

VIRTUAL CARE

Critical Considerations for Prescriptions, Medication Management and 340B Eligibility

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Caution

These slides were prepared on May 14, 2024. They are intended to provide talking points and may no do not constitute legal advice. The laws and regulations applicable to Virtual Care are frequently changing and any application is highly fact-specific. What was the law yesterday, may not be the law today. Please use caution in reference to these slides.

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Overview

- Virtual Care Prescriptions (generally)
 - Regulatory Environment
 - Need for Layered Analysis
 - Federal law considerations
 - State law considerations
 - Update: Medication Assisted Treatment
 - Game Plan
- Considerations for Pharmacy/340B
 - Telepharmacy vs. Telehealth
 - Telepharmacy vs. Collaborative Practice
 - 340B Eligible Patient Standards
 - 340B and Pharmacist MTM Clinics



Regulatory Environment

- High Demand + <u>High Variability</u> + Increased Oversight = <u>Perfect Storm</u>
- Virtual Care Prescriptions considered an area ripe for abuse
 - "National Enforcement Action Results in 78 Individuals Charged for \$2.5B in Health Care Fraud" – June 28, 2023
 - "....The conspiracy allegedly resulted in the submission of \$1.9 billion in false and fraudulent claims to Medicare and other government insurers for orthotic braces, prescription skin creams, and other items that were medically unnecessary and ineligible for Medicare reimbursement."
 - Per DOJ Press Release
 - "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..... We are grateful to our partners who stand with us to keep our communities safer and healthier through our collective efforts to prevent the misuse and over-prescribing of controlled medications."
- Professional Liability

Virtual Care Prescriptions – the analysis

- Evaluating prescriptions through Virtual Care is a multi-step analysis:
 - Compliance with Standard of Care
 - Federal Rules
 - Ryan Haight Online Pharmacy Consumer Protection Act (2008)
 - Current COVID Exception and Expectations for new DEA proposed rules
 - Reimbursement considerations (e.g., in-person visits, technology requirements)
 - Digital Health, AI, others....
 - State Rules (highly variable)
 - State "telemedicine" and "telehealth" laws
 - "Practice of Medicine"?
 - General Virtual Care practice requirements/limitations
 - Provisions specific to Prescriptions
 - State Controlled Substance Registration requirements
 - Scope of Practice Considerations
 - Underlying prescriptions requirements (i.e., not specific to Virtual Care)
 - Considerations specific to Medication Assisted Treatment

Standard of Care

Universally, must be able to meet <u>in-person</u> standard of care



- Ryan Haight Online Pharmacy Consumer Protection Act
 - Enacted in 2008 "to prevent the illegal distribution and dispensing of controlled substances by means of the internet.
 - Named after Ryan Haight, a California high school student who died in 2001 from an overdose of controlled substances that he had purchased from an online pharmacy."
- The Act requires that a qualified practitioner perform at least one (1) in-person medical examination of a patient prior to prescribing that patient a controlled substance, except:
 - When a "covering practitioner" (as defined) or
 - Engaged in "the practice of telemedicine" (as defined)
- In all instances, the prescription must be provided by an appropriately licensed/registered practitioner, in the usual course/scope of practice, for a legitimate medical purpose.

(See, 21 U.S.C.A. § § 802 and 829)

- "In-person medical evaluation" means "a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals."
 - Act does <u>not</u> specify a requisite time period for the performance of this in-person exam.
 - But see below regarding "Covering Practitioner"
 - Other professional practice/reimbursement requirements not specific to the Act
 - The Act does provide that no provision in the Act "shall be construed to imply that 1 inperson medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice."
- "Covering Practitioner" means "a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:
 - Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and
 - Is temporarily unavailable to conduct the evaluation of the patient."

