Utah Telehealth Study - Phase 3 Report

Prepared by Pilot Healthcare Strategies for the Utah Division of Occupational and Professional Licensing

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Executive summary and overview

This phase of the Utah Telehealth Study features a compilation and analysis of federal law governing the administration of telehealth services by health care professionals. As described in the technical proposal for this project phase, a summary chart of relevant federal statutes, regulations and guidance organized by each of these categories was prepared. The chart contains three sections as follows:

- Definition of telehealth, practitioners and scope of services
- Practitioner requirements
- State mandates

In addition, federal court decisions pertaining to the delivery of telehealth services with public safety and economic impact implications are included in this phase of the project.

The federal government defines and regulates the delivery of telehealth services in these contexts:

1. Medicare and Medicaid and practitioner reimbursement;

2. Home And Community-Based Services For Elderly And Disabled Individuals;
3. Food and Drug Administration law relative to online pharmacy; and
4. Federal health care programs including the Public Health Service, Indian Health Service, and the Veterans Health Administration.

Methodology

Federal statutes and regulations relating to the delivery of telehealth services were researched utilizing Lexis/Nexis with the search phrase "telemedicine or telehealth." In addition, the web sites of the Social Security Administration (SSA) and the Center for Medicare & Medicaid Services (CMS) were searched using the search phrase to identify guidance from these agencies on the use of telehealth services by health care professionals as well as to supplement the Lexis/Nexis search. Finally, a Lexis/Nexis search of federal court decisions pertaining delivery of telehealth services was conducted using the search phrase.

Findings of review of existing federal statutes, regulations and guidance

As might be expected, the federal government has not adopted a single definition of telemedicine or telehealth applying uniformly across the four categories identified above.

Relative to Medicare, federal statute (the Social Security Act) defines "telehealth service" as "professional consultations, office visits, and office psychiatry services…and any additional service specified by the Secretary." The Social Security Act also defines telehealth services using located-based parameters including "originating site" (where the patient is located when receiving services) and "distant site" (the location of the practitioner while patient services are being delivered) as well as the scope of practitioners who may provide telehealth services.

Medicare rules define "telehealth services" as encompassing an interactive telecommunications system using multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The definition also includes the transfer of patient information to another provider for confirming a diagnosis and/or treatment plan.

Regulations promulgated by the Drug Enforcement Administration (DEA) define the "practice of telemedicine" as "practice of medicine in accordance with applicable Federal and State laws by

a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system..."

DEA regulations implementing the statute set forth requirements for online pharmacies relative to web site disclosure requirements, a list of the states in which the pharmacy is licensed to dispense controlled substances, and information on practitioners having a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances. The rules require prescribing practitioners to have conducted at least one prior in-person medical evaluation or a medical evaluation via telemedicine. Related federal statute authorizes the U.S. Attorney General to issue a special practitioner registration to engage in the practice of telemedicine; no governing rules were identified.

Mental health services permitted by telehealth, but only when delivered in federal health care centers

In the context of federal health care centers, federal statute specifically recognizes the definition of telehealth as including mental health service and broadly defines it as "the use of electronic information and telecommunications technologies to support long distance clinical health care, patient and professional health-related education, public health, and health administration."

Use of telehealth services in Medicare limited to specified health care settings in low population areas

For the purposes of Medicare, the law contemplates telehealth services as serving areas where there are fewer available practitioners, limiting their delivery to rural Health Professional Shortage Areas, either located outside of a Metropolitan Statistical Area (MSA) or in a rural census tract or counties outside of a MSA.

Notably, the statute specifies originating sites can only be physician offices and specified health care facilities. It does not specifically refer to patients' private homes as either an eligible (or ineligible) originating site. However, CMS rules governing home and community-based services for elderly and disabled individuals allow the use of telemedicine under specified conditions.

Medical professionals are not required to present the beneficiary to the physician or practitioner at the distant site unless medically necessary as determined by the physician or practitioner located at the distant site.

Eligible Medicare providers and services

The types of practitioners who may be reimbursed under Medicare for telehealth services are listed in two categories. The first is physicians, broadly defined as:

- Physicians and osteopaths
- Dentists
- Podiatrists
- Optometrists
- Chiropractors

The second category is defined in statute as "practitioner" and includes:

- Physician assistants, nurse practitioners, or clinical nurse specialists
- Certified registered nurse anesthetists
- Certified nurse-midwives
- Clinical social workers
- Clinical psychologists
- Registered dietitians or nutrition professionals

The CMS Medicare Benefit Policy manual lists a wide scope of medical services that are approved for use of telecommunications as substitute for an in-person patient encounter. (See "Approved use of telecommunications as substitute for in person patient encounter" in the Guidance column starting at page 5 of the accompanying chart)

Professionals are required to be licensed in the state in which they perform functions within the scope of their licensure. Medicare regulations specifically require the physician or practitioner at the distant site be licensed to furnish the service under state law.

Medicaid

While no specific statutory or regulatory requirements relative to the Medicaid program were identified, the CMS web site states that "For the purposes of Medicaid, telemedicine seeks to improve a patient's health by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site. This electronic

communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and video equipment." The web site also defines "telehealth and telemonitoring" as "the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance."

