

Overview

- We are discussing telehealth from the perspective of the technology
 - e-commerce
 - privacy and security
 - fraud and abuse implications with provision of telemedicine equipment
 - data management and retention
 - interoperability and
 - technical function and limitations.
- Post Public Health Emergency
- Vocabulary
 - Origination Site Patient
 - Distant Site Provider

Telemedicine delivery models

In-Patient

- Provider to Provider Consult
- Virtual clinical service (telestroke, telepsych)
- Remote monitoring (vICU)
- Follow-up care to in-patient services

Ambulatory

- Scheduled with primary care provider
- Urgent care (On demand)
- Rehab Services
- Behavioral Health

Mobile Health Apps

- Patient portal or personal health record via mobile device
- Assists in communicating their health status and any changes

Functional Requirements

- Video/Audio
- Patient to provider matching
- Access for those with limited English proficiency
- Access for those living with disabilities
- Reason for Appointment, Patient Submission of Additional Information, Medical History, Notice of Privacy Practices, Telemedicine Consent, Consent, Demographic Information.
- Encounter Documentation (Capturing clinical notes)
- HIM and EHR integration
- Revenue Cycle
- Payment (Cash or third-party payor)
- Prescribing

Technology

- Telemedicine Carts (In-patient)
- Telemedicine kiosks
- Digital Camera
- Mobile App
- Patient Portal (either native or 3rd party video solution)
- Websites
- Telephone (where permitted)
- Store and forward
- Remote patient monitoring
- Application Programming Interfaces (API)
- Know where the data is and how it is retained.

There is no one size fits all solution...

Key Considerations

- Patient technical sophistication
- User relationship (medical staff, contracted coverage, employed, etc.)
- Provider technical sophistication
- Connectivity
- Standard of care for intended use
- Integration with existing workflows
- Reimbursement
- Integration with existing technology

Legal Considerations for the Technology

- Patient encounter When does the patient encounter begin?
- FTC and consumer protection laws fraudulent business practices
- Data Privacy
 - HIPAA and state data privacy
 - Information Blocking Data access rights
 - Mental/behavioral/substance abuse disorder records
- Patient inducement rules
- Fraud and Abuse
- EHR Interoperability Program
- Intellectual property license and use restrictions
- State video surveillance laws (patient monitoring)

The encounter...

- Patient to provider matching
- When is a technology vendor a business associate?
 - Vendor end user terms of use and privacy policy
 - Healthcare provider terms of use and privacy policy
 - Healthcare provider Notice of Privacy Practices (NPP).
- Encounter demographic data gathering.
- Encounter process documents (NPP, consent, acknowledgement of financial responsibility, TCPA express consent).

Data privacy

- HIPAA Right of Access and the obligations of Information Blocking requires that Covered Entities be able to produce a complete copy of the Patient's electronic health record.
- If the telemedicine platform allows the patient to upload pictures or data files, consider both the associated security risks and how the information is incorporated into a system accessible by the HIM department.
- Psychotherapy Notes are narrowly defined and are excluded from the patient right of access and Information Blocking prohibition. If providing virtual psychotherapy, ensure Psychotherapy Notes are isolated consistent with HIPAA obligations.
- a covered entity is not responsible for the privacy or security of individuals' health information once it has been received by the individual's phone or other device. (June 13, 2022 OCR Guidance on How the HIPAA Rules permit Covered Health Care Providers and Health Plans to Use Remote Communications Technologies for Audio-Only Telehealth)

OCR Guidance on post PHE audio only technologies

- In response to the PHE, OCR issued the Telehealth Notification, which
 permitted covered health care providers to use any available non-public facing
 remote communication technologies for telehealth, even where those
 technologies, and the manner in which they are used, may not fully comply
 with the HIPAA Rules.
- The HIPAA Security Rule provides a conduit exception for traditional analog telephone communications.
- OCR clarified that newer technologies are not subject to the same exception; i.e. Voice over Internet Protocol (VoIP) and mobile technologies that use electronic media, such as the Internet, intra- and extranets, cellular, and Wi-Fi. The HIPAA Security Rule applies when a covered entity uses electronic communication technologies. Covered entities using telephone systems that transmit ePHI need to apply the HIPAA Security Rule safeguards to those technologies.

Providing equipment

- Grant funded equipment
- After PHE waivers
- Provision of equipment to patients
- limited function equipment
- Telehealth for In-Home Dialysis. An amendment to the definition of "remuneration" in the CMP rules at 42 C.F.R. § 1003.110 interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients.

