The Shifting Legal Landscape of Telehealth

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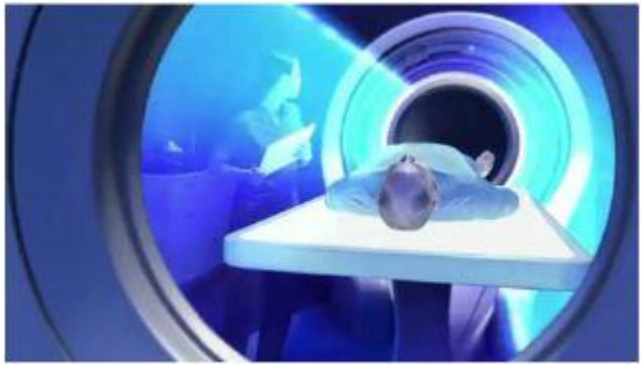
Agenda



- What is telehealth?
  - Background and History
  - Implications of Covid-19
- Key Legal Issues
  - Licensure/Scope of practice
  - Reimbursement
  - Privacy/Security
  - Fraud & Abuse
- Business Models
- Guidance and Future Developments

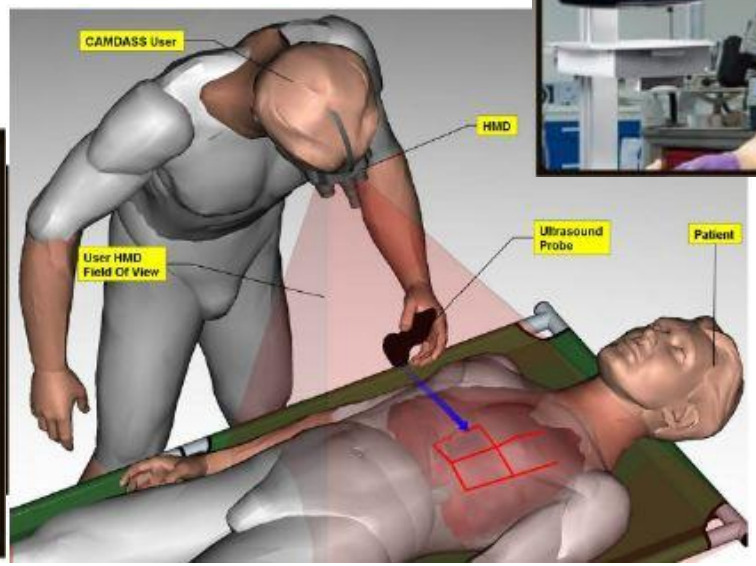
What is Telehealth?

Telehealth

- Use of electronic information and telecommunications technologies to support long-distance clinical health care
  - Can also include patient and professional health-related education, public health and health administration activities
- Terminology and definitions
  - Originating Site: Where the patient is located
  - Distant Site: Where the provider is located
  - Synchronous: Live audio-video communication tools that permit interactive telemedicine
  - Asynchronous/Store and Forward: Technologies that collect images and data to be transmitted and interpreted later, which permits providers to share patient information with other health care professionals or specialists in another location
  - Remote monitoring: Tools that communicate biometric data (e.g., blood sugar or blood pressure), allowing remote caregivers to monitor patients by using mobile medical devices to collect data
- Use of terms/definitions vary by state, agency, payor, etc.

Reasons for Growth of Telehealth

- Advances in technology
- Physician shortage, especially in rural areas
- Efforts to increase access to health care
- Aging population; increase in patients with chronic diseases
- Emphasis on care coordination and shifting care settings
- Global health care



Regulatory Landscape

- Statutes and regulations govern two primary aspects of telehealth:
  - Medical/professional practice
    - What services can be provided
    - Who can provide them
    - Technology that can be used
    - Other requirements that must be met prior to providing telehealth services
      - E.g., Standards of care
  - Reimbursement
    - Rates of reimbursements
    - Medicare, Medicaid, commercial payor requirements

Regulatory Landscape

- Federal telemedicine laws and regulations
  - Medicare
  - HIPAA
  - Fraud & Abuse
  - DEA
  - Other agency rules (depending on what is being done)
- State laws and regulations
  - Medicaid
  - State insurance law (coverage and parity)
  - Licensure and scope of practice rules
  - Professional practice/prescription standards
  - Corporate practice of medicine doctrine
  - Professional board guidance

Highly variable across states

Impact of COVID-19

- Prior to COVID-19, telehealth was most often used in rural and remote areas where patients would otherwise have to travel long distances to receive care
  - Did not achieve the wide use and popularity that its supporters anticipated
- COVID-19 pandemic has resulted in an unprecedented series of actions by regulators to allow for the expansion of telemedicine
- Many existing telehealth restrictions have been lifted in order to enhance patient access to care services
- Examples
  - Telephone Consumer Protection Act (TCPA)
    - FCC ruling permits automatic calls under TCPA in limited circumstances
    - Hospitals, health care providers, state and local health officials, and other government officials may now communicate information as well as mitigation measures to the public about novel coronavirus without violating the TCPA.

Impact of COVID-19 (Continued)

- State and Federal Waivers
  - Waiver of certain conditions of participation, certification requirements, program participation and pre-approval requirements
  - Waiver of individual state licensing requirements
  - Relaxation of numerous provider enrollment requirements under CHIP and Medicaid
  - “Blanket” Stark Law waivers
  - OIG Special Fraud Alert permitting co-insurance waivers for telehealth services
  - Others

Impact of COVID-19 (Continued)

- DEA
  - Invoked its emergency authority to permit temporary waiver of the in-person examination requirement for prescribing controlled substances to new patients through telemedicine, in certain circumstances
- HIPAA
  - OCR is exercising enforcement discretion to waive potential HIPAA penalties for providers that serve patients via telehealth through “everyday communications technologies”.
  - Permits use of communication tools like Skype, Facebook Messenger, Google Hangouts and Apple FaceTime for treatment purposes, even if the technologies’ use might not fully comply with the HIPAA Security Rule

CMS proposes to make certain telehealth changes permanent for 2021

- Executive Order (Aug. 3, 2020)
  - CMS directed to propose regulations that would extend Medicare coverage for telehealth after expiration of PHE
  - HHS instructed to work with USDA and FCC to develop and implement strategy to improve rural health by enhancing communications infrastructure
- 2021 Physician Fee Schedule Proposed Rule (publication scheduled for Aug 17, 2020)
  - CMS issued a proposed rule that announces and solicits public comments on policy changes for Medicare payments under the PFS
  - Would make permanent certain telehealth and workforce flexibilities provided during the COVID-19 PHE
- **Public comments due by October 5, 2020**

