# Telehealth: Emerging Technology Engenders Emerging Risks

Carson Porter, Esq.
Rebecca E. Gwilt, Esq.
March 30, 2014

*Disclaimer: The material in this presentation was created as of the date set forth above and is based on laws, court decisions, administrative rulings and congressional materials that existed at that time, and should not be construed as legal advice or legal opinions on specific facts. The information in this publication is not intended to create, and the transmission and receipt of it does not constitute, a lawyer-client relationship.*

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Presentation Overview

* Telehealth's fractured legal framework
* Physician practice standards
* Technology Regulation
* Privacy, security and confidentiality
* Medical malpractice
* Fraud and abuse
* Telepharmacy/Internet Prescribing

HSC
HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# The Lombardi Lesson

Don’t make it too complicated.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# What is Telehealth?

* Telehealth vs. Telemedicine
* Multiple definitions

| | | |
|---|---|---|
| CMS | HRSA | Joint Commission |
| PHSA | WHO | ATA |
| Controlled Substances Act | State Law | Carve-outs |

**Key takeaway**

A determination of what does and does not constitute telemedicine or telehealth requires an assessment of each applicable federal or state law or accreditation standard.

HSC HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# YOU and Telehealth

## What is your current level of interaction with telehealth?

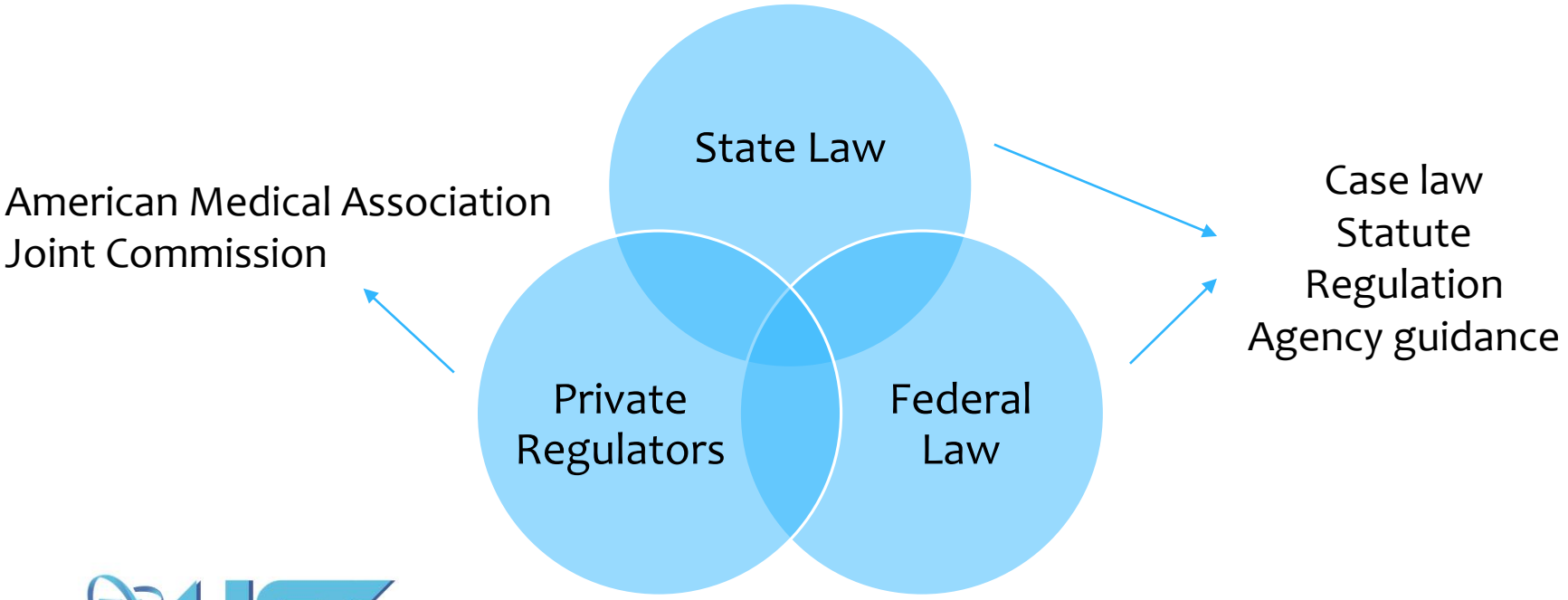
- ❑ No prior experience, but interested in exploring
- ❑ New user (1-3 yrs)
- ❑ Seasoned user (more than 3 years)
- ❑ Vendor

