Telehealth & Covid: What's Happening Now and What Might Be Next

Jesse A. Berg, J.D., M.P.H

St. Louis Area Health Lawyers Association

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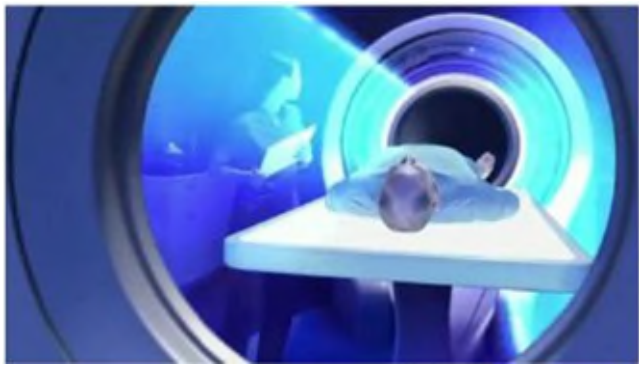
Lathrop GPM

Agenda

- Why telehealth?
  - Background and History
  - Implications of Covid-19
- Key Legal Issues
  - Licensure/Scope of practice
  - Medicare / Medicaid Policy
  - Reimbursement
  - Privacy/Security
  - Fraud & Abuse
- Future Developments



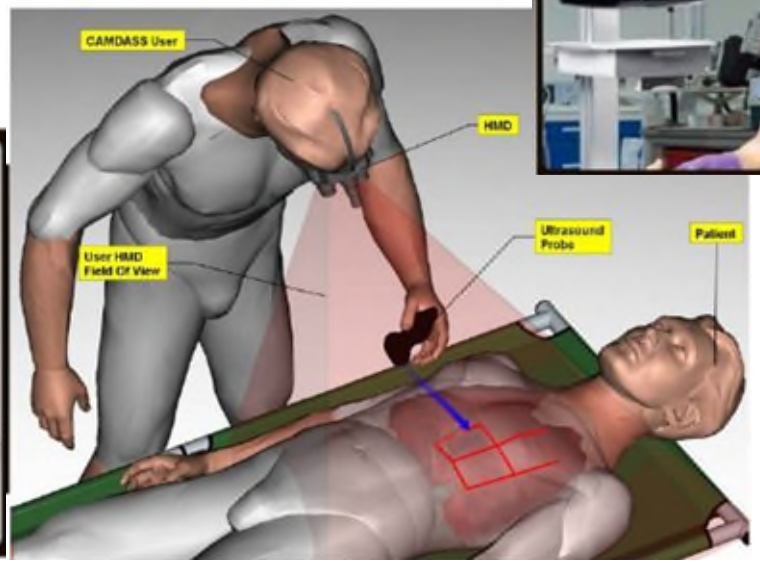
Telehealth

- 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.

Why Telehealth?

Reasons for Growth of Telehealth

- Advances in technology
- Physician / provider 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 reimbursement
    - Medicare, Medicaid, commercial payor requirements

Regulatory Landscape

- Federal telemedicine / telehealth 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 has resulted in an unprecedented series of actions by regulators to allow for the expansion of telehealth
- 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
  - Follow on Anti-kickback Statute policy statement
  - 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

Making Telehealth 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 (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
  - Comment period closed Oct. 5, 2020
  - Final rule posted to Federal Register on December 2, 2020
- Executive Order (Sept. 24, 2020)
  - Secretary of HHS directed to make permanent policies that improve the accessibility and availability of telehealth services

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
  - E.g.: 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
  - Many states have waived licensure requirements
  - 41 states with waivers, 2 with waivers (not allowing new applications) & 7 without waivers). 6 states have scaled back waivers since July.
  - Examples:
    - *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

Licensure examples (continued)

- *E.g., Illinois Executive Order 2020-9*
  - Expands “Telehealth” services to include all health care, psychiatry, mental health treatment, substance use disorder treatment, and related services provided to a patient regardless of their location via electronic or telephonic means
  - Out of state health care providers not licensed in Illinois may continue to provide health care services to IL patients via telehealth only where there is a previously established provider/patient relationship
  - Any site that allows for the patient to use an authorized communication or technology system may be an originating site.
- *Eg. Missouri Executive Order 20-04*
  - Physicians and surgeons licensed in another state can provide care to MO patients in person or via telehealth, as long as they are actively licensed in good standing in another state.
  - Temporarily suspends physical exam requirement
- *Eg. Missouri HB 1682, signed July 7, 2020 / Mo. Rev. Stat. 191.1146*
  - Allows physicians to establish physician-patient relationship via telemedicine encounter if the standard of care does not require an in person encounter, and in accordance with evidence based standards of practice.

