

Telehealth Legal and Compliance Issues

Nathaniel Lacktman, Esq.  @Lacktman
Anna Whites, Esq.



Health Care
Compliance
Association



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Anna Whites
Law Office

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Overview

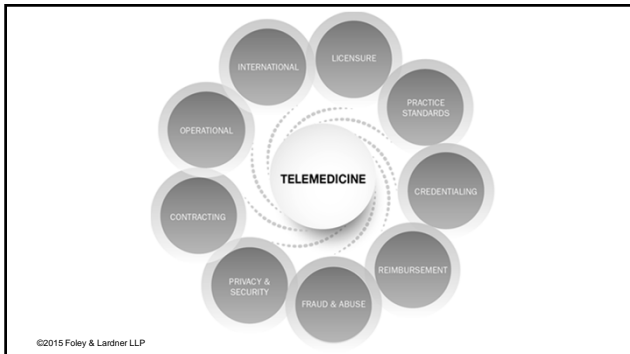
- Licensure and exceptions
- Online Second Opinions
- Multi-state telemedicine services
- Medicare coverage
- Medicare mysteries

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Overview

- Telehealth medical practice standards
- Telehealth in mental health and crisis management
- HIPAA privacy and security
- Medicaid coverage and billing

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Telehealth and Licensure

Basic rule:
Physician must be licensed in the state where the patient is located at the time of the consult.

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Licensure Exceptions

Consultation	Bordering State	Special License or Registration	Follow-Up Care	FSMB Compact
<ul style="list-style-type: none"> • Allows unlicensed physician to practice medicine in peer to peer consultation with a physician licensed in the state 	<ul style="list-style-type: none"> • Allows practice of medicine by out-of-state physicians who are licensed in a bordering state. 	<ul style="list-style-type: none"> • Abbreviated license or registration for telemedicine-only care 	<ul style="list-style-type: none"> • Allows physician to provide follow-up care to his/her patient (e.g., post-operation) 	<ul style="list-style-type: none"> • Allows reciprocity in participating Compact states. <div style="text-align: center; font-size: x-small; margin-top: 5px;"> </div>

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Telehealth and Destination Medicine

“Ten years from now, there will emerge just a few medical centers with the reputation for health care excellence and patient-focused outcomes that will attract patients from all over the world.”

John H. Noseworthy, M.D.
President and CEO of Mayo Clinic

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7

Online Second Opinions

- Patient desires 2nd opinion via provider's website
- Patient's PCP completes a request for a consult
- PCP provides charts and records

2nd Opinion Request

2nd Opinion Consult Performed

- Provider's coordinator reviews materials and selects physician to perform 2nd opinion consult
- Physician reviews materials and writes opinion

- Provider's coordinator sends 2nd opinion to PCP to discuss with the patient

Consult Sent to PCP

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International Telehealth Arrangements

The Health Care Provider's Guide to Building United States to China Telemedicine Arrangements



Table of Contents

About the Authors	1
China Telemedicine Opinions and Guidance for United States Providers	3
China Anti-Corruption Efforts in Medical Institutions	6
Data Flow Restrictions in China and the Healthcare Industry	8
United States Medical Institution Advertisements in China	10
Offering Online Second Opinions in China	12
Protecting Intellectual Property in United States to China Telemedicine Arrangements	14
Data Privacy and Security in United States to China Telemedicine Arrangements	16
China Telemedicine and Long-Term Data	18
China Expands Telemedicine Programs to Provinces	19
Telemedicine Overview	21
Appendix	25
For More Information**	27

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9

Multi-State Telehealth Services

- **Fraud & Abuse Considerations Under State Law**
 - Fee-Splitting Laws
 - State Self-Referral Laws
 - Patient Brokering & All Payer Kickback
 - Corporate Practice of Medicine
 - Insurance Laws

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Telehealth and Medicare

1. Patient in a qualifying rural area
2. Patient at one of eight qualifying facilities ("originating site")
3. Service provided by one of ten eligible professionals ("distant site practitioner")
4. Technology is real-time audio-video (interactive audio and video telecommunications system that permits real-time communication between the beneficiary and the distant site provider)
5. The service is among the list of CPT/HCPCS codes covered by Medicare

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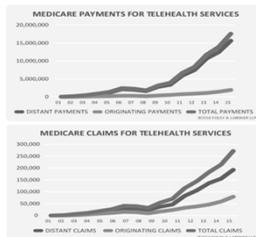
Telehealth and Medicare

1. GT vs GQ modifier
2. POS Code 02
3. GY modifier

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Medicare Mysteries

- Charging beneficiaries out of pocket for telehealth services?
- Reassignment to originating site hospital?
- Interjurisdictional reassignment of claims?
- Overseas providers?
- Enrollment of national physician group?



