K&L GATES

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Part II - D2C Telehealth Services: Legal and Regulatory Considerations

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Telehealth Reimbursement

MEDICARE TELEHEALTH REIMBURSEMENT: NORMAL RULES

- Medicare Telehealth reimbursement rules are very restrictive
  - Qualifying originating site type requirements (e.g., practitioner office, hospital, rural health clinic, etc.)
    - Beneficiaries' homes are not eligible
  - Originating site geographic location requirements (e.g., located in certain rural areas)
  - Limited set of eligible CPT codes
  - Limited types of eligible practitioners
  - Limited modality (e.g., "interactive telecommunications system" audio and video equipment permitting two-way, real-time interactive communication)

MEDICARE TELEHEALTH REIMBURSEMENT EXPANSION DURING COVID-19 PHE

- CMS expanded payment policies during the PHE (and for at least 151 days after end of PHE)
  - No geographic restrictions on eligible originating site
  - All health care providers eligible to bill Medicare can bill for telehealth services
  - Expanded eligible CPT codes under CMS List of Telehealth Services
  - Audio-only permitted for some CPT codes
  - Cost-sharing amounts may be reduced or waived
  - Providers can furnish services outside of their state of enrollment
  - Practitioners can provide services in states in which they are not licensed (subject to state licensure rules)

PERMANENT FLEXIBILITIES UNDER CY22 MPFS FOR TELE-MENTAL HEALTH

- Removed geographic restrictions/added beneficiary's home as a permissible originating site for telehealth services if:
  - Face-to-face visit within six months prior to the initial telehealth service
  - After initial telehealth visit, face-to-face visit with practitioner at least every 12 months, with allowance for exceptions documented in the patient's medical record
- Permits audio-only tele-mental health services furnished to established patients if:
  - Practitioner has audio-video capability
  - Beneficiary is incapable of, or fails to consent to, the use of audio-video
  - Beneficiary is located at his or her home when service is delivered
  - Practitioner documents reason for using audio-only technology in the patient medical record and uses the appropriate service level modifier

NEW REMOTE THERAPEUTIC MONITORING (RTM) CODES UNDER CY22 MPFS

- RTM is designed for the management of patients using medical devices that collect non-physiological data
  - Five (5) CPT codes (CPT 98975, -76, -77, -80, -81)
  - Requires the use of FDA-approved device
  - Limited to the status of the respiratory and musculoskeletal system as well as therapy adherence, and therapy response
  - Eligible practitioners permitted to provide and bill for RTM services include:
    - Physicians and APPs
    - Physical therapists, Occupational therapists, SLP therapists
    - Clinical social workers
  - RTM services cannot be performed by remote clinical staff under general supervision of the practitioner
  - RTM data can be self-reported data (unlike RPM)

PROPOSED FEDERAL LEGISLATION

- Telehealth Modernization Act (S.368 & H.R.1332)
  - Preserves current telehealth waivers for 2 years post-PHE
- CURES 2.0 Act (H.R. 6000)
  - Extensive legislation which (among other things) defines originating site as wherever the beneficiary is located, empowers Secretary to expand eligible practitioners types
  - Allows Secretary to retain the subregulatory process used to expand reimbursable telehealth services post-PHE
- Expanded Telehealth Access Act (S.3193 & H.R.2168)
  - Allows audiologists, PTs, OTs, SLPs to provide telehealth services permanently post-PHE
- CONNECT for Health Act (S.1512 & H.R.2903)
  - Permanently removes geographic restrictions on originating site and allows FQHCs and RHCs to serve as distant sites
  - Allows CMS to waive certain restrictions on technology

EXPANDED MEDICAID COVERAGE

- Federal government issued “Medicaid and CHIP Toolkit” to assist states in adoption of broader telehealth coverage during the PHE
  - Recently updated the Toolkit to help states accelerate adoption of broader telehealth coverage beyond the PHE
- Many states have made expanded coverage permanent but policies vary significantly from state to state and depends on the form of modality, service types, and practitioner performing the service