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
    - Some states explicitly say 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 telehealth 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

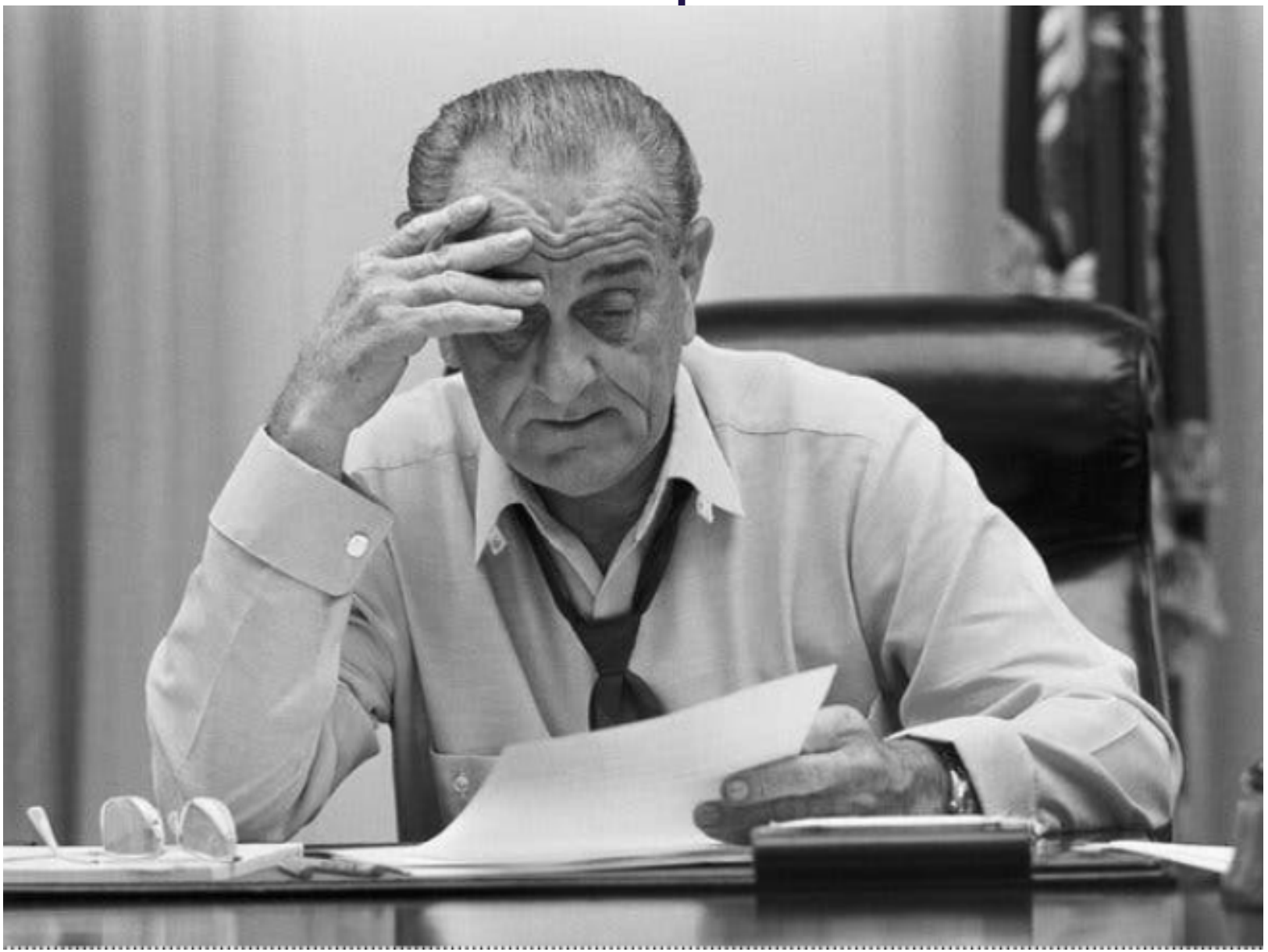
- Some states still require in-person care for specific types of services
- Example: prescribing via telehealth
  - The DEA (under the federal Controlled Substances Act) has historically required in-person exams of patients for a prescription for controlled substances.
    - Note this restriction has 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.

Wrapping Up: Licensure & Scope of Practice

Two critical questions when considering telehealth 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 telehealth (telemedicine)?
  - Where are the practitioners licensed, and where are the patients located?
  - Are there particular practice requirements?

