

VIRTUAL CARE

Behavioral HealthRegulatory Update and Navigating Common Challenges



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Caution

These slides were prepared on July 28, 2022. They are intended to provide talking points. During this period of declared public emergency, the laws and regulations applicable to Virtual Care are frequently changing. What was the law yesterday, may not be the law today. Please use caution in reference to these slides, as the law may have changed.

Virtual Care Series

- Virtual Care Focused Look at Prescription Requirements and Pharmacy Rules
- Virtual Care Technology and Medical Record Strategies
- Virtual Care Reimbursement Update and FAQs
- Virtual Care Behavioral Health Regulatory Update and Navigating Common Challenges -- TODAY
- LET US KNOW WHAT YOU WOULD LIKE TO SEE NEXT

Overview

- Virtual Care Benefits and Regulatory Oversight
- Application of State-specific law
 - General application of Virtual Care Statutes/Rules
 - State requirements specific to Behavioral Health
 - "Pre-Existing" Requirements
- Medication Assisted Treatment (OTP and OBOT)
- Licensure and Certification Requirements and Considerations
- Corporate Practice of Medicine/Fee Splitting
- Medicare Telehealth Coverage
 - Status of Covid Flexibilities
 - Medicare Policy Changes (and what is next)



Virtual Care – the benefits....

- Per its 2021 report ("Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders") SAMHSA concluded that telehealth offers the following benefits:
 - Improved provider experience
 - Provision of timely care
 - Effective care coordination
 - Ability to assess home environment
 - Efficient connections to crisis services
 - Ability to share information for psychoeducation and assessment
 - Reductions in provider burnout
 - Improved client experience
 - · Increased access and continuity of care
 - Increased convenience, which removes traditional barriers:
 - geographic
 - Reduction in stigmas related to serious mental illnesses and substance use disorders
 - accessibility
 - employment
 - childcare
 - team based care

Virtual Care – the benefits....

- Per its 2021 report ("Telehealth for the Treatment of Serious Mental Illness and Substance Use Disorders") SAMHSA concluded that telehealth offers the following benefits: (continued)
 - Decreased Costs
 - For example, reduces organizational need to retain regular, onsite behavioral health care provider
 - Population Health
 - Treatment through telehealth has "been shown to improve health outcomes, including improved quality of life, and access to health care.
- "For patients who have never before sought care from a therapist due to various barriers including concern about being seen at a physical clinic—the option to obtain services online can be a port of entry into mental health care..." (https://www.apa.org/monitor/2020/07/cover-telepsychology)
- "With telehealth, now clinicians don't have to overbook and plan for an in-person appointment being canceled" (https://www.pbs.org/newshour/health/more-telehealth-therapy-means-fewer-skipped-sessions)
- "What we've seen is that telehealth is essentially just as effective as face-to-face psychotherapy—and retention rates are higher...." (David Mohr, PhD, Director of Center for Behavioral Intervention Technologies at Northwestern University's Feinberg School of Medicine)

Virtual Care – the oversight....

- Per United States Department of Justice (https://www.justice.gov/news):
 - September 17, 2021 "National Health Care Fraud Enforcement Action"
 - DOJ announced "criminal charges against 138 defendants, including 42 doctors, nurses, and other licensed medical professionals...in various health care fraud schemes that resulted in approximately \$1.4 billion in alleged losses"
 - "These fraudulent activities prey on our most vulnerable—those in pain, the substance-addicted, and even the homeless—those who are most susceptible to promises of relief, recovery, or a new start..."
 - July 20, 2022 "Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud"
 - "The Department of Justice is committed to prosecuting people who abuse our health care system and exploit telemedicine technologies in fraud and bribery schemes..."
 - June 23, 2022 OIG Audit of New Hampshire OTPs
 - "More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements"
 - July 7, 2022 "Addiction Treatment Facilities' Medical Director Sentenced"
 - Florida doctor sentenced to 54 months in prison for engaging in a telemedicine scheme that fraudulently billed approximately \$112 million for substance abuse services that were never provided or were deemed medically unnecessary
- Professional Liability Claims further reinforce need for legal compliance