Providing equipment

- Antikickback Statute OIG Advisory Opinions (Pre-COVID PHE)
 - OIG Advisory Opinion 11-12
 - OIG Advisory Opinion 18-03
- In its analysis the OIG articulated four considerations:
 - the OIG highlighted that the arrangement would include certain safeguards intended to prevent inappropriate
 patient steering
 - the recipient would remain free at all times to refer its patients to any qualified provider for services (competitive with the proposed telemedicine services) and for follow-up services related to the telemedicine services.
 - the recipient would not be required to refer patients to donor and the recipient would advise all patients who wished to receive telemedicine service virtually that they could receive them either virtually from the provider or another qualified provider or inperson from the provider or another qualified provider.
 - nothing in the donated items would limit or restrict the use or compatibility of the donated equipment with different information technology systems or inhibit the ability of the users of the equipment to communicate or exchange data accurately, effectively, securely and consistently with other providers.
 - The proposed arrangement would be unlikely to result in inappropriate patient steering to the donor.
 - The proposed arrangement would be unlikely to inappropriately increase costs to federal health care programs.
 - The primary beneficiaries would be the patient of the recipient through improved access to HIV treatment where treatment is time sensitive.

Beyond Data

- Technology is generally licensed for specific use cases. Use of technology outside of the scope of use and the assignment, transfer, or provision of access can result in IP liability
- Provision of equipment to patients can lead to compliance concerns and must be evaluated on a case-by-case basis.
- Provision of distant site telemedicine equipment to providers must be evaluated in the context of fraud and abuse.

Data portability

- APIs permit data exchange, but it isn't perfect
- Does the API data feed fulfill documentation necessary for support of claims
- Document retention alignment
- What if telemedicine vendor was my record and they have closed

Telemedicine Technology

- In-Patient (controlled technology environment carts, kiosks, curated cloud services / high degree of device management controls)
 - Provider to Provider Consult (episodic)
 - Virtual Service (Medical Services Arrangement)
 - Remote monitoring (vICU, telestroke)
 - Follow-up care to in-patient services
- Ambulatory (controlled application service apps on patient device / little device management controls)
 - Scheduled with primary care provider
 - Urgent care (On demand)
 - Rehab Services
 - Behavioral Health

Pandemic Telehealth Approach

- Behavioral Health saw 1:1 use between Telemedicine and in-person visits; trend continues in some regions (Northeast, West Coast)
- Widely differing approaches from using video conferencing to highly integrated offerings integrated with the Electronic Health Record were deployed
- Documenting care for Telehealth visits is crucial for maintaining clinical care record continuity and establishing basis for billing
 - Prepare for integration when you decide on Telehealth direction
- Major EHR vendors have Telehealth approaches that tightly integrate documentation into the patient's unified record



Practical Concerns

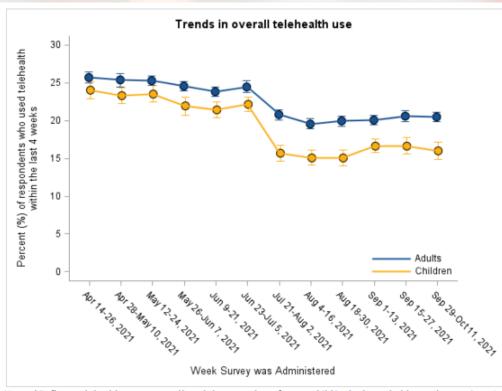
Did you stand up a temporary non-HIPAA-compliant solution to meet pandemic need?

Risk Thoughts:

- ✓ Encryption of images in transit and at rest
- ✓ Retroactive inclusion/import of data into the patient's record
- ✓ Scrub any temporary storage

State of the technology

- Virtual care/Telehealth/Telemedicine use increased during pandemic
- EHR vendors expanded Telehealth planning and implementation with both vendor partners (plus acquisitions) and internal development
- Standalone Telehealth vendors have widely varying abilities to integrate with your organization's EHR



Note: *Reflects telehealth use reported by adult respondents for any child in the household over the previous 4

Telehealth / EHR Integration

Inpatient vs Outpatient

Capture visit details

APIs, HL7 interfaces – FHIR capable?

Integration TCO

Preparation pays off



Data Flow: EMR Provided Telemedicine

- EMR Integrated Solution:
- Configure telemedicine solution
- Validate regulatory requirements
- Ensure documentation/flags complete

Data Flow: Standalone Telemedicine

- Standalone Telemedicine Solution:
- Configure telemedicine solution
- Validate regulatory requirements
- Configure API/HL7 interface to/from EMR
- Test data elements (documents/flags) in EMR to ensure billing compliance components are complete



Perform Telemedicine Readiness Assessment

- Review Telemedicine technology and data requirements.
- API / Integration analysis.
- Future-proof Telemedicine strategy.
- Maintain compliance.





Thank you for your time.



Michael Batt
Hall Render Killian Heath & Lyman, P.C.
mbatt@hallrender.com
(317) 977-1417



Mark Branstetter
Hall Render Advisory Services, LLC
mbranstetter@hallrenderas.com
(615) 423-6651