



COVID-19 and Telehealth: Guidance for Healthcare Providers

Women of Post & Schell Webinar - May 7, 2020

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Overview

- Legal Framework
 - CARES Act and Federal Telehealth Waivers
 - Pennsylvania Legal Landscape
 - New Jersey Statute, Regulations and Waivers
- Operationalizing Telehealth Services
 - Privacy and Security
 - Contracting Challenges
- Liability Exposures

Telehealth Technologies

- Real-time, interactive two-way communication (visual/audio).
- Asynchronous store-and-forward.
- Remote Patient Monitoring (“RPM”).
- Mobile medical devices.



Telehealth Services Paid for by Medicare

- **Providers**

- Physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals.

- **Types of Visits**

- **Medicare Telehealth Visit.** Real-time, two-way, audiovisual patient/provider evaluation (new or existing patient).
- **Virtual Check-In:**
 - ▶ Brief check-in via telephone or other device to decide whether an office visit or other service is needed **or**
 - ▶ Remote evaluation of recorded video and/or images submitted by an established patient.
- **E-Visit.** Communication through an online patient portal.

- **Locations (expanded during COVID-19)**

- From/to: hospitals, FQHCs, RHCs, LTCFs, clinics, dialysis facilities, physician offices, *homes*.
- Across state lines.

CARES Act

(3/27/20)

Infusion of Federal Funding for Telehealth

- **Tit. III, Sec. 3212:** Authorized nearly \$150 million in new grant funding under the Public Health Services Act to develop telehealth in underserved and rural communities.
- **Title V:** Authorized an additional \$200 million in funds to the FCC for the provision of telecommunications services, information and devices to facilitate the provision of telehealth services during the COVID emergency.

Removal of Regulatory Barriers During COVID-19 Emergency

- **Sec. 3703:** Expanded CMS's 1135 Waiver authority to include telehealth.
- **Sec. 3707:** Authorized and encouraged CMS to use 1135 Waiver authority for the provision of home health services via telehealth, including expanded use of remote patient monitoring.
- **Sec. 3704:** Amended SSA to authorize payment for telehealth services provided by FQHCs and RHCs.
- **Sec. 3705:** Amended SSA to allow physician visits by telehealth for ESRD patients receiving home treatment.
- **Sec. 3706:** Amended SSA to permit physician and NP visits for hospice patients to be conducted via telehealth.
- **Sec. 3708:** Amended SSA to broaden scope of practitioners that can do care planning for home health services, beyond physicians.

CMS Section 1135 Blanket Waivers for COVID-19 Emergency

- **Licensure:** practitioners not required to be licensed in the state where the patient is located, provided: (i) enrolled in Medicare, (ii) validly licensed, (iii) furnishing services in a COVID-emergency location, and (iv) not excluded from practice.
- **Telemedicine contract:** Hospitals do not need a written contract with their telemedicine contractors.
- **Hospital credentialing:** Credentialing procedures not required.
- **EMTALA:** Emergency patients not required to be screened in the Emergency Department.
- **Verbal Orders:** Easing of authentication requirements and use of preprinted standing orders, order sets and protocols.
- **Physician attending:** Hospital patients not required to be admitted under the care of a physician.

CMS Section 1135 Blanket Waivers for COVID-19 Emergency

- **LTCFs/SNFs:**
 - In-person visits by physicians and APPs not required.
 - SNFs: Physicians now permitted to delegate specified tasks and physician visits to qualified PAs, CRNPs, and CNSs.
- **Home Health:**
 - Initial assessments may now be performed via telehealth (or by record review) and may be done by OTs where any therapies are part of the POC.
 - Bi-weekly onsite nursing visits for home health aide supervision not required (but virtual supervision is encouraged).
- **Hospice:** Bi-weekly onsite nursing visits for hospice aide supervision not required.

CMS Section 1135 Blanket Waivers for COVID-19 Emergency

- **ESRD:**

- Monthly in-person physician or APP visits to in-center stable patients not required.
- Quarterly in-person physician visits (and monthly for first 90 days) for home dialysis patients not required.
- Relaxation of PCT training and certification requirements.
- Credentialing is transferable – if a practitioner is credentialed at one Medicare-certified facility, that will suffice.
- Dialysis may be provided onsite in NFs/SNFs.