- In-person examination is not required when a practitioner is engaged in the "practice of telemedicine" and using an appropriate "telecommunications system"
- The "practice of telemedicine" is narrowly defined to include:
 - Treatment in a DEA registered hospital or clinic....
 - Treatment in the physical presence of a DEA registered practitioner....
 - Indian Health Service or tribal organization
 - Department of Veterans Affairs Medical Emergency
 - Special Registration
 - Public Health Emergency

- Use of appropriate "Telecommunications System"
 - DEA generally tracks (in its <u>proposed</u> rules) CMS definition for "Interactive Telecommunications System"
 - CMS definition for Interactive Telecommunications System requires:
 - Interactive Audio <u>and</u> Visual Technology
 - Exception for Mental Health Treatment when:
 - Practitioner has capability to provide visual connection;
 - Patient does not have the capability or does not consent to visual connection:
 - Practitioner can meet Standard of Care; and
 - Audio-only is in compliance with applicable State law.

DEA/Prescribing – Current State

COVID EXCEPTION TO RYAN HAIGHT ACT STILL IN EFFECT:

- Expansive COVID 19 exception
- Per temporary rule, effective (at least) through 2024:
 - Licensed practitioner and within scope of practice
 - Synchronous audio and video technology
 - Meets in-person standard of care
 - Compliant with all relevant state laws

DEA/Prescribing – Expectations

- DEA proposed <u>final</u> rules released in early 2023
 - two (2) separate rules
 - Behavioral Health/MAT
 - General addition to telemedicine exceptions
 - quite different than COVID exception
- Would <u>add</u> a telemedicine exception to Ryan Haight Act
- Would <u>not</u> impact the current (narrow) telemedicine exceptions

DEA/Prescribing – Expectations

2023 Proposed Rule (continued):

- Would effectively create two (2) additional pathways to prescribe controlled substances when there has been no previous in-person exam by the prescriber:
 - Qualifying Telemedicine Referral
 - Telemedicine Prescription (when no qualifying referral)
- DEA received extensive comments during notice/comment period
- DEA has withdrawn/is currently revising these proposed rules due to responsive comments
- Expectations for new DEA rules......

Reimbursement Considerations

- Medicare:
 - Mental Health Treatment:
 - "Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service..."
 - Implementation postponed to (at least) services on or after January 1, 2025

Virtual Care Prescriptions - State Law

- State Requirements specific to Virtual Care prescriptions
- Most (but not all) Virtual Care statutes/rules address prescriptions
- High variability here as well:
 - Controlled Substances vs. Non-controlled legend drugs
 - Many statutes prohibit certain prescriptions through Virtual Care
- State Controlled Substance Registration requirements:
- Per DEA:
 - Alabama, Connecticut, Delaware, DC, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana,
 Maryland, Massachusetts, Michigan, Missouri, Nevada, New Jersey, New Mexico, Oklahoma,
 Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Wyoming
 - See: https://www.deadiversion.usdoj.gov/drugreg/reg_apps/pract-state-lic-require.html
 - NOTE: Many of these rules "pre-exist" Virtual Care and may require physical practice location within the state

Medication Assisted Treatment

- <u>NEW</u> Rule per SAMSHA "Medications for Treatment of Opioid Use Disorder"
 - Specific to Opioid Treatment Programs ("OTPs")
 - Permits audio-visual and audio-only telehealth visits for the initiation and ongoing management of buprenorphine treatment for opioid use disorder (OUD) without an in-person visit requirement
 - Other aspects of rule:
 - OTPs permitted to induct new patients into methadone treatment pursuant to an audio-visual telehealth visit. However, the patient will still be required to obtain doses of methadone in person at the OTP clinic and does not allow methadone treatment to be initiated via audio-only telehealth because of the risk factors of the medication.

Medication Assisted Treatment

- Other aspects of rule (continued):
 - Provides that telehealth can also be used to provide the psychosocial assessment required within 14 days of induction into treatment
 - Secures other pandemic-era flexibilities such as making it easier for patients to obtain take-home doses by removing as sole consideration the length of time the person has been in treatment
 - Removes the one-year eligibility requirement and allows split dosing and harm reduction activities; removes what it calls outdated and toxic language about opioid use disorder and its treatment
 - Puts into effect the removal of the Drug Addiction Treatment Act waiver -or X waiver -- which was removed by statute
- See FAQ at: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs