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Telehealth and Medicare

- Telehealth services billed through a single physician group but the physicians themselves are physically located throughout the country.
- The group provides Medicare telehealth services to patients located at various originating sites across the country.
- Physicians reassign claims to the group, which does all the billing itself.

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Telehealth and Medicare

- **Enrollment**
- **Interjurisdictional reassignment of claims**
 - 42 CFR § 414.65(a)(2), (3); 424.80(b)(2), (d)
 - Program Integrity Manual Ch. 15, section 15.5.20.1, 15.5.4.2.D
 - Claims Processing Manual Ch. 12 § 190 et seq.
 - CMS 855-R
 - The reassigned claims are billed by the originating site hospital to the A/B/MAC(B) located in the distant site physician's jurisdiction.

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Kentucky Statutes

- Kentucky Revised Statute 205.510 defines terms used in healthcare coverage. Subsection (15) provides that "Telehealth consultation" means a medical or health consultation, for purposes of patient diagnosis or treatment, that requires the use of advanced telecommunications technology, including, but not limited to:
 - Compressed digital interactive video, audio, or data transmission;
 - Clinical data transmission via computer imaging for teleradiology or telepathology;
 - Other technology that facilitates access to health care services or medical specialty expertise.

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Direct to patient services

- In 2016 a modification was proposed to Kentucky Revised Statute Chapter 216 which would have defined "Telehealth" as:

"Tele-health" and "Tele-Communication Services" refers to a mode of delivering health care, counseling and public health services by way of federally compliant information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management and self-management of a patient's healthcare while the patient or consumer is at an originating site, including but not limited to the patient's or consumer's home, and a health care provider at a distant site.

- Medicaid was uncomfortable with expansion that would have permitted "direct to patient" services in the patient's home. The direct to patient language was stricken from the statutory amendments. Many providers are using direct to patient services, but are not billing for them.

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Covered providers

- 907 KAR 3:170 is the administrative regulation addressing reimbursement for telemedicine in Kentucky. At Section 2 (b) the Regulation affirms that a Medicaid Managed Care entity may, but is not required to reimburse for care provided via telehealth.
- Section 2(b)(2) outlines when telehealth is not required to be reimbursed. This section provides:
 - (2) A telehealth consultation shall not be reimbursed by the department if:
 - (a) It is not medically necessary;
 - (b) The equivalent service is not covered by the department if provided in a face-to-face setting;
 - (c) It requires a face-to-face contact with a recipient in accordance with 42 C.F.R. 447.371;

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- Cont.

Covered providers

- (d) The telehealth provider of the telehealth consultation is:
 1. Not currently enrolled in the Medicaid program pursuant to 907 KAR 1:672;
 2. Not currently participating in the Medicaid program pursuant to 907 KAR 1:671;
 3. Not in good standing with the Medicaid program;
 4. Currently listed on the Kentucky DMS List of Excluded Providers, which is available at <http://chfs.ky.gov/dms/provEnr>; or
 5. Currently listed on the United States Department of Health and Human Services, Office of Inspector General List of Excluded Individuals and Entities, which is available at <https://oig.hhs.gov/exclusions/>; or
- (e) It is provided by a telehealth practitioner or telehealth provider not recognized or authorized by the department to provide the telehealth consultation or equivalent service in a face-to-face setting.

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Cost control

- One provider can treat more patients via telemedicine than with separate in-person visits. Cost-effective counseling model. Expenses of travel are reduced, it's easier for patients to keep scheduled appointments, there is increased access to care, and reduced stigma for patients who don't want to be seen at a counselor's office. Benefits include improved and faster care delivery, expanded staff capacity, enhanced training for providers, cost savings for payors.
- <https://www.hrsa.gov/publichealth/guidelines/BehavioralHealth/behavioralhealthcareaccess.pdf> (2012)

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Who may provide services

- Medicaid in Kentucky has a spoke and hub coverage model which requires both sides of the telehealth encounter to be at sites (usually a hospital or CMHC) approved by the state telehealth board. See: 907 KAR 3:170(3)(a) holding that:

A telehealth provider shall:

 - Be an approved member of the Kentucky Telehealth Network; and
 - Comply with the standards and protocols established by the Kentucky Telehealth Board.