Essential Concepts



Professional Practice



Reimbursement

Behavioral Health – State Law

- General Considerations
 - Remains highly variable (except in relation to compliance with in-person standard of care)
 - Most (but not all states) have implemented some degree of a "telemedicine statute or rule"
 - Licensure/Registration (<u>NOTE</u>: Availability of Licensure Compacts)
 - Scope of Practice requirements/limitations
 - Establishing a valid provider/patient relationship
 - Technology requirements
 - Data/Privacy requirements
 - Consent/Medical record requirements
- Considerations specific to Behavioral Health
 - Variable sources for applicable rules and guidance
 - May bear on who can/cannot provide virtual care services (and related qualifications)
 - May effectively limited the type of services that can be provided
 - May require particular elements for notice and consent
 - May bear on the type of technology that can be used

- Maryland (excerpts from Administrative Regulations)
 - Professional Counselors and Therapists
 - Teletherapy means the use of interactive audio, video, or other telecommunications or electronic media by a counselor or therapist to deliver counseling services...."
 - Teletherapy does <u>not</u> include: a telephone call, email exchange, or text message exchange
 - Standards of Practice
 - Before providing teletherapy, a counselor or therapist shall develop and follow a procedure to:
 - Verify the identification of the client receiving teletherapy services;
 - Obtain informed consent specific to teletherapy services using appropriate language understandable to client;
 - Prevent access to data by unauthorized persons through encryption, or other means
 - Provides a secure and private teletherapy connection and complies with federal and state privacy laws; and
 - Establish safety protocols to be used in the case of an emergency, including contact information for emergency services at the client's location.

- Maryland (excerpts from Administrative Regulations)
 - Standards of Practice (continued)
 - A counselor or therapist shall:
 - Obtain or confirm an alternative method of contacting the client in case of a technological failure;
 - Determine whether the client is in Maryland and identify the client's specific location;
 - For an initial teletherapy interaction, disclose the counselor or therapist's name, location, license number, and contact information;
 - Identify all individuals present at each location and confirm they are permitted to hear the client's health information; and
 - Be held to the same standards of practice and documentation as those applicable for in-person sessions.
 - A counselor or therapist may not treat a client based solely on an online questionnaire.

- <u>Colorado</u> (excerpts Psychology Board, 30-1 Teletherapy Policy)
 - Multiple definitions provided:
 - "Teletherapy" means a mode of delivery of mental health services through telecommunications systems, including information, electronic, and communication technologies, to facilitate the assessment, diagnosis, treatment, education, care management, or self-management of a person's mental health care while the person is located at an originating site and the provider is located at a distant site. The term includes synchronous interactions and store-and-forward transfers.
 - ".....This policy defines "telehealth" for purposes of compliance with the Mental Health Practice Act.
 Teletherapy may be defined differently in different statutory contexts, including but not limited to, insurance requirements or reimbursement."
 - Policy Requirements:
 - Psychologists must carefully identify and address issues that involve:
 - The agreed upon therapeutic means of communication between the client and the licensee (i.e. if/when will face-to-face contact be appropriate, what method(s) of electronic communication will be utilized, what is the structure of the contractual relationship);
 - Implementing consent form(s) and proper disclosure(s) including, but not limited to the client's knowledge regarding security issues, confidentiality, structure, etc.

- <u>Colorado</u> (excerpts Psychology Board, 30-1 Teletherapy Policy)
 - Policy Requirements (continued):
 - Psychologists must carefully identify and address issues that involve:
 - Ensuring that the therapeutic means of communication includes confidentiality and computer/cyber security;
 - Ensuring that the licensee, certificate holder, or registrant is practicing within his/her scope of practice;
 - Ensuring the therapeutic means of communication chosen does <u>not</u> cause any potential harm to the client.
 - Psychologists must additionally be prepared to (among other things):
 - Verify the identity of the client and determine if they are a minor;
 - Provide the client with procedures for alternative modes of communication when there is possible technology failure;
 - Assess how to cope with potential misunderstandings when the visual cues that would normally occur during face-to-face visits do not exist;
 - Assess how to address crisis intervention when necessary;
 - Upon request, have the ability to capture and provide client treatment notes, summaries or other information that is received via the electronic technology;
 - Disclose that health insurance coverage may not exist for psychotherapy service that is provided through technological means.