- **DMEPOS:**

- May be replaced without face-to-face visit & physician order.

Fraud and Abuse

CMS – Stark

Stark waivers:

- **OK** to provide free telehealth equipment.
- **OK** to waive co-payments & deductibles.
- **OK** to issue low-interest loan to help establish telehealth.
- **OK** to negotiate physician contracts at above or below FMV.
- **OK** to provide nonmonetary and incidental benefits in excess of statutory limits.
- **OK** for physician to refer a patient to her own group practice for DHS that is not provided in the usual “same building” practice setting – e.g., the patient is in a nursing home, assisted living facility, or home.
- **OK** for a physician to refer to an entity with which he has an unsigned compensation arrangement that is otherwise Stark compliant.

Fraud and Abuse

OIG – AKS

Anti-Kickback Statute:

- **Still applies.**
- AKS risk arising from the provision of “free” equipment and services as an inducement to the patient/originating site to use the telemedicine services.
 - OIG Adv. Op. 11-12: Telestroke.
 - OIG Adv. Op. 18-03: HIV Prevention Services.
 - OIG Adv. Op. 19-02: “Free” Cell Phone to Low Income Patients.

Prescribing DEA

- **In person examination** not required for prescribing of Schedule II drugs.
 - Legitimate medical purpose/usual course of practice,
 - Acting in accordance with state law, through
 - Audiovisual real-time two-way interactive system.
- **Record-keeping requirements** are relaxed for emergency oral orders for Schedule II drugs.
- **State-specific DEA registration** not required.

CAUTION!

**Important not to lose sight of
other regulatory requirements**

**They may still be in play even during the
pandemic and enforcement will certainly resume
after the emergency subsides.**

Pennsylvania Legal Landscape

- Pennsylvania has no Telehealth statute.
- SB 857 (2019) enacted April 21, 2020 – **vetoed** April 29, 2020
 - Would have extended to: medicine, pharmacy, OT, Speech, audiology, dental hygiene, social work, RN, and genetic counseling.
 - Licensing boards would issue regulations within 24 months setting forth practice standards and disciplinary provisions to regulate telemedicine services within their specialty areas.
 - Insurance plans issued in PA would be required to provide coverage for medically necessary telemedicine services delivered by a participating network provider who provides a covered service consistent with the insurer's medical policies.
 - ▶ Insurers could not exclude services solely on the basis that they are provided via telemedicine.
 - ▶ The proposed law would not require “payment parity” between in-person and telehealth services, but would require a negotiated rate filed with and subject to review by the DOH.
- May 6, 2020 Executive Order
 - Provides limited immunity for the COVID-19 Emergency
 - ▶ Excludes Facilities and Private Practice groups

May 6 Executive Order

- Provides immunity to any healthcare practitioner who is licensed, certified or registered in PA and who is engaged in COVID-19 related services in the following settings:
 - Healthcare facility, nursing facility, personal care home, assisted living facility; or
 - Alternate care site, community based testing site, nor non-congregate care facility;
 - *But not the facilities themselves;*
- From civil liability for death or injury of any person as a result of the COVID-19 related professional services, except in the case of willful misconduct or gross negligence.
 - Effective immediately and “for the duration of the disaster emergency.”

State Licensure - Pennsylvania

- **Pre-COVID-19 Rule:** telehealth provider must be licensed in the state where the patient is located (originating site) and where the provider is located (distant site).
- **Pennsylvania COVID-19 Waiver:** Out-of-state healthcare providers may provide telemedicine to Pennsylvania residents if they:
 - Are licensed and in good standing in their home state or territory;
 - Provide the relevant PA Board the following information:
 - ▶ Full name, home or work address, telephone # and email;
 - ▶ License type, number and other ID that is unique to their professional practice, and identify the issuer.
 - Boards affected by the emergency order:

Chiropractic	Dentistry	Medicine
Nursing	Optometry	Pharmacy
Podiatry	Psychology	Osteopathic
Nursing Home	OT	PT
Counselors, etc	Speech, etc.	Veterinary

State Licensure – Pennsylvania (2)

- **Pennsylvania Boards** have also made it easier to get licensed during the COVID-19 pandemic:
 - **State Board of Medicine:** Streamlined temporary license process – waiving requirements such as letters of good standing, criminal history checks, NPDB, and CME.
 - **State Board of Osteopathic Medicine:** Streamlined regular license process similar to SBOM (also a “camp license” option).
 - **State Board of Nursing:** Temporary permits for nurses licensed in other states can be issued immediately after verification through NURSYS. CME requirements are waived.
 - **Other Boards:** similar waivers.
 - ▶ Check dos.pa.gov/Pages/COVID-19-Waivers.aspx.