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Telehealth and the Law

## The fractured legal framework:




HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# The ground is shifting

In February, **more than one hundred** telemedicine-related bills were introduced in state legislatures across the country related to:

* Defining telehealth and telemedicine
* Licensed provider practice standards
* Reimbursement
* E-prescribing
* Scope of practice


HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Emerging Risks and Liabilities

HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Physician Practice Standards

## Informed Consent

* Formal **process** critical for high risk procedures
* Risk may increase due to the nature of telemedicine
* IC May be required before ANY telehealth-delivered service
* Failure to properly obtain informed consent can increase a provider's risk of facing consent-based negligence claims

**KEY TAKEAWAY:** Consider state law related to requirements for informed consent and develop a robust informed consent protocol

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Physician Practice Standards

## Dr.-Patient Relationship

* Needed to establish a duty of care
* Telemedicine negates the traditional physicality component
* AMA, ATA, FSMB reinterpreting the creation of the relationship
* State medical boards are providing state-specific guidance
* States are legislating requirements to form Dr.-patient relationship

**KEY TAKEAWAY:** Consider state law and clinical, operational and technical guidelines related to formation of the Dr.-patient relationship

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Physician Practice Standards

## Licensure/Scope of practice

* Licensure determined the lawful scope of practice
* Defined by state laws, licensing bodies, and regulations
* Rules govern practice based on geography and function (prescribing, treatment, diagnosis)
* Practicing medicine without a license in the State in which you are electronically practicing, may incur civil and/or criminal penalties

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Physician Practice Standards

## Licensure/Scope of practice

* Must be licensed where you practice AND where your patient is located
  * Full license
  * Licensure by endorsement
  * Reciprocity
  * Special purpose telemed license
  * Mutual recognition
* Exception for provider-provider consultation, emergencies, border states

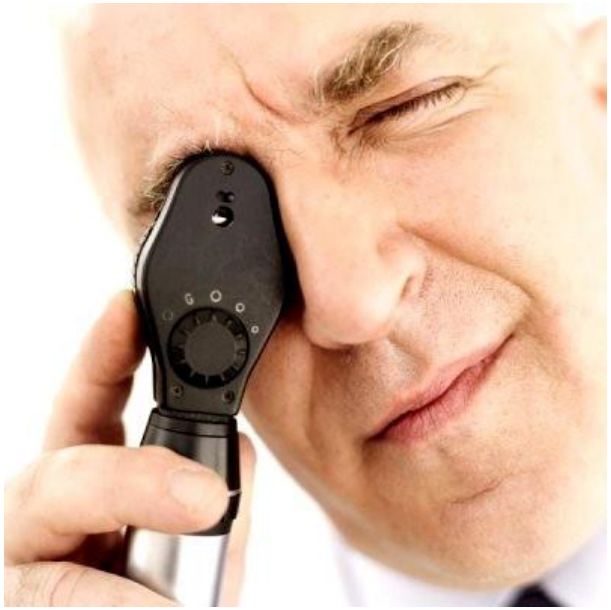
**KEY TAKEAWAY:** Know the state licensure laws in any state in which you practice or deliver health care services.

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Physician Practice Standards

## Dr. Clearview:



### Dr.-patient relationship

- Use of optometrist intermediary

### Licensure

- Consultation Exemption

### Informed consent

- Distant site client consent

HSC
HEALTHCARE SOLUTIONS CONNECTION

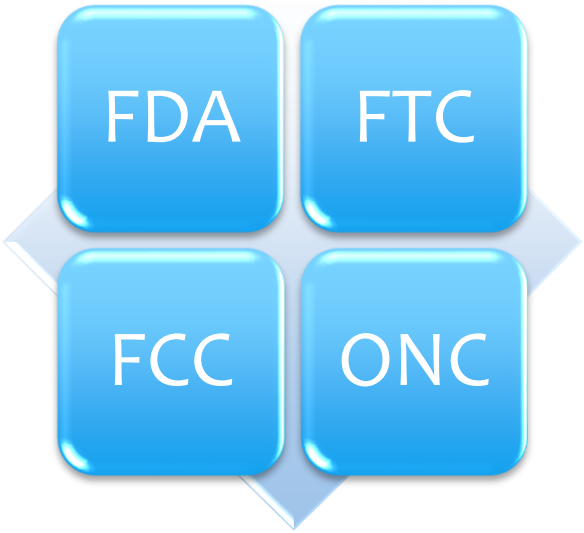
NIXON LAW GROUP LLC

# Telehealth Technologies

"Technologies and devices enabling secure electronic communications and information exchange between a licensee in one location and a patient in another location with or without an intervening health care provider."