Medicare & Medicaid Developments



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

- 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 2020, state Medicaid policy included the following characteristics
  - 50 states offered some coverage for telehealth services (interactive live video)
  - 18 states offered coverage of asynchronous telehealth services, or “store-and-forward”
  - 21 states offered coverage of telehealth-based home health services (including remote patient monitoring)
  - 32 states paid an additional transmission or facility fee when telehealth used
  - 27 states reimburse services to the home
  - 26 states reimburse services in the school-based setting

Historic Telehealth Reimbursement: Commercial Payors

- Commercial Payors
  - Even more scattered than Medicare & Medicaid
  - As of 2020, 43 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 & 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)
  - Several sets of CMS rulemakings: First Interim Final Rule, Second Interim Final Rule, Medicare Advantage Final Rule & 2021 Physician Fee Schedule
  - How to keep track of it all?
  - https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf
- 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

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, extended through end of PHE).
    - 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, extended through end of PHE)
    - 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
  - 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.
  - Permitted use of audio-only equipment to furnish some 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?

- 2021 Physician Fee Schedule Final Rule (Dec. 2020)
  - Proposed rule requested comment about services added during PHE that would not be made permanent
  - CMS explained that it is difficult to make the regulatory waivers permanent without congressional action. Bills have been introduced but not moved forward.
- Adds numerous services to Medicare coverage list. Examples:
  - Visit complexity code for office / outpatient E & M services, home visits (established), prolonged services, group psychotherapy, psychological and neuropsychological testing, care planning / cognitive assessment, domiciliary, rest home or custodial care (established)—all covered permanently
  - Other services added to coverage list for remainder of year in which PHE ends::
    - E & M for established patients (other home, domiciliary, rest home and custodial care), ED visits, nursing facility discharge day management, other psychological and neuropsychological testing (multiple codes), PT / OT (all levels, multiple codes), ESRD, critical care, hospital discharge day management, inpatient neonatal and pediatric crucial care, others.
  - Coverage of other services ends with PHE (e.g., initial nursing facility, initial hospital care, radiation therapy management, home visits (new), MNT, audio-only telephone E & M, others)

Making Changes Permanent? Other 2021 MPFS Changes

- Relaxed frequency limits for certain services (nursing visits via telehealth covered as 1 visit every 14 days (proposed rule would have been 3 days)
- LCSWs, PTs, OTs, SLPs and clinical psychologists can furnish online assessment and management services, virtual check-in and remote evaluation services
- Clarified that services are not considered telehealth when provider and patient are at the same physical location, even if technology is used to facilitate the encounter.
- Pharmacists can provide services incident to physician services
- Finalized that teaching physicians' ability to provide services of residents via telehealth will extend through December, 2021.
  - Expanded set of services residents can provide and coverage of services by residents outside scope of GME and furnished to inpatients of teaching hospital through the end of December 2021.
  - CMS declined at this time to extend beyond 2021 or make the changes permanent.

Making Changes Permanent? Other 2021 MPFS Changes

- CMS finalized permanent changes to supervision of diagnostic tests by Nonphysician Practitioners
  - Allows nurse practitioners, clinical nurse specialists, physician assistants and certified nurse-midwives to supervise the performance of diagnostic tests in addition to physicians
- Final rule allows direct supervision to be provided using real-time, interactive audio and video technology through Dec. 31, 2021
  - Excludes telephone that does not also include video
- Clarifies provision of other services. Examples:
  - Expansion of coverage for remote physiologic monitoring (RPM) services
- Numerous other changes
- Obstacles to permanency?
  - Statutory restrictions on geographic sites, originating sites, eligible technology, eligible providers, FQHCs, etc.

Medicaid: New Approach to Telehealth- MN

- 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
- Created streamlined enrollment process for provider who were not previously providing telehealth prior to PHE
- Expanded categories of providers eligible to provide telehealth
- Suspended recertification and recordkeeping requirements tor certain services

Medicaid: New Approach to Telehealth- MO

- Effective 3/1/2020 through duration of PHE
- Adopted all waivers granted by CMS as applicable to state licensure standards, waived requirement that out of state providers obtain license in MO
- Requires health carriers to provide same coverage for telehealth as in person visits.
- Allows healthcare providers to provide telemedicine in alternate sites.
- Allows telehealth without established physician-patient relationship and allows phone visits
- Any provider may provide telehealth services within their licensed scope of practice to any participant with the same standard of care as in-person services. This expanded telehealth services for speech therapy, physical therapy, and occupational therapy
- Increased flexibility for outpatient behavioral health providers and targeted case management, including telephonic and other electronic means of providing services.
  - continue payments and FFS for services delivered via non face to face telehealth methods
  - waived client signatures on some required documents like ISP

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)

Trends: What Has All of this Meant?

What has all of this meant?