- Mississippi (excerpts Rules for Licensed Professional Counselors)
 - Rule 7.5: Practice of Distance Professional Services:
 - Any person providing counseling or supervision services through the means of Distance
 Professional Services (Telemental Health) must meet the following requirements:......
 - Submit to the Board verification of training....by completing one of the following:
 - Show completion of the Board Certified-TeleMental Health (BC-TMH) credential from the Center for Credentialing and Education, Inc. (CCE), an affiliate of the National Board of Certified Counselors (NBCC), or an equivalent credential as recognized by CCE.
 - A minimum of nine (9) clock hours of professional training that includes:
 - » HIPAA compliance for Telemental Health
 - » Ethical and legal issues in Telemental Health, including confidentiality/privacy issues
 - » Crisis planning & protocols in Telemental Health
 - » Choosing and using technology in Telemental Health
 - » Orienting clients to Telemental Health
 - » Telemental health settings and care coordination
 - » Appropriateness of Telemental Health

State Law Considerations

- Do not forget "pre-existing" practice standards and requirements, such as:
 - Consent Requirements (adults vs. minors)
 - Professional Disclosure Requirements
 - Certain states require (defined) professional disclosures be provided (in writing)
 - Certain states require such disclosures as a precondition to payment
- Do not forget that state law considerations are in addition to:
 - Reimbursement requirements
 - Applicable Federal Requirements (e.g., prescription requirements, MAT requirements, etc.)

State Law Considerations

- Considerations for establishing "interstate" approach to practice
 - Establish Virtual Care Policies and Procedures, but be deliberate in approach
 - What Services, What Practitioners, What Locations?
 - Not "one size fits all"
 - What is your organization's risk tolerance?
 - What is the purpose of your Virtual Care Policy?
 - Options for approach:
 - General Guardrails/Issue Spotting Approach
 - State Specific Approach
 - "Best Practice" Approach
 - Consider relevant national guidelines (when applicable)
 - Example: American Psychological Association Guidelines for the Practice of Telepsychology (https://www.apa.org/practice/guidelines/telepsychology/)

Medication Assisted Treatment

- Opioid Treatment Program ("OTP")
 - In addition to other detailed program requirements, SAMHSA generally requires an <u>in-person</u> <u>assessment</u> of the patient prior to initiating Medication Assisted Treatment ("MAT")
 - Program requirements must be evaluated through universal requirement to meet in-person standard of care
 - SAMHSA exception regarding use of Virtual Care to initiate Buprenorphine during the Federal Public Health Emergency ("PHE").
 - This exception does <u>not</u> apply to Methadone (which still requires an initial in-person examination).
 - This exception <u>does</u> extend to the maintenance of both Buprenorphine and Methadone for an established patient through Virtual Care.
 - DEA has recognized the exception (above), as long as these medications are prescribed in accordance with the DEA's own COVID-19 exception (discussed below)
 - OTPs <u>additionally subject to pertinent state law, which may be more restrictive</u> (particularly related to prescriptive authority)

Medication Assisted Treatment

- Office Based Opioid Treatment ("OBOT")
 - Drug Addiction Treatment Act of 2000 created a pathway for qualified physicians to apply for a waiver (separate from OTP Requirements)
 - Still subject to State law requirements/restrictions and DEA prescription requirements
- DEA (Ryan Haight Act) generally requires at least one in-person exam prior to controlled substance prescription (unless a "covering practitioner" or one of a few narrow "telemedicine" exceptions apply)
- Current DEA COVID exception permits prescription of controlled substances through telemedicine if:
 - Legitimate medical purpose by appropriate licensed practitioner;
 - Synchronous (audio and visual) technology is used; and
 - Practitioner acts in accordance with applicable federal <u>and state law</u>.
- Still await (new) "special registration" rules for telemedicine services



Behavioral Health Licensure & Certification Requirements

- What, if any, license/certificate(s) are required to provide behavioral health services through virtual care?
- Typically Consist of:
 - General Behavioral Health Licensure Requirements
 - Behavioral Health Certification Requirements
 - Special Licensure and/or Certification Requirements for Substance Use Disorder Treatment Program

General Behavioral Health Licensure Requirements: *Kansas*

- Under Kansas law, it unlawful for *any person or entity to operate a center, facility, hospital,* or be a provider of services within the state, unless that person or entity first obtains a license for that purpose from Kansas Department of Aging and Disability Services. Kan. Stat. Ann. § 39-2006.
 - Facility: means any place other than a center or hospital that meets the requirements as set forth by regulations created and adopted by the secretary, where individuals reside and receive treatment or services provided by a person or entity licensed under this act. Kan. Stat. Ann. § 39-2002(e)
 - Provider: means a person, partnership or corporation employing or contracting with appropriately credentialed persons that provide behavioral health, excluding substance use disorder services for purposes of this act, intellectual disability, developmental disability or other disability services in accordance with the requirements as set forth by rules and regulations created and adopted by the secretary. Kan. Stat. Ann. § 39-2002(k)
 - Services: means the following types of behavioral health, intellectual disability, developmental disability and other disability services, including, but not limited to:
 - residential supports, day supports, care coordination, case management, workshops, sheltered domiciles, education, therapeutic services, assessments and evaluations, diagnostic care, medicinal support and rehabilitative services. Kan. Stat. Ann. § 39-2002(p)