Medication Assisted Treatment

- Despite new SAMSHA Rule, <u>must</u> still comply with pertinent aspects of State law
- State law
 - Highly variable state to state (particularly in relation to OBOT)
 - Certain states anticipate at least some degree of "in-person" office visits "throughout the treatment"
- Should determine which services can/cannot be provided through telehealth (within standard of care)

Game Plan for General Compliance

- In order to apply the applicable law/regulation, be clear <u>up front</u> on the specifics:
 - What type of provider(s) will be prescribing?
 - Where will the practitioners be located?
 - What type of medications may be prescribed?
 - Where will patients be located?
 - Will these new patients and/or established patients?
 - Will these be adult patients only or also minors?
 - What technology will be used to facilitate the visit?
- Can these providers legitimately meet the requisite standard of care in relation to the intended practice?
- Understand reimbursement requirements are <u>in addition</u> to above

Game Plan for General Compliance

- Based upon initial analysis above, establish appropriate parameters and best practices
 - Establish a Virtual Care Compliance policy
 - Use this policy to establish basic prescription guardrails as part of a more comprehensive policy
 - Depending on nature of organization, additionally establish specialty and/or service-specific parameters
 - Virtual Care approach:
 - Consider navigating state law variability through "best practice" approach
 - Develop these best practices in accordance with the requisite standard of care
 - Depending upon relevant jurisdictions, track "most stringent" approach for process compliance
 - Be clear on who is permitted to prescribe and in what jurisdictions
 - Consider whether services will be available to new and/or established patients
 - Consider whether to permit prescription of controlled vs. non-controlled substances
 - Clearly identify what medications may not be prescribed and/or that require additional review/approval
 - Be particularly careful (per State law, when applicable) regarding prescription of opioids, chronic pain management, medication-assisted treatment, abortion inducing drugs, medical marijuana

Game Plan for General Compliance

- When possible, consider aligning "prescription requirements" with other relevant requirements for the provision of Virtual Care services to create a single standard
- For example:
 - Consider a single benchmark for in-person examination requirements
 - Establish technology requirements that require synchronous audio and visual connection
 - Address prescriptions as part of a more comprehensive written form of consent
 - Address patient follow-up and geographically proximate resources
 - Ensure medical record documentation requirements and medical record availability
- Consider the (current) lack of certainty in relation to the Ryan Haight Act/Special Telemedicine Registration
- Consider your organization's risk assessment and risk tolerance

NABP Model Act:

- "<u>Telepharmacy</u>" means the Practice of Pharmacy by registered Pharmacists... through the use of telepharmacy technologies between a licensee and patients or their agents...
- "<u>Telepharmacy Technologies</u>" no longer defined.

ASHP:

"Just as many definitions of <u>telehealth</u> include a broader scope of virtual healthcare services than does telemedicine, ASHP believes 'telehealth pharmacy practice' is a more appropriate overarching term for the virtual delivery of pharmacists' patient care services than 'telepharmacy.'"

- Telepharmacy includes:
 - Pharmacologic management
 - MTM
 - Disease state management
 - Remote order entry/verification
 - Remote Monitoring and Surveillance
 - Connected Diabetes Monitors
 - Medication Management
 - Patient Counseling (telephonic, computer)
 - Remote Dispensing
 - Remote IV admix verification

- Remote Dispensing (NABP Model Act)
 - Dispensing under direct, remote supervision of a pharmacist where a certified pharmacy technician fills prescriptions and maintain drugs at a location other than where pharmacist is located;
 - Pharmacist-in-Charge is responsible for operations of RDS (e.g., controlled substances, record-keeping, access, supervision, etc.)
 - Must:
 - Use A/V system for communication between pharmacy and RDS must be "secure"
 - Provide an adequate number of views of the entire site and record surveillance
 - Facilitate adequate pharmacist supervision and provide for staff (e.g. technician)
 - Allow appropriate exchanges of communications for patient counseling and other matters
 - Not be open or allow employee access unless a pharmacist is present
 - Distinguish prescriptions dispensed at RDS from pharmacy's

