




Post-Pandemic Enforcement in Telehealth and Behavioral Health Care

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Agenda

- Post-Covid landscape
- Update on enforcement actions
- Securing patient data
- Standardizing telehealth practices
- Addressing disparities in access to care
- Compliance tips
 - Licensure requirements
 - Reimbursement criteria
 - Documentation

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“Telehealth is an effective tool that expands access to behavioral health services.”

Health and Human Services

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Telehealth Behavioral Services



- One on one therapy
- Group therapy
- Text therapy
- Addiction counseling
- Medication prescribing for mental health conditions
- Medication-assisted treatment for substance use disorders
- Medication monitoring
- Mental health screening
- Referrals
- Anxiety and depression monitoring

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Post-Covid Telehealth

Permanent and Temporary Changes After the Covid-19 Pandemic



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Expansions of Telehealth Access Options

Permanent

- Medicare patients can receive telehealth services for behavioral/mental healthcare in their home
- FQHCs and RHCs can serve as a Medicare distant site provider for behavioral/mental telehealth services
- No geographic restrictions for originating site for Medicare behavioral/mental telehealth services
- Behavioral/mental telehealth services in Medicare can be delivered using audio-only communication platforms
- Marriage and family therapists and mental health counselors can permanently serve as Medicare distant site providers

Temporary

- An in-person visit within six months of an initial Medicare behavioral/mental telehealth service, and annually thereafter, is not required through September 30, 2025
- For FQHCs and RHCs, the in-person visit requirement for mental health services furnished via communication technology to beneficiaries in their homes is not required until January 1, 2026

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Controlled Substances

Expires December 31, 2025

- Third Expansion of telemedicine flexibilities for the prescribing of controlled medications
- A DEA-registered practitioner can prescribe a schedule II-V controlled substance to a patient using telemedicine without having conducted an in-person medical evaluation if required conditions are met

Required Conditions

- The RX is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice
- The RX is issued pursuant to a communication between the practitioner and a patient using an interactive telecommunications system
- The practitioner is:
 - Authorized under their registration to prescribe the basic class of controlled substance specified on the RX
 - Exempt from obtaining a registration to dispense controlled substances
 - The RX is consistent with all other requirements of 21 CFR part 1306

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Enforcement Update

Recent Civil, Criminal, and Administrative Enforcement Actions



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U.S. DOJ- Fraud Section

Done Global, Inc.

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“Founder and CEO of digital health company and its clinical president arrested in connection with scheme to distribute Adderall over the internet”

- Currently under indictment
- \$100 million in loss
- Criminal drug distribution and health care fraud
- Monthly subscription fee
- 40 million pills of Adderall and other stimulants
- Limited information of users to Adderall-only medications
- Limited info to prescribers
- Disincentivized follow up care

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U.S. Attorney's Office, EDNY

Cerebral

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“Cerebral pays \$3.6 million in connection with business practices that encouraged the unauthorized distribution of controlled substances.”

- Non-prosecution agreement
- ADHD meds
- Generated revenue through monthly subscription plans with ability to obtain medications
- Internal measures to increase RX and boost patient retention
 - # of drug RX issued to patients who enrolled in medication management after first 30-minute telehealth visit
 - # of stimulant RX to ADHD patients with no comorbidities.

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U.S. Attorney's Office, Connecticut

Supportive Care Holdings, Inc.

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"[I]mproper and false claims submitted for telehealth originating site facility fees."

- HCPCS Q3014 allows payment for a "telehealth originating site facility fee" in addition to the professional fee for the underlying psychological service
- Code can only be billed by the site, when admin or clinical support is provided
- Billed for services not rendered (patients were inpatient at hospitals and not in the nursing home)

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Securing Patient Data

Recent Enforcement and Best Practices

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Federal Trade Commission

Cerebral



“Cerebral, Inc. has agreed to an order that will restrict how the company can use or disclose sensitive consumer data and require it to provide consumers with a simple way to cancel services....”

- FTC alleged Cerebral failed to secure and protect sensitive health data
- \$7 million fine
- Disclosed patient information to third parties for advertising
- Failed to honor easy cancellation promises
- Used tracking tools on its website and sent the data to third parties

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Federal Trade Commission

Cerebral



“Cerebral, Inc. has agreed to an order that will restrict how the company can use or disclose sensitive consumer data and require it to provide consumers with a simple way to cancel services....”

- Sent promotional postcards to over 6,000 patients that appeared to reveal diagnosis and treatment
- Failed to block former employees' access to patient data
- Failed to ensure providers only accessed their patients' records
- Single sign-on method that exposed confidential information

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Securing Patient Data



Best Practices- Provider

- Multi-factor authentication
- Secure communication protocols to encrypt information
- Encrypt data at rest (patient data is stored securely in the cloud or on a device)
- Encrypt data in transit
- HIPAA compliant forms
- VPNs
- Up to date software

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Securing Patient Data



Best practices- Provider to Patient

- Up to date technology
- Confirm identity and demographics at start of appointment
- Patient portals used to send and receive messages
- Instruct patient on:
 - Not using public Wi-Fi
 - Using password protected devices
 - Using a private area for appointment
 - Using headphones if private area is unavailable

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Expanding Access to Care

Telehealth is an effective tool that expands access to behavioral health services.