Behavioral Health Certification Requirements: *Oregon*

- A current certificate is required for *each provider offering* behavioral health treatment services *by contract* with the *Health Systems Division of the Oregon Health Authority*, by contract with *a public body*, or *by receipt of other public funds* except as provided in subsection (4) of this rule. Or. Admin. R. 309-008-0250(1).
 - "Provider" means an individual, organizational provider as defined in ORS 430.637(1)(b), tribal organization, or CMHP that holds a current certificate listed in OAR 309-008-0100(2) to provide behavioral health treatment services pursuant to these and applicable service delivery rules. Or. Admin. R. 309-008-0200(19)
 - "Behavioral Health Treatment Services" means mental health treatment, substance use disorder treatment, and problem gambling treatment services.
 Or. Admin. R. 309-008-0200(4)

Substance Use Disorder Treatment Program Licensure Requirements: *Illinois*

- No <u>person or program</u> may provide the services or conduct the activities described in this Section without first obtaining a license therefor from the Department of Human Services, unless otherwise exempted under this Act:
 - Treatment Services: Categories of service authorized by a treatment license are Early Intervention, Outpatient, Intensive Outpatient/Partial
 Hospitalization, Subacute Residential/Inpatient, and Withdrawal Management.
 Medication assisted treatment that includes methadone used for an opioid use disorder can be licensed as an adjunct to any of the treatment levels of care specified in this Section.
 - Intervention Services: Categories of service authorized by an intervention license are DUI Evaluation, DUI Risk Education, Designated Program, and Recovery Homes for persons in any stage of recovery from a substance use disorder. 20 III. Comp. Stat. Ann. 301/15-10

Virtual Care Considerations for Behavioral Health Facility Licensure & Certification

- In most states, the delivery of behavioral health services is regulated at the "facility" level (*Directly* or *Indirectly*)
- What is a behavioral health facility in the context of a virtual care delivery model?
 - The organization, agency, program, or entity responsible for the delivery of the services
 - The place where services are provided



Direct Facility Regulation: Pennsylvania

- No person shall maintain, operate, or conduct any facility without having a license therefore issued by the department.
 62 Pa. Stat. Ann. § 1002
 - "Person" means any individual, partnership, association or corporation operating a facility. 62 Pa. Stat. Ann. § 1001
 - "Facility" means an adult day care center . . . mental health
 establishment, personal care home . . . 62 Pa. Stat. Ann. § 1001
 - "Mental health establishment" means any premises or part thereof, private or public, for the care of individuals who require care because of mental illness, mental retardation or inebriety but shall not be deemed to include the private home of a person who is rendering such care to a relative. 62 Pa. Stat. Ann. § 1001

Indirect Facility Regulation: *Utah*

- Except as provided in Section 62A-2-110, an individual, agency, firm, corporation, association, or governmental unit acting severally or jointly with any other individual, agency, firm, corporation, association, or governmental unit may not establish, conduct, or maintain a human services program in this state without a valid and current license issued by and under the authority of the office as provided by this chapter and the rules under the authority of this chapter. Utah Code § 62A-2-108(1).
 - "Human services program" means: (i) a foster home; (ii) a therapeutic school; (iii) a youth program; (iv) an outdoor youth program; (v) a residential treatment program; (vi) a residential support program; (vii) a resource family home; (viii) a recovery residence; or (ix) a facility or program that provides: (A) adult day care; (B) day treatment; (C) outpatient treatment; (D) domestic violence treatment; (E) child-placing services; (F) social detoxification; or (G) any other human services that are required by contract with the department to be licensed with the department. Utah Code § 62A-2-101(25(a)

Licensure and Certification Takeaways

- Considerable variation from state to state
- Behavioral health licensure and certification rules are often archaic and may not contemplate the use virtual care
- May require complex regulatory analysis
- State regulators are still playing catch up
- Penalties for non-compliance maybe significant



Corporate Practice Restrictions

- Many states have codified restrictions on the corporate practice of behavioral health professions
- The extent of corporate practice restrictions and related exceptions vary significantly
 - such restrictions may generally align with the corporate practice of medicine doctrine, but confirmation needed on a state-bystate basis
- <u>Public policy rationale</u>: An unlicensed person should not interfere with a licensed professional's clinical judgment