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Key Legal Issues

Licensure

- **General rule**: Provider must be licensed by state in which the patient is located
- Many states have enacted rules specific to telemedicine licensure
  - Requirements are often less burdensome than full licensure
  - Examples:
    - Special purpose license
    - Telemedicine license or certificate
    - Registration
- Many states have consultation exceptions
  - Consultation exceptions vary
    - Some allow for frequent remote consultations while others are more restrictive
  - Minnesota allows an out-of-state physician to consult with a Minnesota physician if the Minnesota physician "retains ultimate authority over the patient"

Licensure

- State terminology and definitions vary
  - The term “Practice of Medicine” is defined by state law
  - Often tied to the provision of services to residents in that state—but the definition may be broader than this
    - Certain actions may constitute the “practice of medicine” if performed within the state even though not performed on behalf of a resident of that state
- Can impact licensure requirements. For example:
  - Massachusetts Board of Registration in Medicine includes telemedicine in their definition of the “practice of medicine”, which means that a physician must have a license to practice medicine in Massachusetts to be able to provide telemedicine services
  - Virginia explicitly requires that individual providers be licensed not only in the state where the patient is located, but also the state where the provider is located

Licensure

- Changes due to COVID-19
  - *CMS waived licensure requirement* as long as the provider is licensed and in good standing in another state
    - Does not supersede state licensure requirements
  - *States have also waived licensure requirements* during the Covid-19 pandemic
    - *E.g., Minnesota Executive Order 20-46*
      - Authorizes certain out-of-state healthcare professionals who hold an active license from a different state to render services in Minnesota during the peacetime emergency
    - *E.g., Minnesota Executive Order 20-28*
      - Authorizes out-of-state mental health providers to treat Minnesota patients via telehealth to help ensure that the mental health needs of Minnesotans are met
    - *E.g., CMS approval of Minnesota's state Medicaid waiver*
      - Temporarily waives the requirement that out-of-state providers be licensed in Minnesota

Scope of Practice

- Establishment of patient-provider relationship
  - Rules vary by state – generally a fact-specific analysis
    - Typically arises once provider affirmatively acts in a patient's case by examining, diagnosing, treating, or agreeing to do so and the patient accepts
      - Lack of direct contact in itself does not preclude a patient-provider relationship
    - MN: Physician-patient relationship may be established solely by telemedicine
  - Provider generally has a right to choose whether to treat
    - Exceptions: Emergency care, anti-discrimination, etc.
    - Ability to "reject" or "best direct" patients may be limited by technology & business model
- Providers that provide telehealth services are subject to the same standards of practice and conduct as if the services were provided in person

Scope of Practice

- Services provided via telemedicine must comply with scope of practice requirements
  - Must meet the practice standards of the state in which the patient receives care.
  - Limits what services can be provided, just as with traditional in-person care
- Requires consideration of a number of different issues:
  - What type of provider is providing the telemedicine services?
    - Requirements vary for non-physician practitioners (PAs, NPs, RNs, therapists, social workers, etc.)
    - Consider whether they are permitted to practice telemedicine (many states speak only to physicians)
  - Supervision/oversight requirements
    - The scope of physician supervision or oversight depends on the other non-physician practitioners involved and the requirements of state law

Scope of Practice

- Some states still require in-person care for specific types of services
- Example: prescribing via telehealth
  - The DEA (under the federal Controlled Substances Act) has historically required in-person exams of patients for a prescription for controlled substances.
    - Note this restriction has been suspended during the COVID-19 pandemic
    - DEA permits the exam to occur via telehealth using real-time, two-way audio visual communications.
  - State law often includes similar in-person requirements
    - E.g., Minnesota requires that in-person exams be performed in the event certain drugs are prescribed.

Licensure/Scope of Practice

Two critical questions when considering telemedicine expansion:

- What specific services do we want to provide?
  - Can we meet the standard of care?
  - Does state law permit these services?
  - Are there specialty-specific requirements?
  - Will these services involve prescriptions?
- Who will be providing these services?
  - Physicians, APRNS, Psychologists, PTs, etc.?
  - Are these practitioners permitted by the state to engage in telemedicine?
  - Where are the practitioners licensed, and where are the patients located?
  - Are there particular practice requirements?

Making Changes Permanent?

- CMS is proposing to make permanent certain changes related to supervision of diagnostic tests by non-physician practitioners
  - Would allow nurse practitioners, clinical nurse specialists, physician assistants and certified nurse-midwives to supervise the performance of diagnostic tests in addition to physicians
- Proposing to allow direct supervision to be provided using real-time, interactive audio and video technology through December 31, 2021
  - Excludes telephone that does not also include video
- Other proposed changes

Historic Telehealth Reimbursement: Medicare

- Different rules and requirements for Medicare, Medicaid and commercial health plans
- Significant limitations and slow growth in coverage for services rendered via telehealth
- Medicare began covering services in 2000. Coverage has grown slowly (but consistently) since that time.
- Historic Medicare rules included:
  - Services must be a designated “telehealth service”
  - Providers must use synchronous audio/visual technology (real-time communication)
  - Patients receiving services must be located at a qualifying “originating site” at time of service
    - Geographic Requirement—Site must be in “rural” HPSA (includes HPSAs and counties within rural census tracks within MSA) or county outside of MSA.
    - Location Requirement—patient must be at specific location, such as physician/practitioner office, CAH, FQHC, Hospital-based (or CAH-based) dialysis center
  - Specific providers (physicians and practitioners) can be distant site practitioners
  - FQHCs and RHCs prohibited from serving as distant site practitioners
  - Medicare pays distant site provider at the facility rate (place of service -02).
  - Originating site is also paid a nominal facility fee (approx. $25), billed with POS of beneficiary’s location

Historic Telehealth Reimbursement: Medicaid

- Medicaid
  - States free to set own policy on Medicaid coverage and payment, so long as specific federal standards satisfied
  - Resulted in crazy-quilt approach to Medicaid telehealth policy. For example, state Medicaid programs take different approaches on:
    - Covered patient settings
    - Types of practitioners eligible to provide services
    - Technology required to provide services remotely
    - Distance or geographic restrictions (within the state)
    - Special rules for mental and behavioral health services
    - Informed consent requirements
  - As of 2018, state Medicaid policy included the following characteristics
    - 50 states offered some coverage for telehealth services (interactive live video)
    - 9 states offered coverage of asynchronous telehealth services
    - 29 states offered coverage of telehealth-based home health services (including remote patient monitoring)(
    - 30 states paid an additional transmission or facility fee when telehealth used
    - 47 states offered telehealth coverage without geographic limitations (no urban or rural requirement)
    - 40 states permitted the patient's home to serve as an originating site for telehealth