EXPANDED COMMERCIAL COVERAGE FOR TELEHEALTH SERVICES

- Many states have implemented commercial insurance parity laws to ensure reimbursement for telehealth services
  - **"Service Parity"**
    - Require telemedicine services that are medically necessary and meet the same standards of care as in-person services must be covered by state-regulated private plans if they would normally cover the service in-person
  - **"Payment Parity"**
    - Require telemedicine services must be reimbursed at the same rate as equivalent in-person services

SERVICE PARITY EXAMPLE: MAINE

- Me. Rev. Stat. Ann. tit. 24-A § 4316(2):
  - A health insurer "may not deny coverage on the basis that the health care service is provided through telehealth if the health care service would be covered if it were provided through in-person consultation between an enrollee and a provider."
  - Coverage for telehealth services must be "determined in a manner consistent with coverage for health care services provided through in-person consultation."

PAYMENT PARITY EXAMPLE: ILLINOIS

- 215 ILCS 5/356z.22(d):
  - Requires insurers reimburse an in-network provider or facility for telehealth services "provided through an interactive telecommunications system on the same basis, in the same manner, and at the same reimbursement rate that would apply to the services if the services had been delivered via an in-person encounter" by an in-network provider or facility.
  - Payment parity provision becomes inoperative on January 1, 2028, but carves out mental health and substance use disorder telehealth services as being permanently enforced.

FINAL NOTE ON REIMBURSEMENT AND MODALITY

- Providers must consider reimbursement opportunities when developing telehealth business models
  - Reimbursement for asynchronous telehealth services is very limited
    - Questionnaire models are not reimbursable services under government and commercial programs
    - After the PHE, Medicare reimbursement will be available for a limited list of CPT codes provided via audio-only
  - Orders and prescriptions for ancillary services stemming from a telehealth visit may also be limited depending on modality of telehealth service
    - For example, Medicare contractors have taken the position that orders from an asynchronous telehealth visit are also not reimbursable

Fraud & Abuse Considerations

FEDERAL & STATE HEALTH CARE FRAUD AND ABUSE PROVISIONS

- Federal & state laws dictate reimbursement for health care services, generally prohibiting “splitting” health care professional fees with non-health care providers & prohibiting payment for referrals of patients or health care services
  - Federal health care programs are very restrictive, and all digital health arrangements must be compliant with federal Stark Law, Anti-Kickback Statute, & Civil Monetary Penalty (CMP) Law prohibition on inducements to beneficiaries laws
  - Many states have state law “mini-Stark” & “mini-AKS” laws that are more broad than the federal counterparts and apply to services reimbursed by commercial payors & cash pay services
  - Commercial insurance fraud statutes will equally apply to commercial telehealth claims

FINANCIAL ARRANGEMENTS AMONG ENTITIES IN TELEHEALTH

- Federal AKS and commercial fraud laws may be implicated by financial arrangements between health care providers and digital health companies (e.g., telehealth platform providers)
- Cash-pay models may also implicate state AKS laws, which are often broader and include cash-pay patients
  - Telehealth marketing arrangements have been the subject of intense government scrutiny and multibillion dollar fraud sweeps
  - State fee-splitting prohibitions will also generally prohibit percentage of revenue compensation models
- ***Obtaining FMV opinion from third party independent valuation to support financial models will reduce regulatory risk***

FINANCIAL ARRANGEMENTS AMONG ENTITIES IN TELEHEALTH

- Ideally, all financial arrangements are structured to meet AKS Personal & Management Services Safe Harbor, which requires:
  - Signed, written agreement for a term of not less than 1 year
  - The agreement covers all of the services for the term of the agreement and specifies the services to be provided
  - The compensation methodology is set in advance, is consistent with FMV, and is not determined in a manner that takes into account the volume or value of any referrals or business reimbursed under Federal health care programs
  - The services do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law
  - The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services

