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Overcoming Legal Hurdles to Leverage Telehealth Models and Advances in Reimbursement to Increase Revenue for Providers

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Agenda

- Telehealth Overview
- Legal and Regulatory Issues in Telehealth
  - Brief overview of terminology and telehealth technology
  - Corporate practice of medicine and licensing issues
  - Fraud and abuse concerns
- Considerations in Drafting Telehealth Agreements
  - Establishing fair market value
  - Mitigating risk – indemnifications, warranties, liabilities
- Billing and Reimbursement for Telehealth Services
  - Current billing and coding issues
  - Recent developments in Medicare reimbursement for telehealth
  - Trends in state reimbursement laws

Telehealth Overview

- Market Opportunities
- No consistent set of definitions of telemedicine
  - Variance by state and payer
  - "Telehealth" generally broader than "telemedicine" -- The Pennsylvania legislature has not yet defined the "practice of telemedicine" or regulated whether out-of-state physicians providing telemedicine services to in-state patients need to be licensed in Pennsylvania.
  - The state's Medicaid program does reimburse physicians who video conference with Pennsylvania patients in real time, which implies that such a service is considered the practice of medicine. *Medical Assistance Bulletin* 09-12-31, 31-12-31, 33-12-30, PA DEP'T OF PUBLIC WELFARE (May 23, 2012).
  - Key Terms: Originating Site/Distant Site

Telehealth Overview (cont.)

- Modalities
  - Live video (synchronous)
  - Store-and-forward
  - Remote patient monitoring
  - Mobile health
- Sample Telehealth Arrangements
  - Teleneurology
  - Teledermatology
  - Behavioral telehealth
  - Remote monitoring of chronic conditions

Legal and Regulatory Issues

- Telemedicine Laws
  - Most states have relatively new or evolving statutes and regulations governing telehealth – Not directly addressed by statute in PA
    - But PA Medicaid defines "telemedicine" as real-time interactive telecommunications technology that includes, at a minimum, audio and video equipment as a mode of delivering consultation services. *Medical Assistance Bulletin* 09-12-31, 31-12-31, 33-12-30, PA DEP'T OF PUBLIC WELFARE (May 23, 2012).
  - Medicare
  - Insurance statutes and regulations and insurance contracts

Legal and Regulatory Issues

- Licensure
  - Some states implementing state licensure compacts; Interstate Medical Licensure Compact ("IMLC") movement for expedited pathway to licensure in additional states
  - PA currently only issues "extraterritorial licenses" to physicians licensed in adjoining states near the border whose practices expand into PA. 63 P.S. § 422.34. PA has passed legislation to join the IMLC, but implementation has been delayed.
- Practice of Medicine
  - Physician/Patient relationship vary by state
  - Any physician who engages in diagnosing or treating a patient must be licensed to practice in Pennsylvania. 63 P.S. § 422.10.
  - Impacts on qualification of physician/NP providing medical services
  - Practice of medicine ("PoM") occurs where the *patient* is located at time of encounter

Legal and Regulatory Issues

- Special PoM Arrangements
  - Provider to Patient Communications – In most states this will trigger licensure in the Originating Site
  - Provider to Provider – Some states, like PA, do not require the Physician in the Distant Site to be licensed if the Physician's communications are limited to consultation (second opinion) with the treating physician of the patient in the Originating Site (63 P.S. § 422.16). The term "consultation" means a deliberation between two physicians regarding a diagnosis or treatment, but a physician is not merely "consulting" if his contribution to the patient's care rises to the level of "active participation," such as touching the patient or assisting in procedures.

Legal and Regulatory Issues

- Special PoM Arrangements
  - Provider to Provider Extender – This model utilizes allied health professionals, such as a registered nurse, NP or PA to facilitate the communication between the patient in the Originating Site and provider at the Distant Site.
    - The Provider Extenders must be licensed in the state of the Originating Site and the services must be within the scope of such licenses.
    - Supervision Requirements

Legal and Regulatory Issues

- Special PoM Arrangements cont.
  - Provider to Non-Treating Provider to Patient – If non-treating provider is communicating with patient, provider must be licensed in Originating Site. In PA, the consultation exemption makes clear that the act of 'consulting' is strictly conducted between a doctor unlicensed in Pennsylvania and a licensed Pennsylvania doctor, not between a doctor unlicensed in Pennsylvania and a patient. *See Gleeson v. State Board of Medicine*, 900 A.2d 430, 437 (Pa. Commw. Ct. 2006).
    - (Note: If non-treating provider is employed by non-physician owned practice, corporate practice of medicine rules may be implicated)

Legal and Regulatory Issues

- Fraud and Abuse Concerns
  - AKS
  - Stark
  - FCA
  - State AKS/Anti-Referral Laws
- Privacy and Security -- HIPAA
- Reimbursement

Legal and Regulatory Issues

- Informed Consent – Federation of State Medical Boards (FSMB) and AMA have mandated baseline elements in the telehealth context
- Remote Prescribing
  - Some states/medical boards strictly prohibit
  - Some states require at least one in-person medical evaluation of the patient
  - Controlled substances prescribed via telemedicine is under jurisdiction of DEA
- Emergency Care – States, FSMB and AMA have issued rules or requirements for professionals and entities that provide telemedicine services to establish protocols for referrals for emergency services and to develop emergency plans

Considerations in Drafting Telehealth Agreements

- Establishing fair market value
  - Minimum threshold to comply with AKS
  - Are services being provided below FMV?
  - Is equipment being provided?
  - Does the arrangement fit within AKS safe harbors (e.g., physician services, equipment leasing, space rental, EMR)? Stark exceptions (e.g., lease arrangements, personal services arrangements)?
  - Is the arrangement “commercially reasonable?”