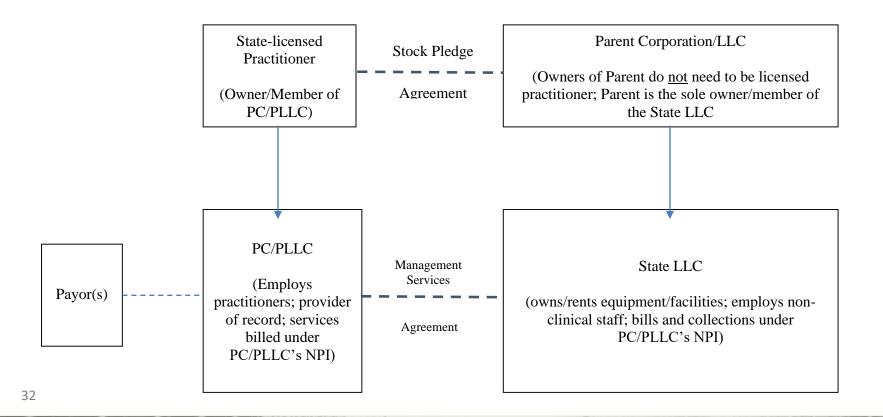
Fee Splitting

- States may also prohibit fee splitting among practitioners and corporations
- Restrict the ability of a corporation or LLC to share in the professional fees charged by the licensed practitioner
- Often prohibit contractual arrangements where compensation is based on "net proceeds" or a "percentage of net collections" related to a practitioner's professional services
- Penalties for violating corporate practice and/or fee splitting restrictions can be significant

Practical Solutions

- Common exceptions
 - Professional entities
 - Practitioner-owned entities
 - Hospitals and other state-licensed entities
 - Provider networks
 - Friendly/captive PC Model

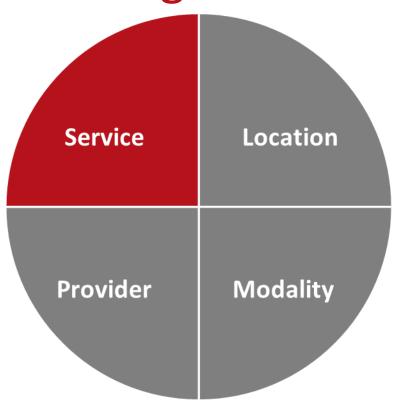
Friendly/Captive PC Model





Medicare Telehealth Coverage

- Narrow focus on coverage for mental health services
- 4 elements typically make up reimbursement payment policy
- Pre-PHE Medicare coverage for telehealth services was limited – SSA § 1834(m)
- Most of these areas require statutory changes and cannot be changed by CMS



Medicare Policy Changes Impacting Telemental Health

- § 1135 Waivers *Administrative Change
- Consolidated Appropriations Act (CAA) of 2021 (Passed December 2020) * Legislative change
- 2022 Medicare Physician Fee Schedule Final Rule
 *Administrative Change
- Consolidated Appropriations Act (CAA) of 2022 (Passed March 2022) * Legislative change

Medicare Policy Changes - 1135 Waivers

- Waiver to allow for audio-only services for certain E/M and behavioral health counseling services
 - CMS designated code list available here
- Once PHE ends, waiver ends
- Additional changes under 2022 MPFS
 Final Rule to permanently allow for audio-only coverage (if certain criteria are met)



Medicare Policy Changes – CAA Of 2021

- Key Changes Impacting Telemental Health Services:
 - Congressional action to amend SSA 1834(m) concerning services for the purpose of diagnosis, evaluation, or treatment of mental health disorders
 - Waives geographic and originating site requirements
 - Allows telemental health services to be provided to beneficiaries at home and in any area of the country regardless of geographic location
 - Becomes permanent after the PHE
 - In-person visit requirements apply
 - 1 in person visit with the provider 6 months prior to initial telehealth encounter

- Key MPFS Changes Impacting Telemental Health Services:
 - Patient's home as originating site
 - BUT must meet certain in-person visit requirements
 - Amended regulatory definition of "interactive telecommunications" to allow audio-only telehealth for mental health services (if certain criteria are met)
 - OTPs to furnish counseling and individual/group therapy services audio-only after conclusion of PHE
 - FQHCs/RHCs can provide mental health visits via live video or audioonly
 - If patient is at home in person visit requirements apply



- In-Person Exam Requirements While Patient is at Home
 - Goes into effect after PHE ends
 - NOT CURRENTLY REQUIRED!
 - Coverage while the patient is at home if all the following conditions are met:
 - Practitioner conducts an in-person exam of the patient within 6 months before the initial telehealth visit
 - Service is furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder; and
 - Practitioner conducts at least one in-person service every 12 months of each follow-up telehealth service (unless an exception applies)

What Constitutes the Patient's Home?