PATIENT INCENTIVES IN TELEHEALTH

- Patient incentives related to telehealth have been the subject of government scrutiny and must be carefully structured
  - CMP Law inducement to beneficiaries provision prohibits free or below FMV items and services to federal and state healthcare program beneficiaries to induce beneficiary to choose provider
  - CMP Law also generally prohibits cost-sharing waivers absent *bona fide* financial need assessment
  - Commercial insurance fraud laws may also prohibit incentives to enrollees by providers
    - Insurers are permitted to offer incentives to its own enrollees to encourage the use of telehealth services
- Improperly structured incentives to use telehealth services can also effect downstream referrals for ancillary services

UPTICK IN AGENCY ENFORCEMENT ACTIONS IN DIGITAL HEALTH SPACE

- Pre-pandemic, national fraud sweeps related to telemedicine schemes were already underway
  - Operation Brace Yourself, Operation Double Helix, Operation Rubber Stamp
- Increased utilization and reimbursement = Increased risk of non-compliance and financial and regulatory risk
- Ongoing OIG Work Plan Audits
  - HIS Telehealth Technologies Cybersecurity Controls
  - Home Health Services Provided as Telehealth Services During the COVID-19 Public Health Emergency
  - Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency
  - Medicaid Telehealth Expansion During the COVID-19 Public

FRAUDULENT BILLING & CODING ENFORCEMENT

- Common forms of telemedicine and digital health fraud mirror billing and coding errors often seen in in-person care:
  - Upcoding
  - Failure to meet reimbursement standards
  - Providing medically unnecessary services
  - Submission of claims for services not provided

FRAUDULENT BILLING & CODING ENFORCEMENT

- Other fraudulent activity is unique to telemedicine/digital services:
  - Failure to use appropriate interactive telecommunications system
  - Billing despite technical issues with technical system and upcoding time spent with the patient
  - Misrepresentation of the type of virtual service provided
  - Ineligible providers
  - Services provided at unauthorized originating sites

STATE ENFORCEMENT ACTIONS ALSO CONTINUE TO INCREASE

- Increase in state licensure investigations for unlicensed or unprofessional practice
- Disciplinary actions taken against physicians for failure to deliver care that meets standard of care
  - Usually a case alleging “unprofessional conduct”
  - Examples include failing to meet the standard of care prior to prescribing; unlicensed practice across state lines
- Scrutiny will also fall on practitioner’s employer in addition to individuals

COMPLIANCE PROGRAMS & RISK MITIGATION STRATEGIES

- Consider compliance comprehensively—for example, develop a data strategies compliance program. Compliance concerns in one area create scrutiny for other areas
- Ensure that state-level requirements to establish a legitimate physician-patient relationship are satisfied (e.g., licensure, technology modality, etc.)
  - Requires evaluating applicable state laws and regulations, which may have changed in light of the PHE and may continue to evolve in real time
- Be diligent in the design and compliance oversight of marketing strategies to confirm that patients are reached through appropriate channels and are not offered impermissible inducements

COMPLIANCE PROGRAMS & RISK MITIGATION STRATEGIES

- Confirm that each partner to any collaboration has a robust compliance program that addresses regulatory compliance
- Carefully review compensation arrangements to ensure permissible under federal and state fraud and abuse laws
- Evaluate and regularly audit billing and coding practices to ensure practices are consistent with both government and commercial payor requirements
  - Requires evaluating applicable federal and state laws and payor policies as they change in real time
- Ensure fulsome Info Sec review processes of vendor systems and solutions and carefully structure BAAs and other data-related agreements to mitigate risk

State Health Care Provider Licensure Considerations

HEALTH CARE PROVIDER (HCP) LICENSURE = STATE WHERE HCP IS PRACTICING MEDICINE

- **State licensure = gating issue for the provision of telehealth services**
  - Many HCPs providing telehealth services are physically located outside of the state where the patient originates
  - Telehealth capabilities enable HCPs to provide care across state lines, but state licensure laws generally require licensure in the state where the patient is located
- **Public Health Emergency (PHE) - Many State Created Exemptions and Waivers ➔ Allowed for Greater Access to Care**
  - Relaxed or waived in-state licensure requirements
  - Granted temporary licenses to out-of-state practitioners
  - Offered expedited in-state licensing
- **PHE declarations are rescinding or lapsing**
  - With PHE ending, regulatory flexibilities impacting telehealth are also ending
- **Need to understand current licensure requirements**

HEALTH CARE PROVIDER (HCP) LICENSURE = STATE WHERE HCP IS PRACTICING MEDICINE

Olden Days…..