- Unprecedented growth in telehealth and influx of new / established patients.
- Between Mar. and Oct. 2020 over 24.5 million beneficiaries received a Medicare reimbursed telemedicine service. Pre-pandemic, approximately 15,000 beneficiaries per week received telemedicine services (translates to 780,000 beneficiaries / year).
- Aug. 2020 telehealth claims were 10X greater in MO than Aug. 2019
- FAIR Health: Telehealth climbed to 5.61% of all Oct. 2020 claims, as compared to .18% in Oct. 2019.
  - Trends were similar across all regions in the US.
  - Mental health by far the largest diagnostic category (51% of telehealth claims involved mental health; next closest was acute respiratory diseases and infections at 3%)
- 340 organizations submitted letter to Congress urging them to make telehealth flexibilities established during PHE permanent.
  - Despite calls to expand telehealth, this fall some payors (Aetna, Anthem, United Health) rolled back some provisions reducing cost sharing for commercial members obtaining virtual visits.

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)

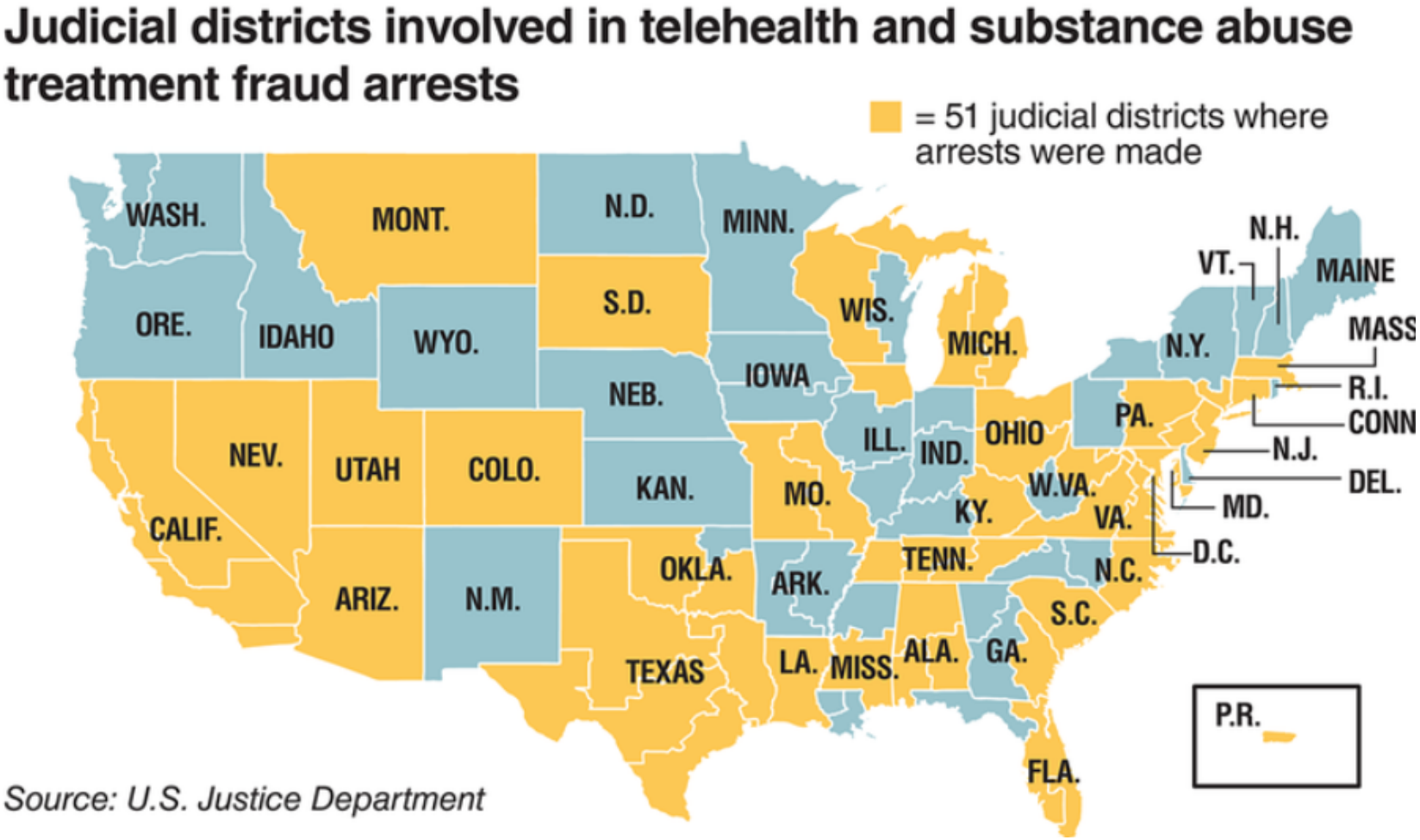
	February		April		
	Total Primary Care Visits	Percent Telehealth	Total Primary Care Visits	Percent Telehealth	Medicare COVID-19 Hospitalizations per Thousand Beneficiaries
US TOTAL	**19,655,604**	**0.1%**	**4,786,049**	**43.5%**	**11.7**
Boston, MA	355,687	0.0%	237,694	73.1%	35.7
Minneapolis-St. Paul, 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