Historic Telehealth Reimbursement: Commercial Payors

- Commercial Payors
  - Even more scattered than Medicare & Medicaid
  - As of 2018, 31 states and D.C. had telehealth commercial payor laws / telehealth parity laws
  - Telehealth coverage laws require plans to cover services to same extent plan covers the service if provided in-person
    - These laws do not expand coverage
    - Prevent plans from imposing different co-payments, deductibles, benefit caps for services rendered via telehealth
  - Telehealth parity laws
    - Providers paid the same amount for telehealth services that provider paid if service delivered in-person
    - Parity laws do not change plan's existing rules on utilization review
    - Goal of these laws is to prevent plans from paying for telehealth services at fraction of reimbursement for in-person care

Medicare Reimbursement: Changes from COVID-19

- Sources of changes to Medicare policy:
  - CMS Waivers/Exceptions
  - The CARES Act (made several policy changes and granted HHS authority to waive various statutory requirements for telehealth services)
  - First Interim Final Rule
  - Second Interim Final Rule
  - Medicare Advantage Final Rule
  - How to keep track of it all?
  - https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf
  - See additional links at end of slides
- Trends: CMS has reduced barriers for each of the following:
  - Significant expansion in scope of covered services:
    https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
  - No geographic restrictions for patients or providers
  - All providers eligible to bill Medicare can bill for telehealth, including FQHCs and RHCs
  - Providers can waive or reduce cost-sharing (copayments and deductibles) for telehealth visits
  - Relaxation of technology requirements for covered services
  - Providers can furnish services outside of state of Medicare enrollment

What has all of this meant?

- Unprecedented growth in telehealth services:
- In FY 2016, Medicare paid total of $28.7 million in telehealth reimbursement (out of $600 billion in total Medicare budget that year)
- CMS covered 1.7 million virtual visits during final week of April, an increase from the standard tally of 14,000 consultations via phone or video before pandemic
- FAIR Health: number of claims to commercial payors for services provided via telehealth was more than 8,000% higher in April 2020 (compared to April 2019)
  - In Midwest region, telehealth claims went from .016% of total claims to 10.72% (6754% increase)
  - Mental health by far the largest diagnostic category (43% of telehealth claims involved mental health; next closest was joint / soft tissue diseases at 4.5%)
  - Medicare / Medicaid not included
- Pressure to make changes permanent. 340 organizations submitted letter to Congress urging them to make telehealth flexibilities established during PHE permanent.
  - Wide range of healthcare stakeholders across all 50 states

Growth in Telehealth for Primary Care Services

Table 1. Proportion of FFS Medicare Primary Care Visits via Telehealth and Medicare COVID-19 Hospitalization Rate, by Core-Based Statistical Area (CBSA)

	February		April		
	Total Primary Care Visits	Percent Telehealth	Total Primary Care Visits	Percent Telehealth	Medicare COVID-19 Hospitalizations per Thousand Beneficiaries
US TOTAL	**19,655,604**	**0.1%**	**4,786,049**	**43.5%**	**11.7**
Boston, MA	355,687	0.0%	237,694	73.1%	35.7
Minneapolis-St. Paul, MN	123,001	0.1%	71,806	63.9%	4.9
Philadelphia, PA	416,398	0.0%	229,355	61.6%	24.0
San Francisco, CA	187,845	0.2%	105,112	60.2%	3.7
Detroit, MI	225,850	0.1%	126,331	59.7%	60.3
New York, NY	1,233,990	0.1%	634,558	56.5%	59.5
Chicago, IL	512,752	0.0%	289,301	52.4%	24.5

Medicare: New Approach to Telehealth

- Medicare approach to licensure
  - Eligible practitioner must typically be licensed in the state where patient is located
  - Requirement waived (under CMS waivers) as long as provider is licensed and in good standing in another state
  - Waiver pertains to Medicare; does not supersede state licensure requirements
  - CMS waived various enrollment / program integrity requirements (written application, enrollment of practitioner's home address as practice location)
- Originating site / distant site requirements
  - Restriction that patient must be located in a designated rural shortage area (with a few exceptions) has been waived (initial CMS waivers).
    - Patients in any geographic area, including urban areas, may receive qualifying telehealth services.
  - Restriction that patient must be located in one of several designated locations has been waived (initial CMS waivers)
    - Patient may receive eligible telehealth services in other locations, including the patient's home
  - CARES Act permits FQHCs / RHCs to serve as distant site for telehealth during PHE

Medicare: New Approach to Telehealth

- Expanded services that telehealth will cover:
  - Waives Pre-Existing Patient Relationship Requirement for “E-visits” and “Virtual Check-ins”
  - Expands telehealth coverage to 135 additional services
    - Examples: ED visits, initial nursing facility and discharge visits, initial hospital care and discharge, initial and subsequent observation, home visits, therapy services, group psychotherapy
    - Must be provided by qualified telehealth practitioner
  - Changes in reimbursement to reflect non-facility place of service
  - Expands potential use of audio-only (not considered “telehealth”)
  - Intention to add new types of telehealth services on a sub-regulatory basis through guidance, instead of the formal notice-and-comment process
- Expanded ability to use telehealth to render care:
  - Can use telehealth to meet many face-to-face visit requirements (e.g., home health, hospice recertification)
  - Clarifies that clinicians can bill for remote patient monitoring technology for individuals with acute and chronic conditions, even unrelated to COVID-19.
  - Providers can use telehealth to meet direct supervision requirements (instead of observing in-person).

Medicare: New Approach to Telehealth

- Billing and reimbursement:
  - Telehealth services paid at the same rate as in-person services
  - Expands the types of practitioners who can bill Medicare for services.
    - Providers such as physical therapists, occupational therapists and speech-language pathologists can receive payment for Medicare telehealth services
  - Expanded list of originating sites:/ payment of originating site fee
    - Will pay for beneficiaries receiving services at home and other temporary expansion sites
    - To hospital where telehealth services are furnished remotely by hospital-based practitioners to patients who are registered as hospital outpatients, including when the patient is at home and when the home is serving as a temporary provider-based department of the hospital.
  - Increased audio-only telehealth for certain services
  - Increased payments for telephone evaluation and management visits / behavioral health counseling and educational services to be the equivalent of Medicare payments for office/outpatient visits.
  - Waived frequency of services requirements for many services
    - Subsequent inpatient and SNF visits can be provided through telehealth, with no frequency limits
    - Critical care consult codes can be furnished beyond once-per-day limitation

Making Changes Permanent?