Bricks and Mortar Facility

- HCP & Patient in Same Location ➔ Licensure is State Where Both are Located
- HCP Located in State #1 (e.g., Illinois), Patients from State #2 (e.g., Indiana or Wisconsin) Come to HCP in State #1 ➔ Licensure is State Where Both are Located for treatment = *Illinois*

Brave New World….

Telehealth Service

- HCP & Patient in Same Location ➔ Licensure is State Where Both are Located
- HCP Located in State #1 (e.g., Illinois), Patients from State #2 (e.g., Indiana or Wisconsin) ~~Come to HCP in State #1~~ Receive a Telehealth Service ➔ Licensure = ?

GENERALLY, HCP CONSIDERED TO BE PRACTICING MEDICINE IN THE STATE WHERE THE PATIENT IS LOCATED - *EXAMPLES*

California Medical Practice Act

- "[A]ny person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted ***in this state***, or who diagnoses, treats, operates for, or prescribes for any ailment . . . or other physical or mental condition of any person. . . " Cal. Bus. & Prof. Code § 2052(a)
- Expressly prohibits out-of-state practitioners from "opening an office, appointing a place to meet patients, receiving calls from patients ***within the limits of this state***, giving orders, or having ultimate authority over the care or primary diagnosis ***of a patient who is located within this state***." Id.
- Some exceptions: out-of-state licensed practitioners who provide consultations to California licensed physicians, professional education lectures or demonstrations through California Medical Association or an approved medical school (Cal. Bus. & Prof. Code § 2060)

GENERALLY, HCP CONSIDERED TO BE PRACTICING MEDICINE IN THE STATE WHERE THE PATIENT IS LOCATED - *EXAMPLES*

New York

- In accordance with New York State statute, full licensure and current registration are required of any professional who practices in New York State. (State Education Department, Telepractice Memo, http://www.op.nysed.gov/COVID19_Telepractice%20memo.pdf)
- Exceptions for physicians licensed in bordering states and residing in such bordering states, out-of-state consultations to in-state providers, physicians visiting medical schools, etc.

Texas Administrative Code: TX Medical Board, Telemedicine (section 174.8)

- "Physicians who treat and prescribe through communications technology are practicing medicine and must possess a full Texas medical license **when treating residents of Texas**."

GENERALLY, HCP CONSIDERED TO BE PRACTICING MEDICINE IN THE STATE WHERE THE PATIENT IS LOCATED - *EXAMPLES*

Virginia Board of Medicine, Guidance Document 85-12, Telemedicine (revised 06/24/21)

- The practice of medicine occurs **where the patient is located at the time telemedicine services are used** & insurers may issue reimbursements based on where the practitioner is located
- A practitioner must be licensed by, or under the jurisdiction of, the regulatory board of the state **where the patient is located** and **the state where the practitioner is located**
- Some exceptions: out-of-state practitioner consulting with legally licensed practitioners in the Commonwealth; certain follow-up care provided via telephone, email fax, where provider-patient relationship previously established

GENERALLY, HCP CONSIDERED TO BE PRACTICING MEDICINE IN THE STATE WHERE THE PATIENT IS LOCATED - *EXAMPLES*

Florida Statutes: Use of Telehealth to Provide Services (section 456.47)