Trends in Primary Care Visits including Telehealth

Enforcement in Telehealth

Enforcement in Telehealth

- DOJ healthcare fraud strikeforce takedown, 345 defendants charged with alleged fraud loss of more than $6 billion. Largest amount of loss was in telehealth and estimated to be $4.5 billion.
- Telehealth co.'s alleged to be paying MDs / NPs to order unnecessary DME, diagnostic tests, lab and genetic tests and pain medications



Enforcement in Telehealth

- 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

Enforcement in Telehealth: OIG Audits

- October 2020- Medicare Telehealth Services During Covid-19 Pandemic: Program Integrity Risks
  - Review program integrity risks associated with Medicare telehealth services.
  - Analyze providers billing patterns for telehealth services
  - Key characteristics of providers that may pose a program integrity risk to Medicare program.

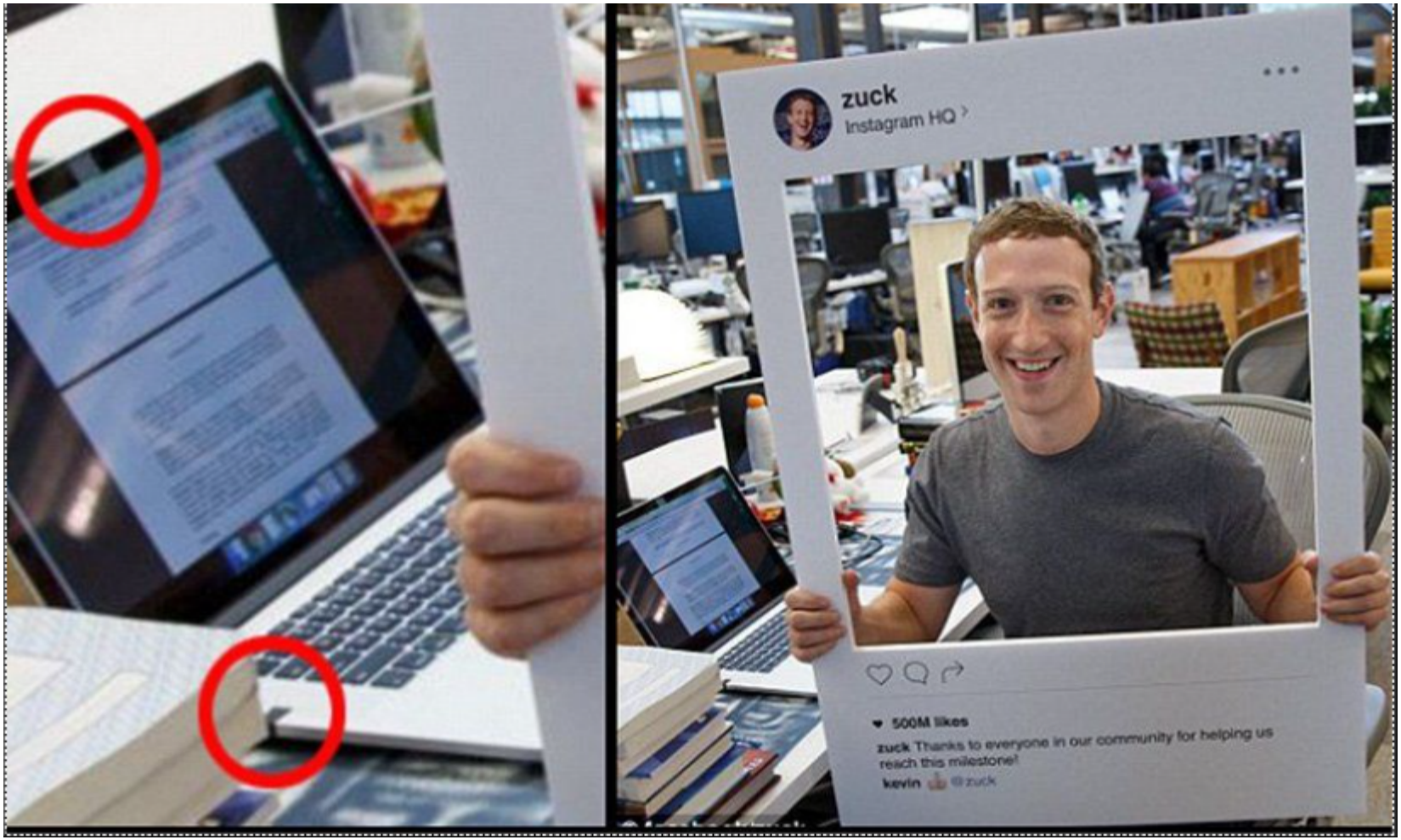
- October 2020- Use of Medicare Telehealth Services During Covid-19 Pandemic
  - Based on Medicare billing and coding, will examine use of telehealth during Covid, the extent to which services are being used by beneficiaries
  - Includes how use of telehealth services compares to use of same services delivered in person and different types of providers and beneficiaries using telehealth.