- Broader than primary residence
- Temporary lodging (e.g., hotels, homeless shelters)
- If the patient travels a short distance from the exact home location during a telehealth service, still considered furnished at the home



- Are There Exceptions to the in-person exam requirement?
 - If the patient is located at a qualifying originating site in an eligible geographic area and the arrangement meets the statutory requirements for telehealth service coverage
 - SUD telehealth Services (SUPPORT Act)
 - If the patient and practitioner agree the benefits of an inperson, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service

- Who Must Conduct the In-Person Exam?
 - Treating practitioner to conduct both the first in-person exam and initial telehealth visit
 - Subsequent 12-month visit can be provided by a clinician in the same subspecialty in the same group if the original practitioner is unavailable
 - Flexibility consistent with other longstanding CMS established policy (similar to critical care services)

- Requirements for Audio-Only when Patient is at Home
 - Interactive telecommunications system
 - Can use audio-only, but only under the following conditions:
 - Patient is located in their home at the time of the service
 - Distant site physician/practitioner has the technical capability to use video; and
 - Patient is not capable of, or does not consent to, the use of video technology for the service
 - Note, CMS clarified that SUD services can be provided via audio-only under the amended regulatory definition of interactive telecommunications system

Medicare Policy Changes – CAA Of 2022

- Consolidated Appropriations Act (CAA) of 2022
 - Passed by Congress in March 2022
 - Delayed In-Person Requirement for Mental Health Services
 - In-person visit every 6 months and subsequent in-person visit every 12 months thereafter
 - Intended to take effect when PHE ends, BUT delayed until the
 152nd day after the PHE sunsets
 - » CMS proposed to implement this delay in its 2023 MPFS Proposed Rule

What Does This All Mean?

- As of August 2022 the PHE flexibilities are still in effect:
 - Can provide telemental health services via audio only
 - Patient can be at home
 - Don't need to meet the 6-month in person/12-month subsequent visit requirements for now
- Once the PHE is declared over, the in-person visit requirements will go into effect approx. 5 months after the PHE sunsets unless there are other legislative/administrative changes that occur between now and when the PHE is over
 - Advancing Telehealth Beyond COVID-19 Act of 2021 to delay in-person visit requirement until January 1, 2025
 - Passed the House and was sent to the Senate on 7/28/2022



Medicaid Coverage - Telemental Health Services

- Can't assume state Medicaid will follow Medicare reimbursement rules
- Coverage will vary state by state and policies are changing frequently
- Need to review and consider state PHE Emergency Waivers
 - Many state Public Health Emergency declarations for COVID-19 included waivers to allow for Medicaid coverage of telehealth where that coverage did not previously exist
 - Some states have ended the state PHE waivers, but some are still in effect
- Generally seeing more expanded coverage
 - Indiana Medicaid expanded coverage for IOT services via telehealth via <u>2022 telehealth</u> and virtual services code set
- Medicaid Managed Care Organizations
 - By law, the Medicaid Managed Care Organizations can adopt slightly different payment policies and may cover telehealth where the Fee-For-Service Medicaid does not

Commercial Payor Coverage – Telemental Health Services

- Coverage and requirements will vary payor by payor
- Seeing expanded coverage for mental health/behavioral health services provided via telehealth
- Blue Cross Blue Shield of MI
 - Coverage for psychotherapy, assessments and medical treatments
 - Some visits can be telephone only
 - Originating site can be patient's home
 - IOP and PHP services payable to contracted facilities when delivered via telemedicine for SUD and mental health disorders
 - See <u>Blue Cross Blue Shield Blue Care Network Telehealth for Behavioral Health</u> <u>Providers (July 2022)</u>

Medicaid & Commercial Payor Coverage – Telemental Health Services

Where do I Look for Guidance?

Medicaid FFS	Commercial Payors
Statutes	Provider Manuals
Regulations	Bulletins/Payment Policies
PHE Declarations (Governor's Office)	Payor Communications
Provider Manuals	Contract
Bulletins/Payment Policies	
Medicaid Agency Emails	



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