- Allows for a special registration of out-of-state practitioners for the provision of telehealth to patients located *in Florida*: "A health care professional not licensed in this state may provide health care services **to a patient located in this state** using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule."
- Florida's Division of Medical Quality Assurance (MQA) website notes that it "does not have laws or rule specific to the practice of telehealth services outside of Florida" and **recommends providers seek out laws and rules of the state "where the patient is located."**
  (See https://www.flhealthsource.gov/telehealth/faqs)

CHANGES HAPPENING AT STATE LEVELS

- Some states are making permanent changes that will make it easier for out-of-state health care providers to practice telehealth across state lines
- New permanent pathways for licensure: abbreviated licensure processes similar to Florida

Arizona - HB 2454 (May of 2021)

- Permits out-of-state licensed practitioners to provide telehealth services to patients in Arizona by registering with the appropriate professional board
- Registration process is less robust than the requirements for full in-state licensure
- Only permits the registrant to practice telehealth
- Registration process is in addition to Arizona's participation in the Interstate Medical Licensure Compact (IMLC), another vehicle for the expansion of telehealth across state lines

West Virginia, Kansas, and Connecticut

- Recently expanded state telehealth licensure requirements or made PHE regulatory waivers permanent
- West Virginia = similar law to AZ, allows HCPs licensed and in good standing in another state to pay a fee to register with the West Virginia medical board, become an "interstate telehealth practitioner," and treat patients located in West Virginia
- Kansas = passed a law that allows physicians licensed in other states or who otherwise meet Kansas' licensure requirements to apply for a waiver from the Kansas State Board of Healing Arts to practice telemedicine for patients located in Kansas
- Connecticut = enacted a bill that will allow out-of-state providers to provide telehealth services to patients in Connecticut through 30 June 2023 without obtaining a Connecticut license

CHANGES HAPPENING AT STATE LEVELS

- **Another new permanent pathway for licensure = Interstate Licensure Compacts**
  - Adoption of an interstate compact, such as the Interstate Medical Licensure Compact (IMLC)
  - Binding agreements between participating states
  - Make it easier for providers to render telehealth services across state lines
  - Create expedited path to licensure in participating states
  - physician must hold principal license in a participating state to qualify for an expedited license
  - physician must meet the eligibility criteria established by the IMLC

CHANGES HAPPENING AT STATE LEVELS

- Since the COVID-19 pandemic began, Texas, Delaware, and Ohio have joined the IMLC, and legislation to join is pending in other states (as of last month - Massachusetts, New Jersey, New York, and North Carolina)
- To date, the compact includes more than 30 states, the District of Columbia, and Guam
- There are also interstate licensure compacts for nursing, physical therapy, and counseling
- Some argue interstate compacts are not robust enough to make it easier to practice medicine across state lines, advocate state licensure expansion and flexibility

TAKE-AWAYS

1) Almost every state considers the HCP to be practicing medicine in the state where the patient is located
2) Most states (approx'y 40) require full licensure if treating patients in their state
   - Some states allow a special purpose license, telemedicine license or certificate, or license to practice medicine across state lines
   - Some states allow registration (as opposed to full licensure) to practice medicine across state lines
   - Some states offer reciprocal or regional licenses
   - *This is changing every month! Need to monitor…*
3) State Compacts may ease licensure in some states for physicians currently licensed in a state
4) Look for state law changes

One more thing…

Reimbursement considerations may necessitate licensure in the state where the physician is physically located (e.g., Medicare place of service, commercial payors)

Other Medical Board Considerations

OTHER MEDICAL BOARD CONSIDERATIONS

- **Establishing the Practitioner-Patient Relationship**
  - Fundamental to the provision of acceptable medical care
  - Practitioners must recognize the obligations, responsibilities, and patient rights associated with establishing and maintaining a practitioner-patient relationship
    - Complying with standard of care
    - Obtaining informed consent
    - Maintaining medical records
    - Providing follow-up care
    - Noticing patients of test results, other timely communication

