All physicians and other licensed practitioners who provide services for patients in Pennsylvania licensed healthcare facilities shall currently hold a valid license to practice in Pennsylvania, regardless of whether they are associated with the originating-site or distant-site facility {28 PA Code §107.3} and the state in which they are physically located when rendering telemedicine services.

The originating site hospital may, but not must, accept the provider credentialing of the distant-site hospital specific to the medical discipline in which the provider is practicing telemedicine. Originating site hospitals need only demonstrate verification of provider credentials issued by the distant-site hospital, including verification that each practitioner has sufficient training in the specified medical discipline in which he or she is practicing telemedicine. [§482.12(a)(8) &(9) and §482.22(a)(3)] The distant site facility shall determine “sufficient” training for providers of its telemedicine services.

Distant site providers that are not licensed hospitals must meet the practitioner credentialing requirements of the originating-site hospital. [§482(a)(9) and §482.22(a)(4)]

Governing Board/Authority Review and Approval

The governing board of the originating site hospital must approve all telemedicine contracts, telemedicine related policies and procedures, providers’ authority to practice and, providers’ privileges.

Policies/Procedures

All telemedicine policies should be consistent with current nationally-recognized recommendations and guidelines for telemedicine. In the absence of nationally recognized recommendations and guidelines specific to a service to be provided by telemedicine, the Department of Health will review and approve the facility policies, protocol, and procedures.

Specific policy requirements are outlined below:

Policies for obtaining and documenting patient consent (can be preexisting but videotaped), shall include the patient’s acknowledgment of patient rights and responsibilities with respect to accessing health care via telemedicine technologies and a description of the process for complaints. This is to include a mechanism for obtaining additional patient consent if needed, e.g. if an invasive procedure is to be performed at a later date. [CFR §482.13] This consent need not be separate from any other patient consent for treatment, but may be included therein.

Telemedicine policies and procedures shall comply with legal requirements specific to telemedicine to ensure protection of patient health information, physical security of telemedicine equipment and security of electronic patient health data.

Policy (ies) to assure timely patient transfer to other specialized care when necessary including transfer agreements for the telemedicine services. Transfer agreements need not be specific to telemedicine services.

Policy(ies) to assure continuity of care throughout telemedicine services.

Facility Staff Training

Health professionals practicing in clinical areas where telemedicine services are provided shall have the necessary education, training/orientation, and ongoing continuing education/professional development to ensure they possess the necessary competencies for the safe provision of quality health services in the clinical specialty and use of telemedicine equipment.

Staff training shall include proper use and storage of telemedicine equipment to insure availability of competent staff to use equipment at all times. The facility shall ensure periodic assessment and documentation of staff competencies pertaining to all types of telemedicine equipment used in the clinical area.

Building

Construction or alteration work within the hospital required to accommodate and support the telemedicine services must be reviewed with the Department's Division of Safety Inspection prior to commencement of such work. A formal plan review and onsite occupancy inspection may be required. {28 PA Code §101.42, §101.42a and §101.43} In addition, the clinical area in which the telemedicine service is housed must comply with all applicable building and life safety code regulations.

Technical policies

Ensure equipment sufficient to support diagnostic needs is available and functioning properly at the time of clinical encounters.

For services in which the quality of an image is essential to the understanding of a clinical case, (e.g., radiology or cardiology), system images shall conform to current DICOM Standards or some other nationally recognized standard.

Policies should address issues necessary for the safe use of telemedicine technology and the provision of an environment conducive to patient, employee and equipment safety.

Policies and procedures for the use of telemedicine equipment and patient monitoring equipment must reflect and comply with organizational, legal, and regulatory requirements.

Policies shall address, to the extent necessary, back-up and contingency plans and redundant systems to assure uninterrupted services in case of equipment failure, especially for services where uninterrupted services may be critical such as but not limited to Tele-ER or Tele-ICU.

Technical specifications

Transmission Speed and Bandwidth

In all telemedicine services, except for telemental services, the issue of image quality, bandwidth transmission rates, pixel count and related technological adequacy issues have not been specifically delineated . It is expected that any technology employed for telemedicine services will be good enough for the intended purposes and circumstances of the service being provided, as determined by the facility and are consistent as much as possible with national guidelines if they exist at the time of the established service. These guidelines shall be reviewed and updated as appropriate in accordance with CMS stands for quality reviews. It is expected that there may be a difference in technological adequacy between store-forward and interactive services. Where necessary, it is expected that the electronic exchange rates of telemedicine services shall meet the required messaging standards for sharing of clinical data (HL7) or other appropriate standards.

For telemental programs, transmission speed is critical. Most telemental health programs use systems that transmit data and images at a minimum of 384 Kbps. Research into the quality of data transmission has shown that viewers perceive a marked difference in quality between 128 and 384 Kbps, but report less noticeable difference between 384 and 768 Kbps. Transmission speed shall be the minimum necessary to allow the smooth and natural communication pace necessary for clinical encounters.

APPENDIX A: GUIDELINES AND REFERENCES

The references below are offered as general guidelines only. The Department has not adopted these as enforceable standards.

American Telemedicine Association Resources:

- [Quick Guide to Store-Forward and Live-Interactive Teledermatology for Referring Providers](#) (April 2012) - *Funding support for this initiative was provided by United Health Foundation.*
- [Expert Consensus Recommendations for Videoconferencing-Based Telepresenting](#) (October 2011).
- [Telehealth Practice Recommendations for Diabetic Retinopathy](#) (February 2011)
- [A Blueprint for Telerehabilitation Guidelines](#) (October 2010) –
- [Practice Guidelines for Videoconferencing-Based Telemental Health](#) (October 2009) - [Evidence-Based Practice for Telemental Health](#) (July 2009) -.
- [Core Standards for Telemedicine Operations](#) (February 2008) -
- [Practice Guidelines for Teledermatology](#) (December 2007) -
- [Home Telehealth Clinical Guidelines](#) (2003)
- [Clinical Guidelines for Telepathology](#) (May 1999)

American Heart Association Resources:

- Recommendation for the Implementation of Telemedicine within Stroke Systems of Care: A Policy Statement from the American Heart Association *Stroke* 5/2009; 40:2635-2660