Enforcement in Telehealth: OIG Work Plan Activities

- January 2021- Auditing of HHS provided as telehealth during PHE
  - Use of technology must be related to skilled services being furnished
  - Documented in plan of care with description of how technology will help achieve goals without substituting for in person visit
  - Determine what services were furnished, whether they were administered and billed in accordance with Medicaid requirements, and report as overpayments services improperly billed

- January 2021- Audit of Medicare Part B Telehealth Services During Covid PHE
  - Phase one audit: early assessment of whether services such as E&M, opioid use disorder, ESRD and psychotherapy meet Medicare requirements.
  - Phase two audit: include additional telehealth services related to distant/originating site locations, virtual check in, electronic visits remote patient monitoring, use of telehealth technology, and annual wellness visits

Privacy & Security



Privacy & Security

- Telehealth providers must comply with federal and state privacy and security requirements
- Providers must use platforms that function in accordance with HIPAA requirements 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
  - Discretion in enforcement will also apply to non-public facing web-based scheduling applications for purposes of scheduling appointments for Covid-19 vaccinations
  - Must be "non-public facing" i.e. Does not apply to Facebook Live, TikTok, etc.
  - 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 Developments

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
- AKS Final Rule (Dec. 2, 2020) added new safe harbors and modified others:
  - Value-based arrangements
  - Patient engagement for patient engagement tools and supports furnished as part of a VBE
  - CMS sponsored models
  - Cybersecurity technology and services safe harbor
  - Updated electronic health records safe harbor
  - Safe harbor for ACO beneficiary incentive programs

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
- Stark Law Final Rule (Dec. 2, 2020) expanded to include additional exceptions:
  - New Value Based Care Exceptions
  - New exception for limited remuneration arrangements
  - Updates EHR donation exception

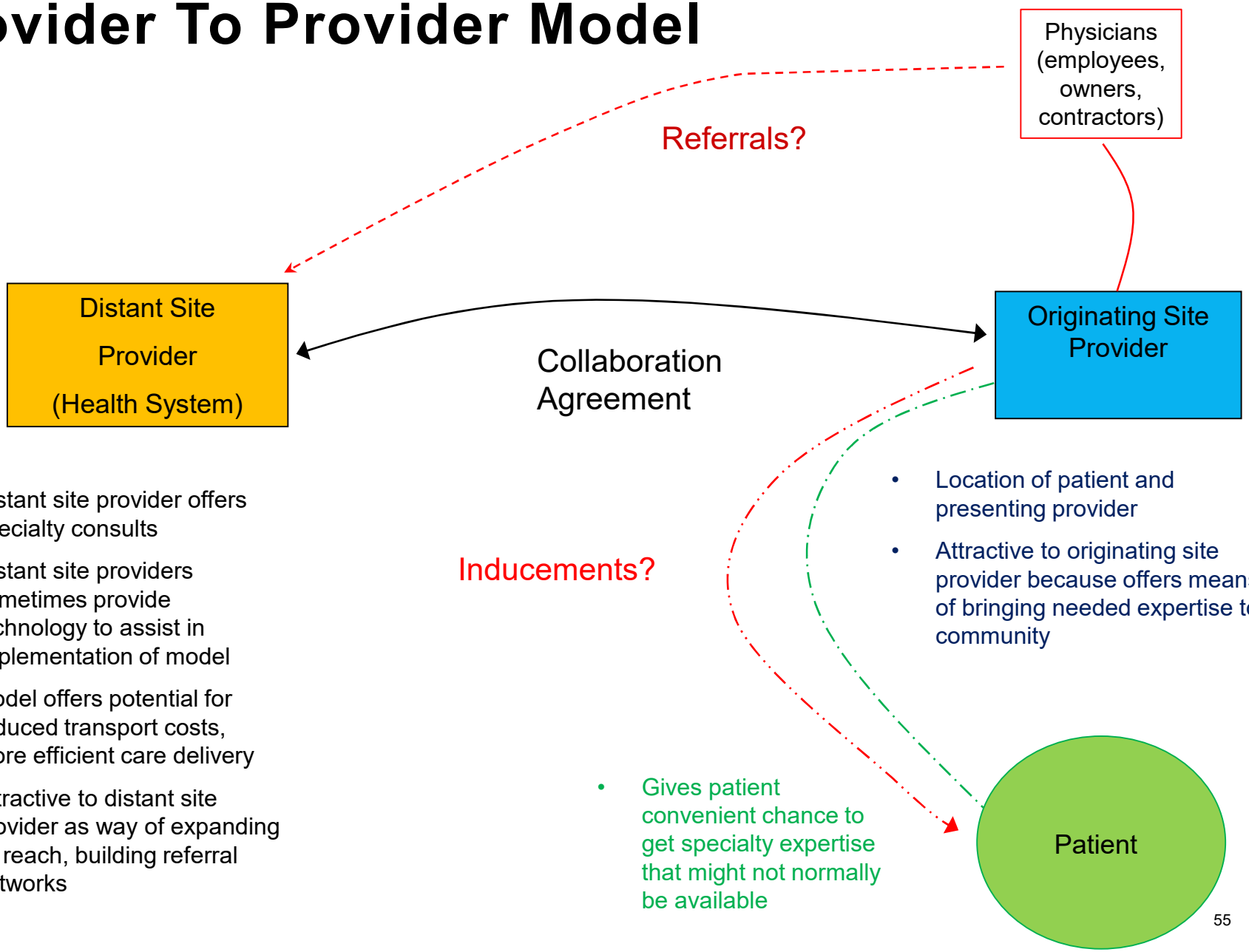
Key Federal Laws: Civil Monetary Penalties Statute