- Executive Order (Aug. 3, 2020)
  - CMS directed to propose regulations that would extend Medicare coverage for telehealth after expiration of PHE
  - HHS instructed to work with USDA and FCC to develop and implement strategy to improve rural health by enhancing communications infrastructure
- 2021 Physician Fee Schedule Proposed Rule (publication scheduled for Aug 17, 2020)
- Adds numerous services to Medicare coverage list. Examples:
  - Visit complexity code for office / outpatient E & M services, home visits, prolonged services, group psychotherapy, care planning, neurobehavioral status exams, domiciliary, rest home or custodial care, others—all covered permanently
  - Other services added to coverage list for remainder of year in which PHE ends:
    - E & M for established patients (home, domiciliary, rest home and custodial care), ED visits, nursing facility discharge day management, psychological and neuropsychological testing
  - Requests comments about services added during PHE that are not proposed to be made permanent
    - Whether audio-only telephone E & M should be covered after PHE
- Clarifies provision of other services. Examples:
  - Remote physiologic monitoring services
  - Direct supervision can be provided via telehealth through Dec 31, 2021

Making Changes Permanent? Other 2021 MPFS Proposals

- Relax frequency limits for certain services (nursing visits via telehealth covered a 1 visit per 3 days vs. 1 visit every 30 days)
  - Seeks comment about whether CMS should remove frequency limits completely
- LCSWs, PTs, OTs, SLPs and clinical psychologists can furnish online assessment and management services, virtual check-in and remote evaluation services
- Clarifies whether telehealth should be billed when provider furnishes service in same location as beneficiary (i.e., remotely via telehealth even though provider on-site)
- Proposes to make permanent NPs, PAs, CNS and CNM ability to supervise performance of diagnostic tests (temporary during PHE)
- Pharmacists can provide services incident to physician services
- Considering whether to extend teaching physicians'' ability to provide services of residents via telehealth, expanded set of services residents can provide and coverage of services by residents outside scope of GME and furnished to inpatients of teaching hospital (all temporary during PHE) either through Dec. 2021 or made permanent
- Many other changes

Making Changes Permanent?

- 2021 Quality Payment Program Proposed Rule
  - QPP is basis under which Medicare's merit-based incentive payment system (MIPS) and alternative payment models (APMs) are operated
  - 2021 payment year was set to implement CMS' MIPS Value Pathways (MVPs) and APM Performance Pathway
  - In recognition of challenges for provider community in meeting demands of COVID-19, CMS proposes to take a number of steps. Goal is to reduce chances of Part B reimbursement cuts because of failure of physicians and other suppliers to hit QPP targets:
    - Delay implementation of MVPs until 2022 (instead of 2021)
    - Modify various QPP reporting obligations and performance targets to account for provider challenges due to COVID-19
    - Increase bonus for treating patients with complex conditions from a 5 point to 10 point maximum for 2020. Goal of offsetting additional complexity of COVID-19 patient population.
    - Reducing number of measures for which ACO reporting is required
    - Waiving requirement for 2020 that ACOs field Consumer Assessment of Healthcare Providers and Systems survey to patients

Medicaid: New Approach to Telehealth

- Expansion of telemedicine visits
  - Services via telephone when provider believes safe and effective
  - Limit of 3 telemedicine encounters per week suspended
  - Covers of E & M services via telephone
- Distant site (provider's location) can be provider's home
- Originating site can be the member's home
- Various categories of services expanded:
  - Targeted case management services can be provided via telephone / video-conference instead of in-person, face-to-face
  - Expanded use of telehealth in HCBS waiver programs so that providers can furnish remote support through phone or other interactive technology
  - Licensed adult day service providers can provide services (up to 4 hours per day) via telehealth to people who normally receive services in adult day settings
  - Personal care assistants can provide services via telehealth (phone or other interactive technology), with MHCP covering up to 310 hours per month
- MHCP created streamlined enrollment process for provider who were not previously providing telehealth prior to PHE
- MHCP also expanded categories of providers eligible to provide telehealth
- DHS has suspended recertification and recordkeeping requirements tor certain services

Commercial Payors: New Approach to Telehealth

- State laws vary on issues of coverage and insurance parity for services rendered via telehealth to beneficiaries of commercial health plans. Examples:
  - Minn. Stats. §§ 62A.67—62A.672 (Minnesota Telemedicine Act). Obligates plans to cover telemedicine in same manner as other covered benefits. Must reimburse providers on same basis and at same rates as would apply if services delivered in person.
  - Mo. Rev. Stat. § 376.1900: Health carriers cannot deny coverage on basis of service being provided via telehealth if service would be covered face-to-face; services provided via telehealth cannot have higher co-payments, deductibles than for services rendered in person, etc.
- Many states have acted to expand providers' ability to render care via telehealth during PHE
  - All 50 states have issued some form of waiver. Many have expanded telehealth in key ways.
- In MN, key changes include:
  - Must cover services from provider at distant site to patient at patient's home
  - Expands list of providers eligible to provide services to include mental health practitioners and respiratory therapists
  - Plans must cover services that consist solely of telephone conversation
  - Plans cannot deny or limit reimbursement solely because services were delivered via telehealth or with specific telehealth technology
  - All of these changes set to expire (60 days after emergency or 2/1/21 (for distant site change)

Enforcement in Telehealth: Reimbursement

- Feb. 2018 Telehealth settlement / self-disclosure
  - Highland Rivers Health self-disclosed billing for psychiatric telehealth services provided from locations that were not eligible for reimbursement. Sites did not qualify as "originating sites".
  - Paid $133,000 to settle matter
- 2018 OIG Report, *CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements*
  - 31% of telehealth claims did not meet Medicare requirements
    - Beneficiaries receives services outside of approved originating sites
    - Clams bulled by ineligible institutional providers
    - Beneficiaries receives services at unauthorized originating sites
    - Unapproved technology / communication tools were used
    - Billing for services that are not covered
    - Physicians outside of U.S. renderings services
- In 2018 Report, OIG recommended that CMS take following steps:
  - Conduct periodic post-payment reviews
  - Ensure Medicare Administrative Contractors enforce all telehealth claims edits outlined in Medicare Claims Processing Manual
  - Offer more training and education to providers

Privacy/Security

- Telehealth providers must comply with federal and state privacy and security requirements
- Providers must use HIPAA-compliant platforms when providing telehealth services
  - Must understand risks associated with the technology being used
- State law requirements may impose requirements in addition to HIPAA
- Consider players involved in the telehealth arrangement
  - Health care provider
    - Will be a Covered Entity under HIPAA
    - Must comply with HIPAA Privacy and Security Rules
  - Vendors
    - Often constitute a HIPAA Business Associate
    - Is a vendor a “conduit”?
  - Patients
    - Entitled to same patient rights (access, authorization requirements, minimum necessary standards, etc.)