## Regulatory Framework

* FDA: telehealth as medical device
* FCC: telehealth and wireless communication
* FTC: telehealth and false/deceptive advertising
* ONC: health IT standards
* OCR: telehealth and privacy/security




HSC
HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Telehealth Technologies

* **Key takeaway**: Be aware that there is much regulatory overlap in the world of telehealth, so vendors and developers should make sure they're consulting with an entity that can help them navigate the web of law and regulation and agency guidance that applies to their industry.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Privacy, Security and Confidentiality

## HIPAA/HITECH

- No special rules for telehealth
- Expansion of risk environment
  - Individuals who manage health IT
  - Individuals on both sides of 2-way transaction
  - 3rd party vendors
  - Hackers
- NO SUCH THING AS HIPAA-COMPLIANT TECHNOLOGY THAT FULFILLS A PROVIDER'S HIPAA OBLIGATIONS

HIPAA
Health Insurance Portability & Accountability Act

HSC
HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Privacy, Security and Confidentiality

## TechnoMed Health System and Smalltown Hospital - Telestroke

### Hub site

- Anyone not visible to patient viewing PHI?

### Spoke Site

- Is ePHI being sent securely (e.g., A, T, P safeguards)?
- Are proper agreements in place with Hub site? Vendor?
- Has patient consented to use of PHI for telestroke?

### Vendor

- Is technical team trained in HIPAA compliance?
- Is technology secure?

HSC HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Privacy, Security and Confidentiality

**Key takeaways**: Providers AND THEIR VENDORS need to make sure they conduct a full security risk analysis, and a compliance assessment including a review of all HIPAA privacy and data breach rules, and state-specific privacy and security law. They should have policies and procedures, staff training programs, standard notices, forms and logs, and updated business associate and data use agreements in place. It is extremely important, as a first step, to understand how and what patient information is being collected and stored.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Medical Malpractice

* Old law, new application
  * Negligence
  * Vicarious Liability (agency)
  * Informed consent
  * Credentialing/Privileging
  * Standard of care
  * Equipment failure
  * Peer Review
  * Medical staff bylaws

HSC
HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Medical Malpractice

## Negligence: Basic elements

**Duty**
- Physician-Patient relationship exists

**Breach**
- Breach of standard of care

**Causation**
- Breach of standard of care caused patient's injury

**Damages**
- Medical expenses
- Lost wages
- Pain and suffering

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Medical Malpractice

## Vicarious Liability

* Could remote providers be characterized as your organization's agent?
  * Healthcare organizations may be held responsible for the actions of remote physicians and other providers.
  * True even where the remote physician is an independent contractor
  * E.g.: outsourced emergency department in a hospital.

## Informed Consent

* Not just a signature—patient must truly be informed
* It's a process!

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Medical Malpractice

## Credentialing/Privileging

* Interaction between originating site and distant site
  * 2011 Medicare COP: healthcare organizations may rely on credentialing/privileging decisions of distant-site hospitals or telemedicine entities if certain conditions are met (credentialing by proxy)
  * Check for conflicting state Medicaid policies
* Written agreements may help mitigate malpractice and negligent credentialing claims

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Medical Malpractice

## Credentialing/Privileging

* Providers need adequate processes to assess quality of practitioners
* Providers need to adequately track those who hold telemedicine privileges, but are not medical staff members (high turnover)


**Key takeaway:** Develop a detailed written telemedicine credentialing policy and procedure that complies with federal and state law and FOLLOW IT

HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Medical Malpractice

## Standard of Care

* Limitations of telemedicine may affect a distant provider's ability to offer a complete and accurate evaluation of the patient's condition

## Equipment failure

* Can lead to patient harm
  * E.g., Nurses in California hospital allege that EHR failure caused by electricity outage shut down the emergency department.
* Need regular equipment maintenance and staff training

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Medical Malpractice

**Key Takeaways:**

* MAKE SURE YOUR MEDMAL CARRIER COVERS YOU AT ALL SITES
* Document EVERYTHING
  * Include description of usage of telemedicine technology where appropriate
  * *If it's not in the patient's record it didn't happen*
* Know and be able to adequately communicate the risks of any telemedicine technology
* Understand state-specific law regarding agency, informed consent, credentialing/privileging, prescribing, duty of care
* Get familiar with guidance regarding services appropriate for telemedicine

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Fraud and Abuse

## Anti-kickback Statute

It is illegal to knowingly pay for, offer, solicit, or receive any remuneration to induce referrals or services reimbursed by CMS

- Space rental
- Equipment rental
- Personal services and management contracts
- Bona fide employees
- Electronic prescribing
- Electronic health records arrangements

**Key takeaway**: Proposed arrangements that involve equipment leases or the provision of free telemedical equipment with referral sources would require evaluation under the fraud and abuse laws.