Other Telehealth-Related PA Waivers

- Telemedicine waivers for hospitals to provide services at:
 - Offsite, alternative care sites, including ASCs.
- Telehealth Pharmacy waivers for:
 - Technicians so that they can perform limited work remotely under supervision.
 - Out-of-state pharmacists can practice in PA.
- Mental health training waivers:
 - Psychology residents, social workers, marriage/family counselors and professional counselors can complete training through telehealth.
- Expanded scope of practice for:
 - Dentists, Oral Surgeons, Athletic Trainers, Chiropractors, Podiatrists Physician assistants, CRNPs, OTs, PTs, Speech and audiologists - some of which will facilitate more services via telehealth to patients in facilities.
- Telehealth waivers for:
 - Remote consultation for Medical Marijuana.
- Expansion of Medicaid payment provisions for telehealth.

State Licensure – New Jersey

- **NJ Telehealth Law**

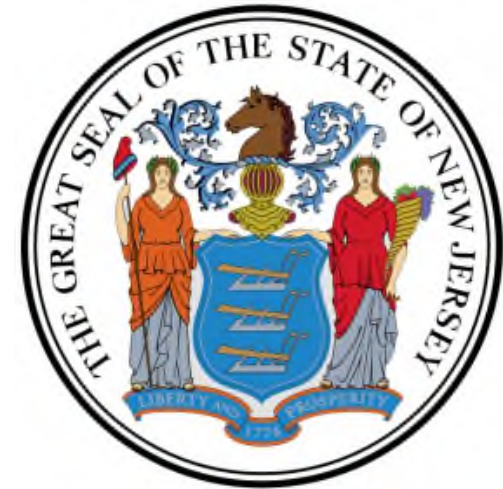
- Permits the full range of professional services recognized in NJ to be provided via telehealth, but requires NJ license or certification.
- The law protects healthcare providers from disciplinary action solely on the basis that the provider was engaging in telemedicine or telehealth.

- **COVID-19 Waivers**

- Out-of-state providers can treat NJ patients within their scope of practice, but for new patients, services are limited to COVID-19 diagnosis and treatment.
- Out-of-state providers can secure NJ license through expedited process with waiver of requirements such as criminal history background checks, licensing fees, and provisions pertaining to minimum malpractice insurance.
- Individual Boards can waive additional requirements.

New Jersey Waivers

- Provider-Patient Location
- Technological Devices
- OCR's HIPAA/Privacy waiver acknowledged
- DEA's Schedule II waiver acknowledged
- Provider/Patient Relationship
- Consent requirements
- FQHC face-to-face requirements
- Medicaid Billing amounts and procedures
- ***Must still practice within the standard of care!***



Facility Credentialing

- CMS has waived federal facility credentialing requirements for Medicare patients, but state requirements and individual facility requirements must be examined.
- Facilities have activated their Disaster Preparedness Plans with streamlined credentialing, but each Facility will have its own requirements.



Telehealth Contracting

- Privacy and Security
- Safety
- System Performance
- Data Rights
- Interoperability and Integration
- Intellectual Property
- Risks and Liability
- Termination and Transition

Privacy and Security

OCR/HIPAA:

- Covered entities not penalized for good faith violations of Privacy, Security and Breach Notification rules during the COVID-19 emergency.
- Telehealth must be an appropriate method for the service being provided.



Privacy and Security

- Less secure communication methods allowed:
 - **YES:** Skype, Apple Facetime, Facebook Messenger, Google Hangouts, Zoom.
 - **NO:** TikTok, Facebook Live, Twitch.
- Less private locations are permitted
 - **YES:** Reasonable distance, lowered voices.
 - **NO:** Speakerphone.
- Providers should notify patients of increased privacy risks and use all available encryption and privacy modes.