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Reimbursement

- The Administrative regulation specifies which provider types can bill for telehealth services. 907 KAR 3:170 Section (3)(2) allows reimbursement to:
 - (A) A physical health evaluation or management consultation provided by:
 - 1. A physician including a physician:
 - a. With an individual physician practice;
 - b. Who belongs to a group physician practice; or
 - c. Who is employed by a federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;
 - 2. An advanced practice registered nurse including an advanced practice registered nurse:
 - a. With an individual advanced practice registered nurse practice;
 - b. Who belongs to a group advanced practice registered nurse practice; or
 - c. Who is employed by a physician, federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;
 - 3. An optometrist; or
 - 4. A chiropractor;

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Reimbursement, con't

- (B) A mental health evaluation or management service provided by:
 - 1. A psychiatrist;
 - 2. A physician in accordance with the limit established in 907 KAR 3:005;
 - 3. An APRN in accordance with the limit established in 907 KAR 1:102;
 - 4. A psychologist.

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Billing

- 907 KAR Section 5 (1)(a) states that the department shall reimburse a telehealth provider who is eligible for reimbursement from the department for a telehealth consultation an amount equal to the amount paid for a comparable in-person service in accordance with:
 - 1. 907 KAR 3:010 if the service was provided:
 - a. By a physician; and
 - b. Not in the circumstances described in subparagraphs 3., 4., 5., or 6. of this paragraph;
 - 2. 907 KAR 1:104 if the service was provided:
 - a. By an advanced practice registered nurse; and
 - b. Not in the circumstances described in subparagraphs 3., 4., 5., or 6. of this paragraph;
 - 3. 907 KAR 1:055 if the service was provided and billed through a federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;

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Billing, con't

- 4. 907 KAR 1:015 if the service was provided and billed through a hospital outpatient department;
- 5. 907 KAR 1:031 if the service was provided and billed through a home health agency; or
- 6. 907 KAR 1:065 if the service was provided and billed through a nursing facility.
- (b)1. Reimbursement for a telehealth consultation provided by a practitioner who is employed by a provider or is an agent of a provider shall be a matter between the provider and the practitioner.
- 2. The department shall not be liable for reimbursing a practitioner who is employed by a provider or is an agent of a provider.
- (c) A managed care organization shall not be required to reimburse the same amount for a telehealth consultation as the department reimburses, but may reimburse the same amount as the department reimburses if the managed care organization chooses to do so.
- (2) A telehealth provider shall bill for a telehealth consultation using the appropriate two (2) letter "GT" modifier.

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Informed Patient Consent

- 907 KAR 1:170 outlines the requirements for informed consent for telehealth services in Kentucky. Before providing a telehealth consultation to a recipient, a telehealth provider or telehealth practitioner shall document written informed consent from the recipient and shall ensure that the following written information is provided to the recipient in a format and manner that the recipient is able to understand:
 - The recipient shall have the option to refuse the telehealth consultation at any time without affecting the right to future care or treatment and without risking the loss or withdrawal of a Medicaid benefit to which the recipient is entitled;
 - The recipient shall be informed of alternatives to the telehealth consultation that are available to the recipient;
 - The recipient shall have access to medical information resulting from the telehealth consultation as provided by law;
 - The dissemination, storage, or retention of an identifiable recipient image or other information from the telehealth consultation shall comply with 42 U.S.C. 1301 et seq., 45 C.F.R. Parts 160, 162, 164, KRS 205.566, 216.2927, and any other federal law or regulation or state law establishing individual health care data confidentiality policies;
 - The recipient shall have the right to be informed of the parties who will be present at the spoke site and the hub site during the telehealth consultation and shall have the right to exclude anyone from either site; and
 - The recipient shall have the right to object to the video taping of a telehealth consultation.