- 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
- 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.
- CMP Final Rule (Dec. 2, 2020) also adds exception for telehealth for in-home dialysis patients.
  - Safe harbor for beneficiary incentives also serves as exception from definition of remuneration for CMP purposes

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

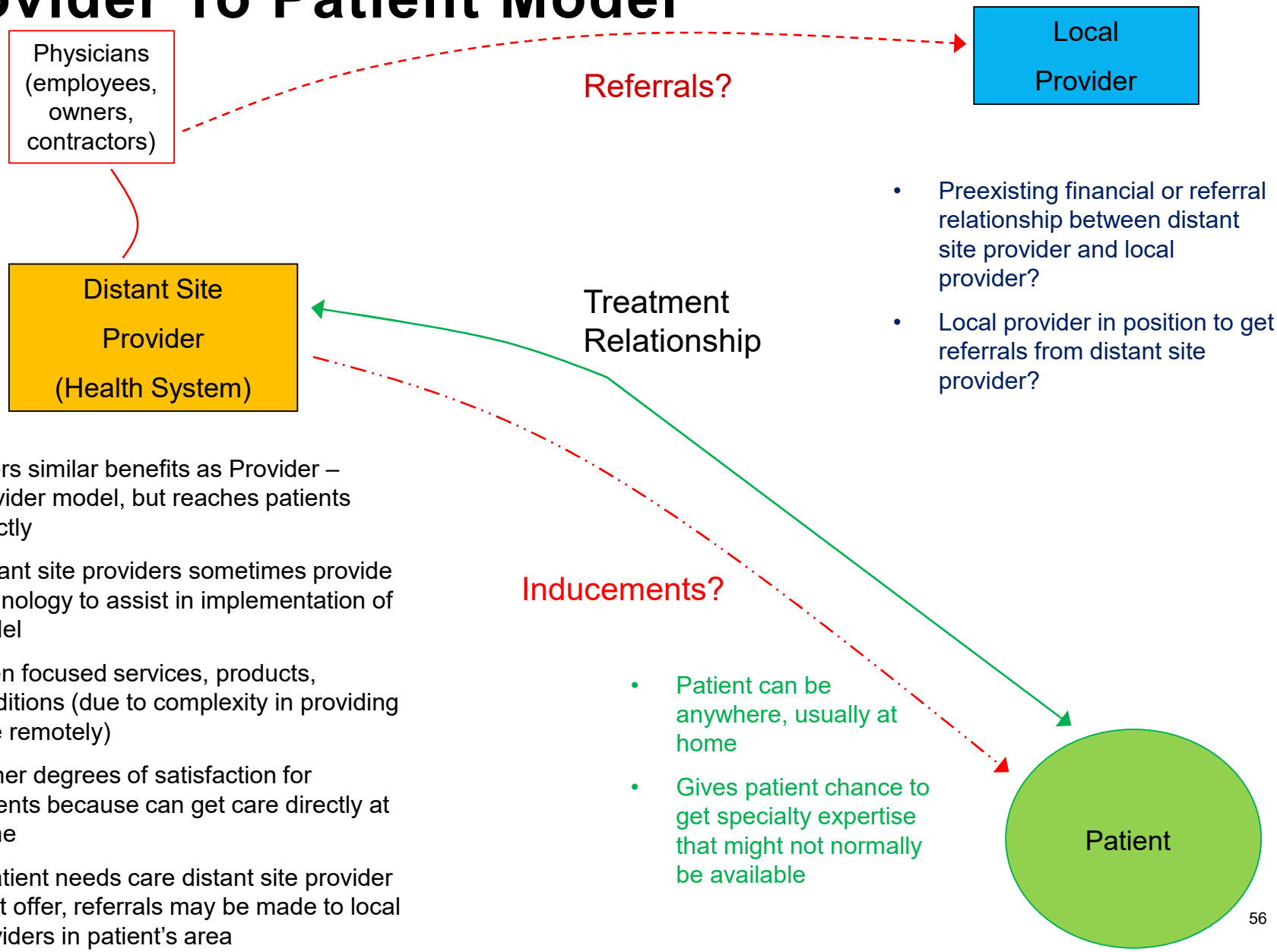


- Distant site provider offers specialty consults
- Distant site providers sometimes provide technology to assist in implementation of model
- Model offers potential for reduced transport costs, more efficient care delivery
- Attractive to distant site provider as way of expanding its reach, building 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 local 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)
- Good faith standard, meaning CMS and OIG may examine the application of waivers to each arrangement to ensure parties are not using them in an attempt to conceal otherwise fraudulent conduct.
  - Blanket waivers do not require submission of specific documentation.

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 of Stark Law Sanctions via email.
- On Jan. 11, 2021 CMS released a new web portal to allow healthcare providers and stakeholders to submit requests for specific waivers of some regulatory requirements under Section 1135 using a standardized form.

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, now extended through April 2021.

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 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.
  - FAQs intended to provide expedited guidance on relatively straightforward Anti-kickback/CMP questions.
  - Currently 15 FAQs available
  - Last updated by OIG on December 14, 2020.

Flexibility Under Stark Law, AKS & CMP

- 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.
- 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 has led to significant changes to 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 created 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

- 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 for initial donation, for replacement or subsequent donation CMS allows for payment at “reasonable intervals”

Key Exceptions & Safe Harbors

- 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) for targeted populations