Patient safety concerns, access to home and community-based telehealth cited in recent CMS rulemakings

Under current CMS guidance, subsequent skilled nursing facility (SNF) care services are among services approved for the use of telecommunications as a substitute for in- person patient encounters, with a limit of one telehealth provider-patient visit every 30 days. As part of a recent CMS final rulemaking taking effect in 2014 addressing Medicare reimbursement policies to reflect changes in medical practice and the relative value of services (CMS–1600–FC), CMS declined to adopt a proposal by the American Telemedicine Association (ATA) to eliminate the limit.

CMS cited patient safety concerns, noting SNF residents given their potential clinical acuity should continue to receive in-person visits "as appropriate to manage their complex care and to make sure that Medicare pays only for medically reasonable and necessary care." In rejecting the ATA proposal, CMS reviewed studies referenced by ATA and concluded they provided no information regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days. "More importantly," CMS commented in the preamble of the final rulemaking, "none of these studies addresses the concerns we have expressed about the possibility that nursing facility subsequent care visits furnished too frequently through telehealth rather than in-person could compromise care for this potentially acute and complex patient population."

In contrast, in another final rulemaking (CMS–2249–F; CMS–2296–F) that became effective March 17, 2014, CMS rejected suggestions that telehealth assessments for home and community-based services be permitted only in limited circumstances, such as when in-person assessments cannot practically be performed. Commenters had suggested telehealth be limited to individuals in rural or medically underserved areas, but not for beneficiaries for whom such circumstances do not create barriers to an in-person and in-home assessment.

Federal court decisions pertaining delivery of telehealth services

Very few federal court decisions affecting the delivery of telehealth services were identified. Two cases of note both involved physicians prescribing controlled substances across state lines.

In *United States v. Quinones et al.*, 536 F. Supp. 2d 267; 2008 U.S. Dist. LEXIS 13085 (February 19, 2008), several defendants were criminally charged with conspiring with and aiding and abetting medical professionals, include a physician licensed in Puerto Rico, to distribute controlled substances outside the usual course of professional practice using Internet web sites in violation of 21 U.S.C.S. § 846 and 21 U.S.C.S. § 841. The defendants unsuccessfully sought to have the charges dismissed, arguing Puerto Rico's Telemedicine Act (20 L.P.R.A. § 6001) authorizes physicians to provide medical services -- including prescriptions -- via "advanced technologic telecommunication means" to patients in "distant geographical areas."

The government argued that *United States v. Rodriguez et al.,* 532 F. Supp. 2d 316, 2007 U.S. Dist. LEXIS 79104, 2007 WL 3125179 (D.P.R. Oct. 24, 2007) does not allow doctors in Puerto Rico to practice via telemedicine nationwide. In *Rodriguez,* the district court ruled as a matter of law, Puerto Rico's Telemedicine Act authorizes the practice of telemedicine only within Puerto Rico:

"Nowhere in the Commonwealth of Puerto Rico Telemedicine Act are herein defendants authorized to provide medical services outside Puerto Rico to patients/customers who are not residents of Puerto Rico since said state law is not a multi-district accreditation for physicians outside the boundaries of Puerto Rico on patients who are not residents herein and/or as to whom, except for their internet communication, there is no prior physician-patient relationship. Thus, the government's response is appropriate in that defendants have never been licensed to practice medicine in the states where the internet customers were located nor where the pharmacy where the controlled substances were dispensed."

The court elucidated a broader principle that could apply to any form of telehealth services:

Regardless of the telemedicine system under which the physician is operating, the principles of medical ethics which are globally binding upon the medical profession must never be compromised. "Physicians practicing telemedicine must be authorized to practice medicine in the country or state in which they are located, and should be competent in the field of medicine they are practicing. When practicing telemedicine directly with a patient located in another country or state, the physician must be authorized to practice in that state or country, or it should be an internationally approved service."

The *Quinones* court concurred with the *Rodriguez* court's view of the scope of the Puerto Rico Telemedicine Act*:*

"The moving defendants contend that the act means that doctors in Puerto Rico may prescribe medication for anyone, anywhere; however, the more reasonable interpretation is that it was intended to afford medical services to those living in remote areas of Puerto Rico not well-served by traditional medical practices. The Court agrees with the magistrate judge in Valdivieso Rodriguez that the act was not intended to authorize doctors in Puerto Rico to prescribe medication to anyone in the United States, thereby stripping every state in the union of its power to regulate the health and safety of its citizens."

Moreover, the *Quinones* court added, "whatever its territorial reach, the Puerto Rico Telemedicine Act requires physicians to obtain "the *oral* and written informed consent of the patient" before performing telemedicine services. Even assuming that the information provided by customers of the moving defendants' web sites constitutes 'written informed consent,' the government alleges that no doctor ever spoke to any customer." (Emphasis in original)

The *Quinones* defendants were convicted and their appeals to overturn the convictions on evidentiary and improper jury instruction grounds were denied; the U.S. Supreme Court declined to hear the case.