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Prescribing

- Kentucky law does not specifically address prescribing. Remote prescribing is generally believed to be at the discretion of the prescribing physician and is held to equivalent standards for in-person encounters. Prescribing may be limited where federal law prohibits internet prescriptions of controlled substances

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Remote Prescribing

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 governs dispensing of controlled substances by means of the internet. The law specifically exempts practitioners of telemedicine from the Act's prohibitions under certain conditions. See: Subsection 309(e) (3)(A) of that Act. The Ryan Haight Act expressly provides that a physician who is acting in accordance with applicable state law and is registered with the state as a telehealth provider or is exempt from such registration, may prescribe after seeing a patient via telehealth. See: Section 53(A)(II) and (III). The Act allows that a patient evaluation permitting prescribing where appropriate need not be in-person if the provider employs technology sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care and the provider is licensed in the state in which the services are being provided. 42 C.F.R. § 482.22(a)(3)(iii)

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Fraud Concerns

- Fraud concerns include services being rendered by unqualified providers, services being billed that are not actually rendered, HIPAA breaches, and business arrangements that breach federal fraud and abuse laws, including the Anti-Kickback Statute and the Stark Law. 42 U.S.C. § 1320a-7b. 42 U.S.C. § 1395nn

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Confidentiality and Privacy

- 907 KAR 3:170 Section 6. Confidentiality and Data Integrity governs the way Kentucky Medicaid wants telehealth privacy and HIPAA concerns managed.
- (1) A telehealth consultation shall be performed on a secure telecommunications line or utilize a method of encryption adequate to protect the confidentiality and integrity of the telehealth consultation information.
- (2) Both a hub site and a spoke site shall use authentication and identification to ensure the confidentiality of a telehealth consultation.
- (3) A telehealth provider or telehealth practitioner of a telehealth consultation shall implement confidentiality protocols that include:
 - (a) Identifying personnel who have access to a telehealth transmission;
 - (b) Usage of unique passwords or identifiers for each employee or person with access to a telehealth transmission; and
 - (c) Preventing unauthorized access to a telehealth transmission.
- (4) A telehealth provider's or telehealth practitioner's protocols and guidelines shall be available for inspection by the department upon request.

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Emergency Treatment and Evaluation

- For patients who may be in crisis, telemedicine provides regular mental health check-ins or quick access to reassurance. In an interactive video format, the provider can observe patient condition as well as speak directly to the patient. This can reduce in-patient care needs since the provider can be reassured as often as daily that the patient is safe and compliant and does not have to be in a hospital or facility.
- In an emergency situation, such as an involuntary commitment or emergency room situation where a mental health expert analysis is required via telehealth, the Kentucky Administrative Regulations hold that the informed consent requirements do not apply "if the recipient is unable to provide informed consent and the recipient's legally-authorized representative is unavailable." 907 KAR 1:170 Section 7(3).

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Pilot Programs

- In 2006, Kentucky piloted a school telehealth program between three hospitals and five schools in which primary care providers used videoconferencing technology to treat and assess elementary, middle and high school students remotely while the children remained in school. The goals were to reduce costs to the Medicaid program while simultaneously reducing absenteeism and increasing access for the young patients. This program was successful as a pilot but was not expanded after the pilot year due to cost.
- In 2015 Humana began using telehealth and direct contact between a patient and a primary care provider or mid-level provider as a means of fostering access to care by patients while encouraging reduced use of hospital emergency departments. The insurer used that coverage to supplement it's "ask a nurse" telephone programs and other educational means of controlling cost for care.
- In 2017, a pilot program between several Home Health entities and patients with chronic conditions such as diabetes, dementia and heart disease will allow providers to videoconference with the patients daily and use remote patient monitoring to capture health data to evaluate. The goal is to reduce readmission for those patients in a cost-effective manner.

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TELEHEALTH: TAKE FLIGHT!



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Tools and Handouts Galore!

- Telemedicine Business & Legal Considerations
- Telehealth Compliance Checklist
- Telemedicine Malpractice Insurance Checklist
- Telemedicine and Controlled Substances Handout
- Hospital Telemedicine Credentialing by Proxy Agreement
- Sample Patient Consent Form
- Kentucky Telehealth Medicaid Statute
- Kentucky Telehealth Medicaid Regulations

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Ask Us Anything*

Nathaniel Lacktman

Foley & Lardner LLP
 813.225.4127
nlacktman@foley.com
www.foley.com/nlacktman
 @Lacktman

Anna Whites

Anna Whites Law Office
 502.352.2373
annawhites@aol.com
www.annawhiteslawoffice.com

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35