- Automated Dispensing (Model Act)
 - Automated Pharmacy Systems include, but not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to storing, packaging, dispensing, or distributing medications, and which collect, control, and maintain all transaction information
 - Can be used to prepackage drugs
 - Pharmacist (or Physician?)-in-Charge is responsible for adopting, implementing, and maintaining system
 - Notify Board of Pharmacy about installation or removal of system

In-Office Dispensing

- An automated system which dispenses the prescription drugs directly to patients at the point-of-care
- Designed for outpatient/clinic use (e.g. in waiting area of an urgent care clinic)
 - Patient receives an electronic prescription order issued by the medical provider
 - Patient uses Instymeds dispenser to obtain medications, no refills
 - Instymeds processes prescription insurance and collects payment as applicable

- Telepharmacy state law variability:
 - Over ½ of U.S. states affirmatively allow, around 20 do not or materially limit.
- State Medical Examiner Boards
 - Contemplate in-office/physician dispensing
 - Jurisdiction over licensees for acts originating or terminating in the state
- State Pharmacy Boards
 - Impermissible "pick-up station?"
 - Obtain a resident/non-resident permit before engaging in telepharmacy

Collaborative Practice

- A pharmacist enters into an agreement with other health care providers
- A licensed provider diagnoses the patient, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions

Independent (Tele)pharmacy

- A pharmacist operates under his or her own license within his or her authorized and legal scope of practice, and bill for services provided as a an independent provider
- Dependent upon state laws including pharmacists as providers and allowing them to be compensated for such services

- Collaborative practice models typically contemplate the following pharmacist-led activities:
 - Assess patients;
 - Order, interpret, and monitor laboratory tests;
 - Initiate, adjust, or discontinue drug therapy;
 - Provide care coordination for wellness and disease prevention;
 - Conduct essential patient education; and/or
 - Provide written or verbal communication to referring prescriber with recommendations.

- Pharmacist scope of practice mainly defined by state laws:
 - These laws vary greatly with regard to:
 - The extent of the authorized services
 - Limits on practice sites and health conditions
 - Restrictions on authority to order lab tests
 - Mechanism for implementation (pharmacist or physician/APC-centric)
- Some states have additional requirements for pharmacists to participate in collaborative practice arrangements
 - California: clinical residency requirement
 - Maryland: residency, certificate training, board-approved exam, clinical experience, and training related to the relevant disease states
 - Virginia: patient's informed consent to be treated via CPA
 - Wisconsin: very broad

- CPAs Formal agreements between a licensed pharmacist and a licensed provider that allow the pharmacist to participate in specific patient care functions
 - Provider: diagnoses condition, supervises care, and refers the patient to a pharmacist
 - Pharmacist: performs specific patient care functions based on the provider's referral and often established protocols. Can include:
 - Assess patients
 - Order, interpret, and monitor laboratory tests
 - Initiate, adjust, or discontinue drug therapy
 - Provide care coordination for wellness and disease prevention
 - Conduct essential patient education
 - Provider written or verbal communication to referring prescriber with recommendations
 - Separate or incident-to payment for the performance of these activities may or may not be available

- State Laws differ in addressing independent practice status
 - <u>Wisconsin</u> addresses provider status through the services that may be delegated by a physician to a pharmacist
 - Wis. Stat. 450.033: "A pharmacist may perform any patient care service delegated to the pharmacist by a physician..."

Reimbursement Considerations:

- Collaborative practice services billable consistent with Medicare incident-to billing guidelines in the institutional (hospital) and freestanding clinic settings.
- Third party payors (medical benefit) generally follow Medicare incident-to billing guidelines, though payor-specific standards may supplement or modify claims payment models.
- MTM model reimbursement, as distinct from collaborative practice reimbursement, addressed further below.