OTHER MEDICAL BOARD CONSIDERATIONS

- **Complying with the Standard of Care for the Provision of Medical Services**
  - Understanding what the Medical Board says regarding standard of care and telemedicine - *examples*
    - TX: the same standard of care that applies to an in-person setting applies to health care services or procedures provided by telemedicine
    - NC: "The Board cautions, however, that licensees providing care to North Carolina patients via telemedicine will be held to the same established standard of care as those practicing in traditional in-person medical settings. **The Board does not endorse a separate standard of care for telemedicine.**" (Position Statement 5.1.4, emphasis in original)
    - NY: "All New York State licensed professionals are responsible for adhering to the same laws, rules and regulations and for upholding the same standards and competencies when engaging in telepractice as they are when practicing without the use of technology over a distance. This understanding is essential to ensure public protection and the integrity of the professions." (State Education Department, Telepractice Memo, http://www.op.nysed.gov/COVID19_Telepractice%20memo.pdf)

OTHER MEDICAL BOARD CONSIDERATIONS

- **Complying with the Standard of Care for the Provision of Medical Services (cont.)**
  - In most states, this may require a deeper dive to fully understand liability and exposure - if standard of care requires application of skill and judgment of a reasonable practitioner with similar training in similar circumstances, is the fact that the practitioner is providing care at a distance relevant to a consideration of "circumstances"?
    - Or does an "in person" standard of care apply, regardless of modality or venue?
    - Federation of State Medical Boards (FSMB) Model Policy: "Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (encounter in person) settings."

Informed Consent

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- Generally, informed consent means communicating the material risks and benefits of a particular treatment or drug to the patient or the patient's surrogate decision-maker
- Informed consent typically occurs at the outset of a patient encounter - in the outpatient setting, that may be for each encounter, or it may be annually, except if specific treatments or drugs are provided
  - Depends on the treatment and the patient's condition - if the risks and benefits of a particular treatment change, the patient may need to be re-consented
- Outside of telehealth, state laws vary re: IC requirements - some require in writing, but most do not
- Medicare has specific requirements for informed consent in certain circumstances *(we are assuming cash pay world, will not address Medicare requirements)*

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- Generally, Medical Boards take the position that an appropriate practitioner-patient relationship requires informed consent, including informing the patient of the identity of the practitioner and authenticating the identity of the patient *(more on this later)*
- Form/contents will depend on state law, and it is intended to (a) address medical malpractice risks as well as (b) comply with state regulatory requirements regarding delivery of health care, *including specific telehealth requirements, if any*
- **Questions to Ask for Telehealth Informed Consent (for each state)**
  - Elements of Telemedicine Consents: What are the elements of consent required to conduct a telemedicine encounter?
  - Format: Does the state require a particular format, e.g. written or electronic?

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- **CA**: Consent is required prior to synchronous & asynchronous encounters; no additional requirements for prescriptions; may be written or electronic, & must be documented
- **IL**: No additional informed consent requirements for the practice of telemedicine
- **TX**: Informed consent required, but no requirements specific to the practice of telemedicine are required
- **UT**: *Seven* specific requirements and/or statements, including notices regarding any additional fees for telehealth, disclosure of PHI, patients' rights regarding PHI, appropriate uses and limitations of the site, information regarding state security and privacy standards, a warning that information may be lost due to technical failures, information regarding the website owner/operator.

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- **NY**: Specifies the elements of consent required in conducting telemedicine under Medicaid laws (no written consent was required during the COVID-19 PHE)
  - Include the right to refuse to participate in services delivered via telehealth, to made aware of alternatives and potential drawbacks of participating in a telehealth visit versus face-to-face; the right to be informed of the location of the distant site and all questions regarding the equipment, the technology, etc., are addressed
  - Have the right to be informed of all parties who will be present at each end of the telehealth transmission
  - Have the right to select another provider and be notified that by doing so, there could be a delay in service and the potential need to travel for a face-to-face visit

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- **VA**: Practitioner is "discouraged" from providing services without
  - fully verifying and authenticating the location and, to the extent possible, confirming the identity of the requesting patient
  - disclosing and validating the practitioner's identity and applicable credential(s), and
  - obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine services