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Fraud and Abuse

## Stark (self-referral) Statute

Prohibits a physician (or an immediate family member) from referring Medicare patients to entities providing health services if that physician or family member has a financial interest in the entity.

- Lease arrangements (rental of office space)
- Lease arrangements (rental of equipment)
- Bona fide employment relationship
- Personal services arrangements
- Electronic prescribing arrangements
- Electronic health records arrangements
- Fair market value compensation
- Certain ancillary services

**Key takeaway**: Proposed arrangements that involve physician ownership, compensation, or investment in an entity to which he or she refers services requires evaluation under state and federal fraud and abuse laws.

HSC HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Telepharmacy/Internet Prescribing

**Telepharmacy refers to a health professional's ability to prescribe drugs to patients he or she is treating via telemedicine**


## Important considerations:

* Has a physician-patient relationship been formed?
* Has there been a physical examination (adequate under your state's laws)?
* Do you have an accurate patient history?
* Do you meet state medical board licensing requirements in the state in which the patient resides?
* Have you examined your state's internet prescribing laws?

HSC
HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Telepharmacy/Internet Prescribing

## Ryan Haight Online Pharmacy Consumer Protection Act (2008)

* Store-and-forward systems are not acceptable—there must be at least one interactive video consultation with the patient before prescribing controlled substances
* It is unlawful to "fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire."

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Reimbursement

## Policies vary among payors

### Medicare

- Limited services
- Face-to-face requirements
- Limits on eligible providers
- Geographic limitations

### Medicaid

- State variation, combined with federal law
- ~45 states require some reimbursement for telehealth

### Private

- State variation, no federal law
- Plan variation
- ~24 states recognize/require reimbursement (MD, VA, KY)

HSC HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Reimbursement

* **Key takeaway**: Providers should determine which services are covered (Medicaid, Medicare, Private) and whether the distant site and/or originating site qualify for reimbursement

HSC HEALTHCARE SOLUTIONS CONNECTION

NIXON LAW GROUP LLC

# Concluding Remarks

* Law is changing and barriers are depleting
* You must assess your risk prior to engaging a telehealth solution
* Carefully review technology contracts
* Review telemedicine contracts with other providers
* Implement regular testing and maintenance of technologies
* Train and manage team: staff, executive leadership, and providers with telemedicine-only privileges
  * ***Everyone has responsibility!***
* Document! Document! Document!

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Concluding Remarks

* Telemedicine has arrived and is here to stay.
* Smart users and vendors will develop active partnerships to provide the best outcome for patients.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Rebecca E. Gwilt, Esq.

rebecca.gwilt@nixonlawgroup.com
757.846.4936

Rebecca Gwilt is a member of the Nixon Law Group and Healthcare Solutions Connection. Rebecca's expertise includes deep knowledge of ACA laws and regulations affecting various stakeholder groups, including large and small employers, state and local governments, insurance companies, agents and brokers, and providers. She brings her knowledge of program and policy design, implementation, and regulatory compliance directly to the clients she serves, and is widely regarded as a thought leader regarding the future of public and private health reforms. In addition, she has extensive expertise in healthcare privacy and security law and policy.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC

# Carson Porter, Esq.

carson.porter@healthcaresolutionsconnection.com
202.262.5784

Carson Porter is Co-Founder and Chairman of Healthcare Solutions Connection and also a partner at Rimon Law. He has extensive private practice experience, including as Counsel with Arent Fox, business experience serving as CEO to several closely-held companies, and not-for-profit experience serving as Director, Board Member and General Counsel of several organizations. Carson co-founded Accountable Care Law & Policy.

Carson has represented many clients in the healthcare field, including accountable care organizations, more than 100 hospitals, long term care and home health operators, and practicing physicians involved in a variety of healthcare ventures. He has negotiated numerous financings and acquisitions of various business enterprises, with an emphasis on healthcare provider entities.

Carson argued and won the first case to be heard by the Medicare Provider Reimbursement Board. He participated on the legal team that structured the settlement of one of the largest fraud and abuse cases ever prosecuted by the United States, and acted as the lead counsel on five Medicare appeals filed on behalf of the Kentucky Hospital Association and its member hospitals.

Carson served as Chief Outside Counsel to NCRIC, a D.C.-based medical malpractice insurer. In that role, he participated in taking the company from a mutual structure to a publicly traded entity and handled contract dispute in federal court which led to successful settlement for the client.

HSC
HEALTHCARE SOLUTIONS CONNECTION

N NIXON LAW GROUP LLC