Privacy and Security

- For providers that want higher privacy protections, OCR notes that the following vendors represent that they have HIPAA-compliant products and will enter into BAAs:
 - Skype for Business/Microsoft Teams
 - Updox
 - Vsee
 - Zoom for Healthcare
 - Doxy.me
 - Google G Suite Hangouts Meet
 - Cisco Webex Meetings / Webex Teams
 - Amazon Chime
 - GoToMeeting
 - Spruce Health Care Messenger
- The vendors are not endorsed by OCR – this is for informational purposes only.
- State law privacy rules apply, unless waived.

Privacy and Security

The HIPAA guidelines on telemedicine are contained within the HIPAA Security Rule and stipulate:

- Only authorized users should have access to ePHI.
- A system of secure communication should be implemented to protect the integrity of ePHI.
- A system of monitoring communications containing ePHI should be implemented to prevent accidental or malicious breaches.



Privacy and Security

Third party data storage

- A medical professional or a healthcare organization creating ePHI that is stored by a third party, is required to have a Business Associate Agreement (BAA) with the party storing the data.
- The BAA must include methods used by the third party to ensure the protection of the data and provisions for regular auditing of the data's security.

Safety and Security

Any telehealth contract should:

- ✓ Assign appropriate roles and responsibilities to both the provider and the vendor, and
- ✓ Ensure that providers are not unreasonably prevented from reporting and discussing patient safety, security and other issues.

Safety

- Ongoing maintenance, upgrades and performance monitoring.
- Internal controls and processes for software and upgrades.
- Investigation and collaboration in response to technology-related deaths, serious injuries, unsafe conditions, complaints and regulatory investigations.
- Transparency about issues.
- Training and education of users.



Security

- Security assessment.
- Independent security audit.
- Provider's information security program and industry standards (e.g., NIST) as the baselines.
- Encryption methodology and secure data retention and destruction.
- Compliance with applicable state and federal data security regulations.



System Performance

- Contract should describe all core service and performance obligations:
 - Acceptance criteria for equipment and software.
 - Uptime and system response time.
 - Quality and timeliness of service.
 - Post implementation support.
 - Performance management strategies – e.g., SLAs for unscheduled system downtime.

Data Rights

- Contract needs to specify that:
 - The provider owns all telehealth data and has timely and reliable access to it.
 - The provider may access data for maximum analytical value.
 - Acknowledge the importance of data in patient care
 - Restrict the scope of vendor's use and commercialization of data.
 - Vendor must adequately respond to emergencies.
 - System will facilitate patient access.

Interoperability and Integration

- Compatibility with the EHR.
- A telehealth contract should not unduly restrict a provider's ability to integrate third party technologies and services that are important to the provider's ability to leverage data to deliver better and more efficient care, or to take advantage of emerging technologies.
- Interface strategy – point-to-point, data feed or batch export capabilities.
- Ability to integrate third party products.



Intellectual Property

- Consider the investments that a health care provider makes in customizing or improving the telehealth software or equipment.
- Provider needs sufficient rights to use all of the vendor's IP that is necessary to support the provider's obligations under HIPAA, Meaningful Use and other federal or state requirements.
- Vendor must indemnify for any IP claims made by third parties.
 - Software or service must be provided without "infringing" or violating the IP rights of others.

Risks and Liability

- Risk and liability should be allocated fairly between a provider and vendor so that risks are borne by whichever party has most control over and ability to mitigate the risk.
- Dollar amount limitations should be based upon the true maximum amount of financial risk exposure.
 - Do **not** accept arbitrary caps on vendor's damages.
- Carve-outs for limitation of liability provisions are appropriate (e.g., personal injury, breach of privacy/HIPAA, willful misconduct).

Termination & Transition

- An telehealth contract should facilitate termination and transition — with minimum cost and disruption — if a provider chooses to terminate the contract or switch telehealth providers (e.g., at the end of the contract term or for material breach by vendor).
 - Length of support commitment.
 - Caps on price increases during the term and upon renewal.
 - Transition – data transfer and conversion.