OBTAINING INFORMED CONSENT FOR TELEMEDICINE ENCOUNTERS

- **Some states follow the Federation of State Medical Boards (FSMB) Telemedicine Informed Consent Guidelines**
  - Identification of the patient, the physician and the physician's credentials
  - Types of encounters permitted using telemedicine technologies (e.g. prescription refills, appointment scheduling, patient education, etc.)
  - Patient understanding and consent that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter
  - Details on security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures
  - Hold harmless clause for information lost due to technical failures
  - Requirement for express patient consent to forward patient-identifiable information to a third party

ADDITIONAL STATE LAW REQUIREMENTS

- **Authentication**
  - Some states have patient identify authentication requirements
- **Questions to Ask for Telehealth Authentication (for each state)**
  - Patient Authentication: Does the state have specific requirements regarding patient authentication?
  - Provider Authentication: Does the state have specific requirements regarding provider authentication?
  - Age Documentation: Does the state specify a required form of documentation to confirm age of majority?
- **Notice to Primary Care or Other Providers**
  - Some states require additional notices to PCPs or others
    - For example, TX requires that a HCP make available a medical record or other report of the telehealth visit to the patient's PC physician within 72 hours of the telehealth visit, with patient consent; must include explanation of treatment and the HCP's evaluation, analysis, or diagnosis

Telehealth Platform Documentation

PUBLIC/PATIENT-FACING DOCUMENTS

- Website Privacy Policy / Website Terms of Use
- Informed Consent
- HIPAA Documents
  - Notice of Privacy Practices (NPP)
  - Authorization

WEBSITE TERMS OF USE / PRIVACY POLICY

- Terms of Use
  - User must agree to certain terms to use the website
  - Typically does not address underlying service

- Privacy Policy
  - Establishes what user information the website will collect and how the company will use/disclose their data
  - Typically does not address HIPAA/PHI, or does so only tangentially (NPP is required to address HIPAA)
  - Should address specific state law requirements

WEBSITE TERMS OF USE / PRIVACY POLICY

- Tailored to comply with consumer protection laws
  - Unfair/Deceptive trade practices (FTC)
  - California Consumer Protection Act (CCPA)
  - Children's Online Privacy Protection Act (COPPA)

- Should address other jurisidictional issues that may affect your business
  - International laws (e.g., GDPR if targeted to E.U. residents)

- Consult with Information Security experts for website Terms of Use and Privacy Policy

HIPAA – NOTICE OF PRIVACY PRACTICES

- Each covered entity must have a Notice of Privacy Practices (NPP)
- NPP must provide individuals with adequate notice of the uses and disclosures of PHI that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to PHI
- Covered health care providers that have a direct treatment relationship with an individual must provide the NPP to the individual no later than the date of the first service delivery (including service delivered electronically)
  - Exception for emergency treatment situations

HIPAA – AUTHORIZATION

- Must be signed by the individual if the covered entity proposes to use/disclose PHI in a manner not otherwise permitted or required under HIPAA
- Authorization not required for uses/disclosures for treatment, payment, or health care operations
- For disclosures to Business Associates -- must have a BAA in place
- Must be retained for six (6) years

HIPAA – AUTHORIZATION

- Core elements:
  - A specific and meaningful description of the PHI to be used or disclosed
  - Identification of the persons or class of persons authorized to make the use or disclosure of PHI
  - Identification of the persons or class of persons to whom the covered entity is authorized to make the disclosure
  - Description of each purpose for which the specific PHI identified earlier is to be used or disclosed
    - When individual initiates an authorization for their own purposes, the purpose may be stated as “at the request of the individual.”

HIPAA – AUTHORIZATION

- Core elements (continued):
  - An expiration date or event (this must be a certain date or an event tied to the individual or the use or disclosure)
  - The individual's signature and date
    - If signed by a personal representative, a description of his or her authority to act for the individual

- Required statements:
  - Individual's right to revoke
  - ***Ability or (more likely) the inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization***
  - Potential for re-disclosure by the recipient of the PHI