HIPAA Privacy Rule Considerations

- What patient data is being transmitted, and what will the data be used for?
  - Treatment only, research, etc.
  - The answer varies depending on the type of telehealth that is being practiced
- Scope of informed consent and patient authorization
  - Patient consent for telehealth services varies depending on the mode of healthcare delivery
  - Does your Notice of Privacy Practices need to be updated?
- Are there protections in place to prevent unauthorized disclosure of PHI?
  - Practical issues associated with video and audio technology
- Do you know all the companies involved in storing, transmitting, and handling your PHI?
  - Are there BAAs in place?
  - Is ePHI being used and disclosed for Covered Entity's purposes or is vendor trying to use ePHI for its own purposes?

HIPAA Security Rule Considerations

- What is happening to protect against unauthorized uses or disclosures?
- Does the technology transmit information securely (is it encrypted)?
- Is the vendor maintaining appropriate physical, technical and administrative safeguards?
- What are the vendor's downstream relationships?
- What is the vendor doing to protect against threats to security or integrity of PHI?
- ***Practical issue***: Providers and patients may have limited expertise with specific telehealth technology and its risks

HIPAA and COVID-19

- CMS Waivers
  - Permits use of smartphones (with audio/video capability) to facilitate eligible telehealth encounters
- OCR exercising enforcement discretion re: HIPAA
  - "Effective immediately, the HHS Office for Civil Rights (OCR) will exercise enforcement discretion and waive penalties for HIPAA violations against health care providers that serve patients **in good faith** through **everyday communications technologies**, such as FaceTime or Skype, during the COVID-19 nationwide public health emergency."
  - Applies to the delivery of care via telehealth for any reason
    - Care does not need to be connected to COVID-19 related services
  - Must be "non-public facing"
    - Does not apply to Facebook Live or TikTok
  - OCR will not impose penalties against providers who use technology without a valid business associate agreement
    - Provided the activity relates to the good faith delivery of telehealth during the current national public health emergency

Fraud & Abuse in Telehealth

- Key fraud & abuse principles
  - Stark Law
  - Anti-kickback Statute
  - Civil Monetary Penalties Law, Beneficiary Inducement Prohibition
  - State self-referral
  - State anti-kickback and fee splitting
- Types of fraud & abuse issues that arise:
  - Claims submission with inaccurate information
    - Incorrect originating site or incorrect distant site practitioner
  - Submission of claims where practitioner not authorized to provide services in both locations
  - Billing for services not covered via telehealth
  - Communications technology not sufficient
- Multi-directional nature of telehealth arrangements can create challenges:
  - Provider –- Provider relationships
    - To facilitate telehealth
    - Outside of telehealth
  - Provider –- patient relationship
    - To facilitate telehealth
    - Outside of telehealth

Key Health Regulatory Laws: Anti-kickback Statute

- Prohibits knowing and willful offer, payment, solicitation or receipt of "remuneration" to induce or reward referral of items or services reimbursable by federal health care programs
- Penalties include felony conviction, fines up to $100,000 for each violation, or imprisonment for not more than 10 years, or both
- Safe harbors exist to protect certain relationships but most are difficult to satisfy
  - Without safe harbor compliance, parties are at risk that OIG will view an arrangement as a way to disguise payments for referrals
  - If a relationship does not satisfy a safe harbor, it is not necessarily illegal: question becomes whether intent to violate law is present
  - An arrangement that does not satisfy a safe harbor, but does not evince the intent necessary to violate the Anti-Kickback statute, is permissible

Key Regulatory Laws: Stark Law

- Unless an exception applies, Stark Law prohibits a physician from referring patients for designated health services ("DHS") to an entity, or the entity from billing for the DHS, if the physician has a "financial relationship" with the entity
- Penalties include: denial or repayment, per claim fines of $15,000, and permissive or mandatory exclusion
  - Violations also typically form basis for False Claims Act prosecutions
- Financial relationships can be based on ownership or compensation and can be direct or indirect
  - Different exceptions exist depending on which type of financial relationship is present
- Unlike the Anti-Kickback statute, Stark only applies if certain elements, with specific definitions, like "DHS," "entity" and "referral," are triggered
- Stark Law is a strict liability statute

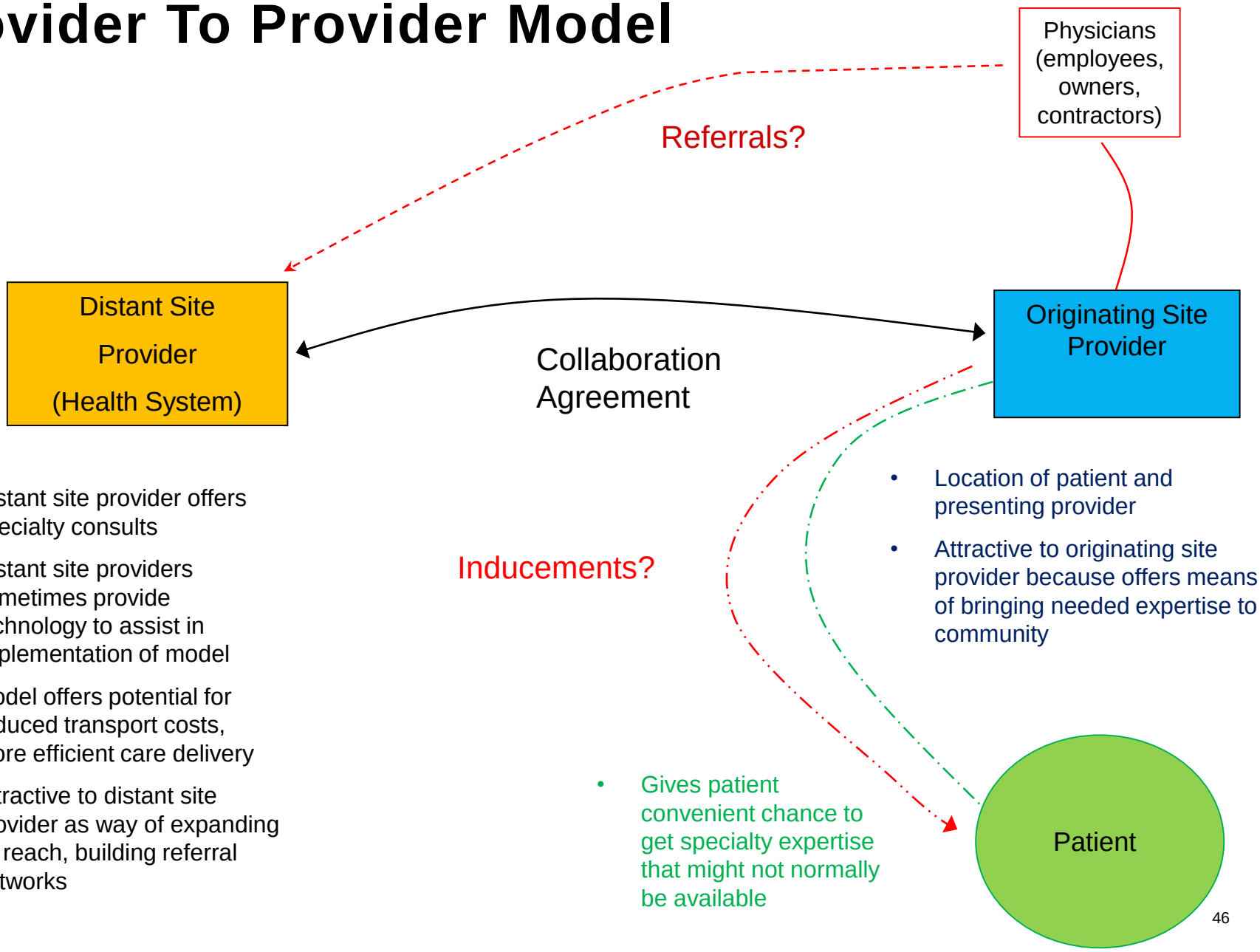
Key Federal Laws: Civil Monetary Penalties Statute