Considerations in Drafting Telehealth Agreements

- Mitigating risk – indemnifications, warranties, disclaimers
  - Define telemedicine practice standards in Telemedicine Service Agreement
  - Warranty that services provided by personnel with required skill, experience and qualifications -- Schedule list of providers
  - Vendor Equipment/Software Agreements – Define licensing terms, inter-operability, up time/down time, vendor reps/warranties to technology complies with regulatory requirements
  - Performance warranty
  - Compliance with laws – list specific laws and level of knowledge qualifiers (disclaimers)
  - Insurance – Support respective indemnification obligations

Billing & Reimbursement for Telehealth Services

Medicare Reimbursement

- Reimbursement for telehealth historically has been limited by the Social Security Act to certain services that directly substitute for an in-person visit.
- Four requirements for reimbursement:
  - "Originating site"
  - "Distant site"
  - Qualifying technology
  - Covered service

Barriers to Implementing Telehealth

- Uncertainties – what services are reimbursable?
- Inadequate payment
- Coverage restrictions
- Restrictions on eligible telehealth originating sites

MedPac Report to Congress

- March 2018
- Mandated by the 21st Century Cures Act of 2016
- MedPac required to provide the following information to Congress:
  - The extent to which the Medicare fee-for-service ("FFS") program covers telehealth services
  - The extent to which commercial insurance plans cover telehealth services
  - **Ways in which the telehealth coverage policies of commercial insurance plans might be incorporated in to the Medicare FFS program**

MedPac Report (cont.)

- Recommendation for policymakers to take a “measured approach” to further incorporating telehealth into Medicare
  - Evaluate individual telehealth services to assess capacity to address “Triple Aim”
  - Permit entities that bear financial risk (Medicare Advantage plans, certain ACOs) greater flexibility to use and evaluate telehealth services

Recent CMS Expansion of Reimbursement

- CMS has promulgated new rules related to telehealth reimbursement across various payment programs:
  - Medicare Shared Savings Program ("MSSP")
  - Physician Fee Schedule for 2019
  - Home Health Prospective Payment System ("HH PPS")

“We now recognize that advances in communication technology have changed patients’ and practitioners’ expectations regarding the quantity and quality of information that can be conveyed via communication technology.”

– Centers for Medicare & Medicaid Services

Changes to the MSSP

- Rule finalized December 21, 2018
- Allow physicians and other practitioners who take risks within ACOs to receive payment for introduction of and reliance on new technologies in their practices
- Changes include:
  - Store-and-forward teledermatology and teleopthalmology services
  - Treatment of patient's home as an "originating site"

2019 Physician Fee Schedule

- Rule finalized November 1, 2018, effective January 1, 2019
- Communicates new interpretation by CMS of applicability of their statutory requirements for reimbursement of remote communication technology as separate from telehealth
- New services added based on this interpretation, which are not subject to originating site or geographic restrictions:
  - Virtual check-ins
  - Store-and-forward images and video
  - Peer-to-peer internet/phone consults

2019 Physician Fee Schedule (cont.)

- Includes new CPT codes to the Medicare telehealth list related to remote patient monitoring ("RPM") services that will more accurately reflect how RPM services are furnished by:
  - Establishing 20-minute intervals tracked by calendar months
  - Providing separate reimbursement for initial set-up of remote monitoring equipment, patient education and onboarding
  - Allowing "clinical staff" to furnish certain services

2019 Physician Fee Schedule (cont.)

- Adds two new codes to the list of telehealth services related to prolonged preventive services in an office or outpatient setting for periods of 30 minutes
- Loosened restrictions on use of telehealth services to treat substance abuse
  - Implemented SUPPORT Act, effective October 24, 2018, which adds the home of an individual as a permissible originating site for telehealth services furnished for substance use disorder treatment or treatment of co-occurring mental health disorders
- Expanded telehealth services for end-stage renal disease ("ERSD") patients who receive home dialysis and acute stroke patients by adding ERSD patient homes and mobile stroke units as originating sites

HH PPS Reimbursement Change

- Rule finalized October 31, 2018, effective January 1, 2019
- Permits home health agencies to report certain RMS expenses as allowable administrative costs on the cost report

CMS' increasing coverage of telehealth services sends a strong message that the services are important, clinically valid tools through which providers can deliver healthcare services.

Other Payors Encouraging Telehealth

- State Medicaid reimbursement
  - 49 states and DC reimburse for live video conferencing services
  - 15 states reimburse for asynchronous services other than teleradiology
  - States increasingly including patient's home as "originating site"
- Pennsylvania Medicaid reimbursement
  - Synchronous services by certain practitioners
  - Specialty consultations, including "endorsed" telepsychiatry services

Other Payors Encouraging Telehealth (cont.)

- Private payors
  - Rapidly expanding coverage
  - 39 states have guidelines in place for private payor reimbursement of telehealth
  - Partial or Full Parity laws

Practice Tip for Providers

- Take the time to truly understand all precise, technical requirements of billing for each service
  - *E.g.*, frequency limitations, new vs. established patients
- Medicare – 2018 OIG Audit Report:
  - **31%** sampled telemedicine claims did not meet Medicare conditions of payment, resulting in **$3.7 million** in overpayments
  - OIG recommended that CMS conduct periodic post-payment reviews to disallow payments for errors

Questions?

Presenters

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