Virtual Health Law & Policy Update

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NOTE: The content in this presentation cannot be considered legal advice for individual purposes.

Virtual Care is not regulated by one single law

There is no overarching law to control all the elements of a virtual medical practice. Different laws control the establishment of the patient provider relationship, authorize the practice of medicine, provider liability, billing, and prescribing medications.

These various laws are changed by Congress and agency action through rulemaking. In addition, during last two years “emergency rulemaking” has been relied upon to change laws at the state and federal levels.

Terms are wild and untamed: “*telehealth” remote* non-clinical services….*“telemedicine” remote* clinical services….SOMETIMES.

Provider- Patient Relationship

The AMA suggests that the Provider-Patient relationship is established, *"when a physician affirmatively acts in a patient's case by examining, diagnosing, treating, or agreeing to do so."*

Covered by State Law

Assumed that Provider and Patient will be in the same state (must be licensed to practice in the jurisdiction where physician-relationship is undertaken).

State law standards of care apply

State standards for professional malpractice apply to virtual care practices

The legal analysis treats virtual care like locum tenens or on-call physician

"that a physician-relationship can be established between a physician who contracts, agrees, undertakes, or otherwise assumes the obligation," without having direct or indirect contact with the patient. The ruling established a doctor-patient relationship linking the supervising physician at a teaching hospital, their students, and the patients they serve. *See*, *Lownsbury v. VanBuren*, 762 N.E.2d 354 (Ohio 2002).

Billing Considerations for Tribal Health Clinics

Congressional intent to provide Medicaid funds to Indian Health Service (IHS) and Tribal governments for the delivery of Medicaid services to eligible members of federally recognized Tribes under Section 1902(a)(73) of the Social Security Act.

Under the rules of Indian Health Service (IHS) and CMS, including the 1996 Memorandum of Agreement (MOA) between IHS and the Health Care Financing Administration (now known as CMS), and CMS State Health Official Letter 16-002 (dated February 26, 2016), IHS health programs may operate in a number of ways.

- Direct IHS Clinic—receives the IHS encounter rate as published annually in the Federal Register
- Tribal 638 Clinic – receives the IHS encounter rate as published annually in the Federal Register
- Tribal Federally Qualified Health Center -- receive payment at the IHS encounter rate under the Alternative Payment Methodology applicable to Tribal FQHCs in the Medicaid State Plan

To be eligible for Medicaid payments, all types of tribal health providers must meet state and federal requirements for Medicaid and meet state laws regarding provider licensure.

Key Medicare changes at a glance

Requirement Type	Pre-COVID-19 PHE Policy	Current COVID-19 PHE Policy
Patient site/geographic location	Payment available only for care at certain facility types with limited services for home-based patients Patient location must be rural or outside a metropolitan statistical area (MSA)	No restrictions on geographic location Patients can be at home or any other setting
Services	Payment available for about 90 services, as captured by CPT/HCPCS codes	Payment available for about 250 services, as captured by CPT/ HCPCS codes, as of March 2021
Telehealth modality	Payment for live video only, except for certain demonstration projects in Alaska and Hawaii	Payment available for live video, with audio-only phone for E/M services, behavioral health counseling, and educational services
Provider type	Payment available for services furnished by limited list of 9 provider types	Payment available for all health care professionals who are eligible to bill Medicare for professional services

SOURCE: https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf

Medical Billing for Virtual Medical Visits

- CMS: In 2022 CMS expanded coverage for the diagnosis, evaluation, or treatment of certain mental health disorders consistent with the Consolidated Appropriations Act.
- Specifically, the Physician Fee Schedule extended Medicare coverage for these services delivered to beneficiaries located in their homes (such that the geographic restrictions applicable to traditional telehealth services do not apply) so long as in-person non-telehealth services are furnished within six months prior to the telehealth visit and at least once within twelve months of each subsequent telehealth service.
- March 2022 Omnibus: Additional extensions for Medicaid reimbursement for virtual care. Watch for Congressional directed Rulemaking by CMS.

Prescribing Authority and Virtual Care, B.T.

Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was a set of critical amendments to the Controlled Substances Act

- Under the Ryan Haight Act, no controlled substance may be delivered, distributed, or dispensed by means of the internet (which, for all practical purposes, includes telemedicine technologies) without a valid prescription.

- “A valid prescription” is one that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner. An “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the prescribing practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

- The Ryan Haight Act makes it unambiguous that it is a *per se* violation of the Controlled Substances Act for a practitioner to issue a prescription for a controlled substance by means of the Internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances.

IHS Policy Guidance for Medication Assisted Treatment via Telemedicine-- 2018

- An official acknowledgment that the Ryan Haight Act created barriers to effective care via telemedicine
- A *qualified* exception to the pre se violation of the Ryan Haight Act applicable to providers who are DEA-qualified to prescribe buprenorphine
  - Provider must be “working for” IHS/638 Tribal Clinic (with MAT in AFA)
  - Acting within scope of employment, contract, compact, pt must be IHS
  - IHS facility designated as Internet Eligible Controlled Substance Provider (IECSP) (IECSP status granted by application from IHS)
  - IECSP must provide annual report of pts served via telemedicine

Public Health Emergency Exemption from the Ryan Haight Act

March 16, 2020– DEA authorized ability to prescribe CS via telemedicine without in-person visit based upon one of the seven statutory exemptions from the Ryan Haight Act.

As long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners may issue prescriptions for all Schedule II-V controlled substances to patients without first conducting an in-person medical evaluation, provided all of the following conditions are met:

1. The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
2. The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system.
3. The practitioner is acting in accordance with applicable Federal and State law.

HHS Secretary Becerra renewed the Public Health Emergency on January 14, 2022. Thus, telehealth for CS is provisionally allowed for all providers who meet the requirements. The IHS policy operates separately from the Public Health Emergency Exemption.