- Beneficiary Inducement “CMP” prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is likely to influence the beneficiary's selection of a provider
- Penalties for violating beneficiary inducement CMP include fines of up to $15,270 per item/service provided
- Various exceptions exist; historically very narrow
- Definition of remuneration amended to include exceptions which went into effect in 2017. New exceptions include:
  - Copayment reductions for certain hospital outpatient department services;
  - Certain remuneration that poses a low risk of harm and promotes access to care;
  - Coupons, rebates, or other retailer reward programs that meet specified requirements;
  - Certain remuneration to financially needy individuals; and
  - Copayment waivers for the first fill of generic drugs

State Fraud and Abuse Laws

- Self-referral
  - Often based on federal Stark Law
    - Similar definitions and concepts (i.e., regulation of ownership and compensation arrangements)
  - Less common than anti-kickback and fee splitting statutes
  - Some apply more broadly than federal Stark Law
    - Regardless of whether insurance covers the referred services
    - Sometimes to referrals from non-physician practitioners
- Anti-kickback / patient brokering
  - Every state has some type of anti-kickback prohibition
    - Sometimes styled as “fee splitting”
  - Many states have Medicaid-specific anti-kickback laws
  - Some states have kickback laws that apply regardless of insurance reimbursement
- Fee splitting
  - Applicability usually depends on practitioner’s category of licensure
  - Some apply where there is a referral nexus; others regulate sharing of revenue from professional services regardless of referrals
  - Issues can arise in percentage-based arrangements (e.g., for management or administrative services)

Provider To Provider Model

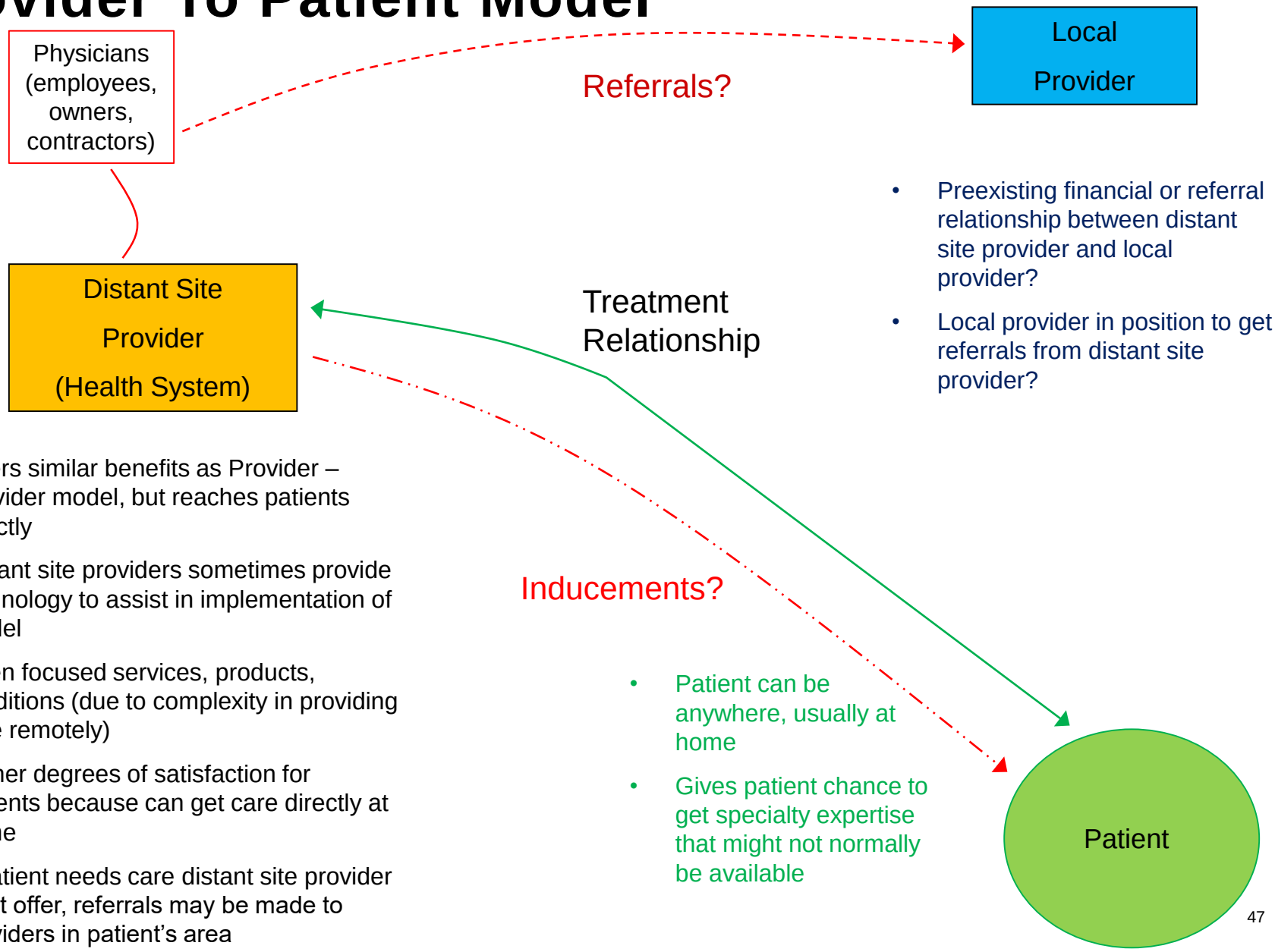


- Distant site provider offers specialty consults
- Distant site providers sometimes provide technology to assist in implementation of model
- Model offers potential for reduced transport costs, more efficient care delivery
- Attractive to distant site provider as way of expanding its reach, building referral networks