340B Program – Scope and Applicability

- "Covered Outpatient Drugs" purchased by "Covered Entity" at a 340B discount and administered or dispensed to "Eligible Patients."
 - Definition references the Medicaid Drug Rebate Program statute (42 U.S.C. 1396r-8). Exclusions are important (e.g., bundled drugs)
- Drugs typically reimbursed by payors in ordinary course of business
- Savings used to support the Covered Entity

340B Eligible Patient Status



340B Drugs can only be Administered/Dispensed to Eligible Patients



Individual is an "Eligible Patient" of a Covered Entity Only if:

- Covered entity has established a relationship with the individual, such that covered entity maintains records of the individual's health care; and
- Individual receives health care services from health care professional who is either employed by the covered entity; or provides health care under contractual or other <u>arrangements</u> (e.g., referral for consultation) such that responsibility for care provided remains with covered entity

340B Eligible Patient Status

• <u>Genesis</u> Judge declared that:

[T]he only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B). (emphasis original)

Further declared that:

[T]he plain wording of the 340B statute does not require the 'covered entity' to have initiated the healthcare service resulting in the prescription."

Government did not appeal order, so reasonable to assume HRSA OPA does not disagree.

340B Eligible Patient Status

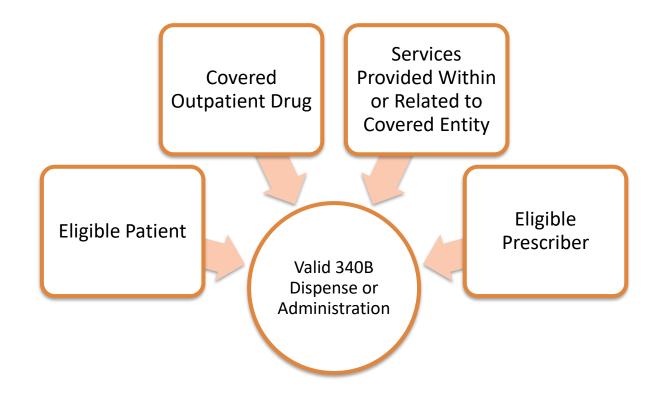
• While we have more clarity regarding what is <u>not</u> an enforceable Eligible Patient standard (*i.e.*, CE site prescription origination), Genesis judge did say:

"HRSA does possess authority to implement its interpretations of the statutory term 'patient' in 42 U.S.C. § 256b(a)(5)(B)."

"HRSA's interpretation of the term 'patient' must be consistent with the plain language of the statute and the intent of Congress."

• So... 340B CEs must make informed, reasonably tailored decisions without clear guidance from HRSA OPA.

340B Eligible Patient Status



Pharmacist Practice / MTM Clinics: 340B

Question	Answer
What is it?	Sites of service where pharmacists operate independently, to the extent permitted under state law. In some cases, prescriptions may qualify for 340B.
How Common Is It?	Growing in popularity
What's HRSA OPA Doing?	No known (direct) guidance
Key Players	Pharmacists Physicians
Other Laws and Authorities	State medical practice act State pharmacy practice act CMS payment rules

Pharmacist Practice / MTM Clinics

- Private payor, some Medicaid state agency reimbursement
 - No Medicare professional component reimbursement for pharmacist services
 - Medicaid Managed Care increasingly common
 - Direct payments incorporating MTM or other codes for billing
 - Folding payment into a capitated or bundled payment model
- Requirements for direct billing
 - Pharmacists must enroll in health plan provider networks
 - May have credentialing requirements
 - May have processes specific to each plan
 - Pharmacists must bill the plan for covered patient care services
 - Pharmacists must comply with the plan's billing requirements

Pharmacist Practice / MTM Clinics

- Provider Status: Why Does it Matter?
 - Neither Pharmacists nor RNs (non-advanced practice) can individually enroll in Medicare as providers or suppliers... yet
 - As a result, they cannot submit Medicare professional claims directly in their own name
- Current Status: Federal
 - For Medicare purposes, pharmacies considered Part B providers solely for the provision of immunizations
 - Pharmacists not included in the statutory definition of "provider" under Medicare Part B (42 U.S.C. § 1395), so they cannot bill directly for patient care services
- Current Status: Private Payors/States
 - Private payors may reimburse pharmacists for patient care services (must in some states)
 - However, because pharmacists generally omitted from Medicare Part B (not "providers" or "suppliers"), most private and state health plans do not compensate for broad spectrum pharmacist patient care services