  - Protects arrangements for patient engagement tools to improve quality, health outcomes, and efficiency
  - Limited to $500 annually (retail value). Excludes some gift cards, cash, and any cash equivalent. Gift card that is limited to certain categories of items could meet the in-kind requirement.
  - Incentives must advance one of several goals (e.g., adherence to treatment regimen, drug regimen, follow-up care, etc.).

What Does the Future Hold?

Future Developments?

- Current expectation is that some waivers/exceptions to be made permanent
  - Executive Orders
  - Attention/Lobbying Effort
  - Practitioner Experience/Patient Experience
- Public Health Emergency has been renewed multiple times. Renewals likely to continue.
- 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

Potential Regulatory Developments

- 2021 Physician Fee Schedule made some changes. Other changes can also be made in rulemaking process:
  - Further expanding services Medicare will cover via telehealth
  - Make higher payment rates permanent
  - Qualifying technology
  - Easing enrollment requirements
  - Eliminating more frequency limitations
- Other COVID 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

Potential Federal Legislative Developments

- Senators Catherine Cortez Masto (D-NV) and Tim Scott (R-SC) will re-introduce bipartisan bill, Ensuring Parity in Medicare Advantage for Audio-Only Telehealth Act, to facilitate access to telehealth. Was first introduced In 2020.
- Rep. Mike Thompson (D-CA) introduced H.R. 366 (1/19/21) with bipartisan support- Protecting Access to Post Covid-19 Telehealth Act, which proposed several actions including eliminating most geographic and originating site restrictions and expanding telehealth. Was first introduced in 2020.
- Rep. Dean Phillips (D-MN) introduced H.R. 8308 (9/17/20)—Telehealth Coverage and Payment Parity Act, which would require private payors to cover certain telehealth services as if they were provided in person. Referred to Energy & Commerce
- Rep. Ann Wagner (R-MO) introduced H.R. 7992 (8/7/20)—Telehealth Act, which aimed to expand telehealth access and coverage. This bill combined several previous bills that also aimed to expand telehealth services prior to Covid-19.

Questions?

Jesse A. Berg
Lathrop GPM LLP
612.632.3374
Jesse.berg@lathropgpm.com