- Location of patient and presenting provider
- Attractive to originating site provider because offers means of bringing needed expertise to community

- Gives patient convenient chance to get specialty expertise that might not normally be available

Provider To Patient Model



- Preexisting financial or referral relationship between distant site provider and local provider?
- Local provider in position to get referrals from distant site provider?

- Offers similar benefits as Provider – Provider model, but reaches patients directly
- Distant site providers sometimes provide technology to assist in implementation of model
- Often focused services, products, conditions (due to complexity in providing care remotely)
- Higher degrees of satisfaction for patients because can get care directly at home
- If patient needs care distant site provider can't offer, referrals may be made to providers in patient's area

- Patient can be anywhere, usually at home
- Gives patient chance to get specialty expertise that might not normally be available

Flexibility Under Stark Law, AKS & CMP

- CMS released Stark Law waivers on Mar. 30, 2020, effective Mar. 1
- Waivers protect remuneration between an entity and physician and referrals from the physician to the entity so long as the remuneration and referrals are “solely related to COVID-19 purposes”
- COVID-19 Purposes include:
  - Addressing medical practice or business interruption due to the outbreak so as to maintain the availability of medical care and related services for patients and the community
  - Securing services of physicians and other practitioners to provide patient care services
  - Ensuring the ability and expanding the capacity of providers to address patient and community needs due to the outbreak
  - Shifting diagnosis and care of patients to alternative settings because of COVID
  - Diagnosing or providing medically necessary treatment of COVID for any patient / individual (regardless of whether diagnosed)

Flexibility Under Stark Law, AKS & CMP

- Waives all sanctions related to the exchange of specific types of remuneration
- 18 separate Stark Law waivers, including:
  - Entity provides free telehealth equipment to physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine
- Other waivers include:
  - Payments that are above or below FMV of services provided, equipment/space leased
  - Loans between DHS entities and physicians that are on favorable terms, including below market interest rates
  - Referrals by physician owners to group practices they own that fail to meet certain elements of relevant Stark Law exceptions
  - Payments that exceed limits established under nonmonetary compensation or medical staff incidental benefits exceptions
  - Arrangements between entities and physicians that fail to meet the “writing” and “signature” requirements of various exceptions
- Providers can also submit requests for individual waivers (via email)

Flexibility Under Stark Law, AKS & CMP

- On Apr. 3, 2020 OIG issued policy statement: OIG will not impose AKS sanctions for remuneration covered under majority of the Stark Law Waivers
  - OIG Policy effective after Apr. 3
- OIG positon applies to 11 of the 18 types of remuneration waived under Stark Law Waivers
- Waivers 12-17 not encompassed under OIG guidance, but likely due to technical differences between Stark Law and Anti-kickback Statute and not policy judgement
- Stark Law waivers and OIG policy terminate at end of Public Health Emergency

Flexibility Under Stark Law, AKS & CMP

- Other OIG guidance:
  - Mar. 17: policy statement making clear OIG would not impose administrative sanctions under Anti-kickback Statute or Beneficiary Inducement CMP for waiving telehealth cost sharing obligations during COVID-19 emergency
    - Means OIG will not view provision of free telehealth service alone as inducement or likely to influence future referrals
  - Mar. 30, "Message from leadership on minimizing burdens on providers": For any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action.
  - New process for FAQs on Anti-kickback Statute and Beneficiary Inducement CMP

Flexibility Under Stark Law, AKS & CMP

- FAQs intended to provide expedited guidance on relatively straightforward Anti-kickback/CMP questions.
  - Currently 11 FAQs published
- Example—Hospital providing free access to web-based telehealth platform to independent physicians on medical staff. Physicians could bill and receive reimbursement for services provided using hospital's technology. Even though arrangement involved remuneration to referral source (without payment for same), OIG approved during PHE because:
  - Technology used for telehealth services
  - Arrangement will end when PHE ends
  - Offered by hospital to all physicians on medical staff on equal basis (though not necessarily accepted by all)
  - Technology will allow increased access to services
  - Not condition on previous or future volume or value of referrals

Flexibility Under Stark Law, AKS & CMP

- Example—OIG approved arrangement in which mental health and substance use disorder providers would provide cell phones, service and data plans to patients as long as following safeguards could be met:
  - Good faith determination that patient in financial need;
  - Good faith determination that patient requires telecommunications technology to obtain medically necessary services for substance use disorder or mental health treatment;
  - Services furnished by provider are medically necessary—important for purposes of lowering risk of overutilization or inappropriate utilization;
  - No marketing of arrangement by provider;
  - Arrangement made available only to “established patients”
  - Provider will make the program available only during the duration of PHE
  - Patients required to return smart phones, payment program / data plan ceases at conclusion of PHE
- Caution—OIG noted that arrangement could potentially be revised to comply with “promoting access to care” exception (to CMP)
  - But no corresponding AKS safe harbor

2019 Stark Law, Anti-kickback Statute CMP Rulemaking

- Proposed regulations from October 2019 would create significant rewrite of these laws
  - 84 Fed. Reg. 55694 (Oct. 17, 2019) (Anti-kickback and CMP)
  - 84 Fed. Reg. 55766 (Oct. 17, 2019) (Stark Law)
- Changes to Stark Law include new exceptions for value-based arrangements, new definitions of fair market value, commercial reasonableness and what it means to take into account the volume or value of referrals
  - CMS also offered several “clarifications” of its current interpretation of key Stark principles
- Changes to Anti-kickback Statute would create new safe harbors for value-based arrangements, new safe harbors for patient engagement, EHRs and modify existing safe harbors
- Changes to Beneficiary Inducement CMP intended to facilitate patient participation in value-based arrangements
- Several provisions of proposed regulations directly impact telehealth arrangements