Pharmacist Practice / MTM Clinics

- MTM and Telehealth:
 - Part B does not cover the professional services of a pharmacist (pharmacists not eligible to enroll as Medicare providers).
 - Pharmacists cannot be rendering provider on a CMS 1500 (whether in person or telehealth).
- CMS: Part B will cover MTM "incident to" a physician's service.
 - In hospital/CAH setting, pharmacist MTM can be billed on UB-04 if 42 C.F.R. § 410.27 requirements are met.
- Hospitals/CAHs cannot bill a facility fee for professional telehealth services.
- During COVID-19 PHE (ending May 2023) CMS permitted hospital staff to furnish outpatient therapeutic services via telecommunications technology to patients located in their homes in certain circumstances.
 - MTM services now need to be furnished in person with both the patient and the pharmacist located in the hospital facility.

Telepharmacy Reimbursement

- Payment for In-Office Dispensing
 - 42 U.S.C. § 1395x- medical and other health services
 - Services and supplies (including drugs and biologicals which are not usually selfadministered by the patient) furnished as incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills

Medicare can reimburse for medication management and reconciliation services. This service is part of an evaluation and management (E/M) service. Medicare would not make a separate payment when performed on the same day as the E/M.

A pharmacist or other clinical staff may provide the service to the patient on a separate date of service. The service must meet the incident to guidelines.

Collaborative Practice: Incident-to Billing

- Medicare Benefit Policy Manual, Chapter 15
 - "[S]ervices performed by these nonphysician practitioners incident to a physician's professional services include not only services ordinarily rendered by a physician's office staff person (e.g., ...blood pressures and temperatures...), but also services ordinarily performed by the physician such... that involve evaluation or treatment of a patient's condition." Medicare Benefit Policy Manual, Pub 100-02, Chapter 15 § 60.2.
- Compliance: Provider must delegate the services to the pharmacist consistent with state law

Incident-to Billing

Medicare Regulations:

- Clinic/Office 42 C.F.R. § 410.26 (Direct Supervision)
 - "Direct supervision... means the physician (or other supervising practitioner) must be present in the office suite
 and immediately available to furnish assistance and direction throughout the performance of the procedure. It
 does not mean that the physician (or other supervising practitioner) must be present in the room when the
 procedure is performed. Through <u>December 31, 2024</u>, the presence of the physician (or other practitioner)
 includes virtual presence through audio/video real-time communications technology (excluding audio-only)."
- Institutional 42 C.F.R. § 410.27 (General Supervision)
 - "General supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service."

Medicaid:

State-specific

Incident-to Billing

- Billing Implementation:
 - Must be medically necessary
 - General supervision standards must be met: 42 C.F.R. § 410.27(a).
 The MTM service is either:
 - initiated by a prescribing practitioner and directly referred to the Covered Entity MTM clinic for a service provided under general supervision; or
 - initiated at the Covered Entity and provided under general supervision.
 - If patient self-refers to an MTM clinic, likely would not qualify as a covered or billable service.
 - G code (G0463) would be submitted on the claim for outpatient therapeutic incident-to services consistent with Medicare requirements.

340B Eligibility – MTM

Summary:

- Not unreasonable for 340B CE to consider patients who only receive pharmacist (non-prescriber) MTM Collaborative Practice services to establish 340B eligibility.
 - Must establish a relationship with the CE such that it is responsible for and maintains a record of their care
 - Consider: Infusion Department
 - Recommend: Document Eligible Patient definition in a written policy and notify HRSA
 OPA anonymously to give them the opportunity to adopt an alternative position
 - Consider: Fact-specific implementation

Telepharmacy vs. Telehealth & 340B

- Summary of Considerations:
 - Is it telemedicine or telepharmacy?
 - Is it telepharmacy or remote dispensing?
 - Is it telepharmacy or collaborative practice?
 - Is it reimbursable (private vs government pay)?
 - Is it permitted (intra and inter-state licensure; originating and distant state)?
 - Scope of 340B eligibility qualificatins: Initial (in-person) vs. subsequent (telepharmacy) visits



Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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