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Access to Care



Expanding Access to Care to Avoid Discrimination

- Federal law provides a general rule that no qualified individual with a disability shall, on the basis of disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a covered entity, or otherwise be subjected to discrimination by a covered entity. See, e.g., 42 U.S.C. §§ 12132, 12182; 29 U.S.C. § 794(a); 42 U.S.C. § 18116

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Hearing Impaired



Providers must communicate effectively with people who have communication disabilities (including certain disabilities affecting speech or motor function) when providing care in person or through telehealth. See, e.g., 28 C.F.R. §§ 35.160, 36.303; 45 C.F.R. § 84.52(d)

- Provide sign language interpreters
- Ensure platform allows for additional person to join appointment
- Use of effective real-time captioning

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Intellectual Disabilities



Health care providers must make reasonable changes to their policies, practices, or procedures, which may include providing additional support to patients when needed before, during, and after a virtual visit, to avoid discriminating on the basis of disability. See, e.g., 28 C.F.R. 35.130(b)(7)(i); 28 C.F.R. 36.302(a)

- Additional time in advance of an appointment to give patient a chance to become familiar with the features of the platform
- Provider should speak directly with patient and take additional time as needed to ensure they understand
- Platform (and provider) should allow attendance of support person

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Vision Impaired



A health care provider's failure to take appropriate action to ensure that care provided through telehealth is accessible can result in unlawful discrimination. *See, e.g.*, 42 U.S.C. §§ 12132, 12182(a); 42 U.S.C. § 2000d; 28 C.F.R. §§ 35.130(a), 35.160, 36.201(a), 36.303; 45 C.F.R. § 84.4(a), (b); 28 C.F.R. § 42.104; 28 C.F.R. § 42.405(d)

- Ensure written follow-ups are screen-reader compatible
- Ensure any videos shown have audio descriptions
- Provide phone consultations

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Limited English Proficient



Recipients of federal financial assistance must take reasonable steps to ensure meaningful access for LEP persons. *See* 28 C.F.R. § 42.104(b)(2); 28 C.F.R. § 405(d) (noting that federal agencies shall take reasonable steps to inform the public, in languages other than English, about program subject to Title VI)

- Oral language assistance provided by interpreter or bilingual employee
- Ensure platform can support inclusion of a telephone/ video interpreter
- Written translation of documents
- Online information about scheduling appointments should contain short non-English statement on topic

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Standardizing Telehealth Practices

Tips for Creating and Implementing Standardized Practices.



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Telehealth Accreditation

- Complete review of a telehealth program by an independent non-profit
- Ensures established standards are met
- Certification programs that focus exclusively on behavioral telehealth
- Accreditation costs money, preparation and implementation takes time
- Maintaining accreditation

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“ Accreditation programs for in-person health care now include telehealth services. The accreditation process aims to improve virtual care services through review of telehealth programs to meet and maintain established standards.”

<https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-accreditation>

- Quality assurance
- Performance measures
- Regulatory compliance
- Risk mitigation

- ** Promotion of trust and confidence in telehealth

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State Regulatory Landscape



Continues to Evolve – Trends Include

- Requirements for physicians
- Requirements for other providers, e.g., social workers, to establish valid provider-patient relationships
- Interstate compacts
- Cross-state practice

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Telehealth Compliance

Tips for addressing licensure, documentation, and reimbursement.



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Telehealth Compliance



Virtual Clinical Care Standards

- Training in telehealth for providers and staff
 - *How to conduct video visits*
 - *Share screens*
 - *Share and discuss documents*
 - *Collect and review information from patient monitoring devices*
 - *Training should be ongoing, periodic assessments, regular updates*
- Training patients
 - *Effective use and engagement*
 - *Confidence and trust*
 - *Digital literacy*
- Business Continuity Plan in the event of an emergency
- OIG Work Plan includes an open audit of Medicare Part B Opioid Use Disorder Treatment Services, and claims and data related to telehealth during the PHE

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Telehealth Compliance



Patient Consent

- Best practices: inform patient about the unique nature of a telehealth encounter, how it works, technology issues, privacy issues, follow up care, prescribing limitations
- Currently, 29 states include some sort of telemedicine informed consent requirement in their statutes, administrative codes and/or Medicaid policies
- The Center for Connected Health Policy (CCHP) (<http://www.cchpca.org>) and
- American Telemedicine Association (ATA) (<http://www.americantelemed.org/home>) provide overviews of current state policies

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Telehealth Compliance



Licensure, Credentialing, Roles and Knowledge

- Staff -- appropriate degrees and licenses to deliver telehealth services
 - Licensed in the state where provider is located
 - Licensed or permitted to practice in the state where patient is located (?)
- Credentialing of all providers
- Roles of staff
- Compliance with federal and state laws
- Regulatory compliance
- Currency of knowledge on telehealth policies and procedures

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Telehealth Compliance



Documentation

- Patient Consent, documented processes for capturing and maintaining
- Encounter notes
 - *Visits*
 - *Consults*
 - *Diagnoses*
 - *Treatment plans*
 - *Accuracy, completeness*
- Technology Policy
- Privacy policy

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Telehealth Compliance



Billing and Reimbursement

- For most telehealth services, reimbursement is the same as in-person
- Medicare Part B pays for many telehealth services. Medicare policies continue to evolve
- Patients – depending on plan criteria – typically pay the same as if in-person
- <https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-behavioral-health/billing-for-telebehavioral-health>
- <https://www.cchpca.org/all-telehealth-policies/>
- Medicaid coverage can differ depending on location
- Through September 30, 2025, telehealth is available at any location in the US including home. In-person visit within 6 months of an initial behavioral mental telehealth service and annually thereafter is not required through 9.30.2025.
- For FQHCs and RHCs, the in-person visit requirement for in-home mental telehealth services is not required until 1.1.2026

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Questions

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