Key Exceptions & Safe Harbors from Proposed Rules

- Cybersecurity safe harbor (Anti-kickback) and exception (Stark)
  - standalone protection for donations of cybersecurity technology and related services
  - Donation must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity
- Electronic health records safe harbor (Anti-kickback) and exception (Stark)
  - Removes sunset provision
  - Updates interoperability provisions
  - Retains 15% recipient cost-sharing requirement
- Telehealth technologies for in-home dialysis (Beneficiary Inducement Prohibition)
  - Exception to the definition of “remuneration” that allows telehealth technologies to be provided on a monthly basis to ESRD patients receiving in-home dialysis
    - 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
    - Telephones, facsimile machines, and electronic mail systems not sufficient .
- Patient engagement (Anti-kickback safe harbor and exception for Beneficiary Inducement Prohibition)
  - Protects arrangements for patient engagement tools to improve quality, health outcomes, and efficiency
  - Limited to $500 annually (retail value). Excludes gift cards, cash, and any cash equivalent.
  - Incentives must advance one of several goals (e.g.):
    - Adherence to a treatment regimen as determined by the patient's licensed health care provider.
    - Adherence to a drug regimen as determined by the patient's licensed health care provider.

Business Models

Increased Complexity

Model 1:
Provider Monitoring of Patient Data

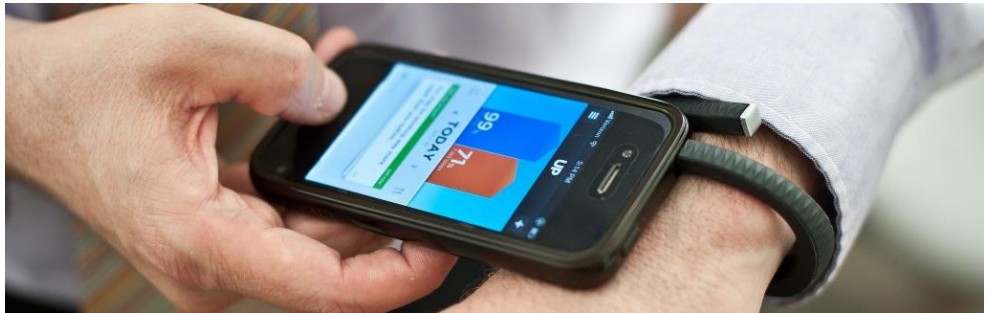
Model 2:
Remote Access to Medical Data

Model 3:
Provider-Provider Virtual Collaboration

Model 4:
Electronic Treatment and Prescribing

Model 1: Provider Monitoring of Patient Data

- HIPAA Privacy and Security
  - What will the data be used for? (treatment only, research, development of new product, etc.)
- Regulatory Considerations
  - How is the provider obtaining the technology?
    - Does vendor make technology available for free or at reduced rate?
    - Does provider purchase other items (or does vendor sell other items) reimbursable by federal or state health care programs?
    - Does the vendor want the provider to “do anything” in exchange for obtaining access to vendor’s technology?



Model 2: Remote Access to Medical Data

- HIPAA Privacy and Security
  - As BA, vendor must comply with Security Rule
  - Complexity increases with personal/mobile devices

- Liability considerations
  - Duty to ensure quality of mobile device used to access information?
  - Auto-correct issues when inputting patient information

Model 3: Provider-Provider Virtual Collaboration

- HIPAA Privacy and Security
  - Risks associated with data transmission
    - Misdirected texts, emails; use of personal email accounts; forwarding emails, use of unsecure channels to communicate; email “auto-fill”; and “reply all”.
    - Downloading third-party applications
    - Cameras make it all worse
  - More complexity where providers are not part of the same “Covered Entity”
- Regulatory Considerations
  - If physicians within same provider organization are consulting, collaborating in care, unlikely to be any regulatory issues created by that relationship
  - Where providers in separate organizations collaborate, the issue may be more complex

Model 4: Electronic Treatment and Prescribing

- HIPAA Privacy and Security
  - Additional complication of communicating directly with patient
- Informed consent becomes more complex
  - Some states specifically address telehealth/telemedicine consent
  - Key Considerations:
    - How to obtain patient's consent? Single or encounter-specific?
    - Content should include definition of telemedicine, alternatives, right to revoke, confidentiality, potential risks/benefits, etc.
- Regulatory Considerations
  - AKS and CMP issues when "remuneration" is given to beneficiaries
  - Referrals to other providers?
- Liability Considerations

Guidance and Future Developments

Future Developments

- Current expectation is that some waivers/exceptions to be made permanent
  - Executive Order
  - Attention/Lobbying Effort
  - Practitioner Experience/Patient Experience
- Current federal Public Health Emergency was set to expire on Jul. 25. Sec. Azar has extended for another 90 days.
- CMS has launched two concurrent reviews of whether COVID-19 telehealth changes should be made permanent:
  - First review examines extent to which telehealth services are being used by Medicare beneficiaries, how the use of these services compares to the same services delivered face-to-fact and the different types of providers using telehealth services.
  - Second review focusing on program integrity risks with Medicare telehealth to ensure their appropriate use and reimbursement
  - Report to be issued in 2021
- State variability will continue
  - In Minnesota, legislature has passed bill that will extend to June 30, 2021 a number of the state flexibilities
    - Waiver of requirements for certain school-linked mental health services, expansion of telemedicine in MHCP, etc.

Future Developments

- 2021 Physician Fee Schedule proposes to make numerous changes. Other changes can also be made in rulemaking process:
  - Expanding services Medicare will cover via telehealth
  - Payment rates
  - Qualifying technology
  - Enrollment requirements
  - Frequency limitations
- Other COVID-19 changes may require Congressional action because Medicare statute (or other federal law) defines terms and/or controlling principles:
  - Qualifying Providers (physician or practitioner)
  - Originating site facility fee (after PHE is over)
  - Originating site location (after PHE is over)
  - Licensure requirements (after PHE is over)
  - Medicare Advantage flexibilities
  - Certain in-person visit requirements (after PHE is over)
- Other changes could be made by rulemaking:
  - Diagnostic testing review
  - In-person visits for various services (hospice, skilled nursing facility, inpatient rehabilitation, home health

Resources and Tools

- First Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- Second Interim Final Rule: https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf
- CMS Telehealth Toolkit: https://telehealth.hhs.gov/providers/
- 2021 Physician Fee Schedule Proposed Rule: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-17127.pdf (it's 1400 pages, so don't just hit, "send to printer" ☺)

Questions?

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