Professional Liability Concerns

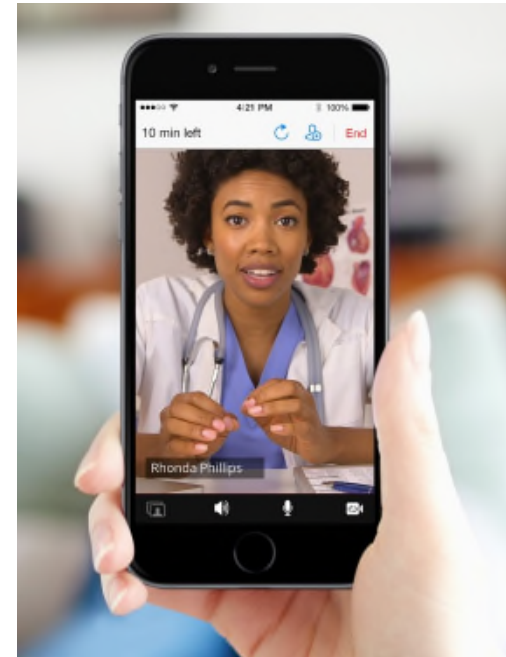
- Telehealth services carry liability risks similar to in-person medical contacts.
 - Standards/good practices gleaned from proposed SB 857.
 - Potential liability considerations/mitigation of risk.
 - Benefits of a telemedicine program.

Risks to Providers

- To date, no Pennsylvania law authorizes or prohibits the practice of telemedicine, (but good practices proposed in SB 857).
 - May be increased risk to provider when there is no in person contact with the patient.
 - Must follow the standard of care, and any laws or regulations and practice within the scope of the license.
 - Documentation still a priority.

Risks to Providers

- Establishing a relationship with the patient is harder to do over a video conference.
 - Develop strong communication skills.
 - Be a good listener.
 - Answer all questions.
 - Make sure the patient understands the symptoms and treatments and instructions.
 - Document discussion.



Risks to Providers

- Make sure that there is access to all of the patient's records so that there is a full understanding of the patient's underlying condition, prior treatments, and a full review of their records can be undertaken of all relevant data, so informed decisions can be made.



Risks to Providers

- Hospitals and providers need to collaborate to ensure that there good information access and communication among providers who are in the hospital with those who are acting virtually, so that informed decisions are being made.



Good Practices

- Implement qualified technologies.
- The proposed legislation discussed the use of interactive audio without store and forward technology but only after access and review of the patient's medical records.
 - And only if the provider determines they can meet same SOC if the services were in person.

Good Practices

- Option to use audio is in proposed legislation, but would require that the HCP inform the patient that they have the option to request interactive audio and video (proposed SB 857).

Good Practices

- Verify and document the location and identity of the individual receiving care.
- Disclose the:
 - HCP identity
 - Geographic locations
 - Medical specialty and credentials
(proposed SB 857 would require this if no prior provider-patient relationship exists).

Good Practices

- Obtain and document informed consent regarding the use of telemedicine technologies from the patient or other person acting in a health care decision-making capacity.
- Include documentation of patient understanding of information provided during the consent process.



Good Practices

- Informed Consent should include:
 - Discussion about telehealth technology.
 - Privacy and security considerations.
 - Consent document for patient to sign.
 - Protocols in place to protect personal health information in compliance with HIPAA.



Good Practices

- Provide and document an appropriate examination using telemedicine technologies.
- Ensure that there is care coordination and information sharing between virtual care providers and in person providers.

Good Practices

- Create and maintain a HIPAA compliant electronic medical record or update an existing record contemporaneously with interaction but no longer than 24 hours.
- Maintain the electronic medical record in accordance with HIPAA electronic medical records privacy rules.



Good Practices

- Establish and document a diagnosis and treatment plan or execute a treatment plan and provide a written visit summary to the patient if requested.
- Have a written emergency action plan/protocol in place for health emergencies and referrals.

Documentation

- Document information known about the patient, detailed explanation of the medical decision making and basis for same, the patient's understanding of their condition, instructions, and any next steps discussed with the patient.



Benefits to Patients

- Telemedicine may save time and lives.
- Improves availability of healthcare options to:
 - People in rural or urban areas who have to travel very far to receive medical care.
 - Homebound seniors.
 - People with chronic illnesses.
 - COVID-19 pandemic impacting ability to conduct in person examinations.



For direct links to government guidance documents and other helpful resources regarding the COVID-19 pandemic, go to:

<http://www.postschell.com/practices-industries/98-coronavirus-covid--taskforce>

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