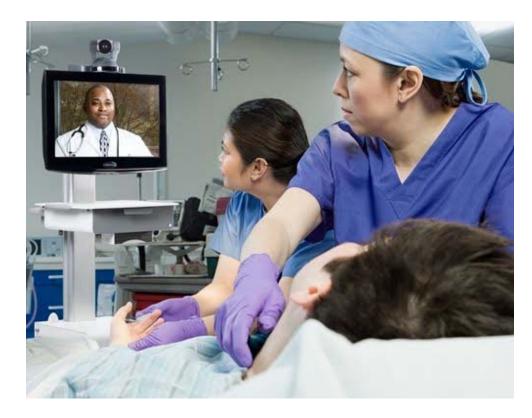
#### **Telehealth**



#### Kim C. Stanger

Compliance Bootcamp (3/17)



This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.



#### **Overview**

- Providing Care Through Telehealth
  - Idaho law re remote prescribing
  - Idaho Telehealth Law and Regulations
- Licensure Issues
- Privacy and Security
- Liability Issues







### Written Materials

- Idaho Law re Prescribing Without an Exam, IC 54-1733
- Idaho Telehealth Law and Regulations, IC 54-5701 et seq.
- Board of Medicine Regulations, IDAPA 22.01.15
- MedLearn, *Telehealth Services* (12/14)
- Medicaid, *Telehealth Policy*(7/14)
- Idaho Board of Medicine, *Guidelines for Appropriate Regulation of Telemedicine*



#### Restrictions on Remote Prescribing or Treating

ACCESS

DENIED

No appointments, no prior prescription required, no waiting rooms, no hassle. Online-Pharmacy

> Prescription Medications Free Online Medical Consultations 24/7 Customer Care Center Simple Online Ordering System Guaranteed Lowest Prices



#### **Restrictions on Remote Prescribing**

- Early internet pharmacies were prescribing based solely on online questionnaires or similar methods.
- In response, many states or medical boards required an inperson physical exam before allowing the practitioner to prescribe or render treatment.
  - Medical practices act
  - Statement of medical boards

See <u>http://www.fsmb.org/pdf/InternetPrescribing-</u> <u>law&policylanguage.pdf</u>.



#### **Idaho Statute re Prescribing**

**Prescriber-Patient Relationship** 

"(1) A prescription for a legend drug is valid only if it is issued by a prescriber for a legitimate medical purpose arising from a prescriberpatient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment."

"(3) Treatment, including issuing a prescription drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose."

"(5) [It is unlawful] to prescribe drugs to individuals without a prescriber-patient relationship, unless excepted in this section."

Prescriber is subject to Board discipline for violations.

(IC 54-1733)



#### **Idaho Statute re Prescribing**

**Exceptions:** licensed prescriber may do the following even though they do not have prescriber-patient relationship:

"(a) Writing initial admission orders for a newly hospitalized patient;

"(b) Writing a prescription drug order for a patient of another prescriber for whom the prescriber is taking call;

"(c) Writing a prescription drug order for a patient examined by a physician assistant, advanced practice registered nurse or other licensed practitioner with whom the prescriber has a supervisory or collaborative relationship;

"(d) Writing a prescription drug order for a medication on a shortterm basis for a new patient prior to the patient's first appointment"; (IC 54-1733(2))



#### **Idaho Statute re Prescribing**

**Exceptions (cont.):** licensed prescriber may do the following even though they do not have prescriber-patient relationship:

"(e) Writing a prescription for an opioid antagonist per IC 54-1733B;

"(f) In emergency situations where the life or health of patient is in imminent danger;

"(g) In emergencies that constitute an immediate threat to the public health...;

"(h) Epinephrine auto-injectors in the name of a school per IC 33-520A; and

"(i) If a prescriber makes a diagnosis of a sexually transmitted disease in a patient, the prescriber may prescribe or dispense antibiotics to the infected patient's named sexual partner ... for treatment of the sexually transmitted disease as recommended by the most current [CDC] guidelines."

(IC 54-1733(2))



FRIDAY, AUG. 21, 2015, 3:30 P.M.

# Doctor fights for her career after Idaho telemedicine sanction

🖌 Twitter

**f** Facebook

💮 Reddit

Dr. Ann DeJong has had to sell her house in Wisconsin and is \$200,000 in debt. Now her medical career is in jeopardy, all because she was sanctioned by Idaho for prescribing a common antibiotic over the phone.

At the time, Idaho law required a face-to-face exam for a prescription. This year, lawmakers changed that to allow for consultations through telemedicine. DeJong was working for such a company, Consult-a-Doctor, when she prescribed the medication; it subsequently pulled out of Idaho. DeJong says if Idaho doesn't modify its order by October, she'll lose her board certification in family practice, and thus her job and livelihood. "It would keep me from practicing anywhere," said DeJong, who was





Applies to providers of telehealth services.

- **Providers** = persons licensed under Title 54 (e.g., physicians, physician's assistant, respiratory therapist, polysomnographer, dietician, or athletic trainer) who provides telehealth services.
- Telehealth services = "health care services provided by a provider to a person through the use of electronic communications, information technology, asynchronous store and forward transfer or synchronous interaction between a provider at a distant site and a patient at an originating site. Such services include, but are not limited to, clinical care, health education, home health and facilitation of self-managed care and caregiver support.
  (IC 54-5603 [54-5703]; IDAPA 220.014.011)

Licensure.

- Provider offering telehealth services must act within scope of the provider's license and applicable rules.
- "Any physician, physician's assistant, respiratory therapist, polysomnographer, dietician, or athletic trainer who provides any telehealth services to patients located in Idaho must hold an active Idaho license issued by the Idaho State Board of Medicine for their applicable practice."

(IC 54-5604 [54-5704]; IDAPA 22.01.15.011)



**Provider-Patient Relationship.** If a provider of telehealth services does not have an established provider-patient relationship, the provider shall take appropriate steps to establish a provider-patient relationship by use of two-way audio <u>and</u> visual interaction.

**Exceptions:** may have electronic communications between:

- Pre-existing provider-patient relationship.
- Provider to provider with preexisting relationship w/patient.
- Provider taking call for another provider in same community with preexisting relationship w/patient.
- Emergency. (IC 54-5605 [54-5705])



**Provider-Patient Relationship.** During the first contact with patient, a provider of telehealth services shall:

- Verify the location and identity of the patient;
- Disclose to patient the provider's identity, their current location and telephone number and Idaho license number;
- Obtain appropriate consents from the patient after disclosures regarding the delivery models and treatment methods or limitations, including a special informed consent regarding the use of telehealth technologies; and
- Allow the patient an opportunity to select their provider rather than being assigned a provider at random to the extent possible.

(IDAPA 22.01.15.012)



**Informed Consent.** Informed consent for telehealth technologies must be obtained and maintained at regular intervals consistent with the community standard of care, including:

- Identification of patient, the provider and provider's credentials;
- Agreement of patient that provider will determine whether the condition being diagnosed and/or treated is appropriate for telehealth services;
- Info on the security measures taken with the use of telehealth technologies (e.g., encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques) and potential risks to privacy and notwithstanding such measures;
- Disclosure that information may be lost due to technical failures. (IC 54-5610 [54-5708]; IDAPA 22.01.15.014)



Standard of Care.

- A provider of telehealth services to patients located in Idaho must comply with the applicable Idaho community standard of care.
- Standard of care is the same as in-person setting.
- Provider is responsible for familiarizing themselves with the applicable Idaho community standard of care.
  (IC 54-5604 [54-5704]; IC 54-5606 [54-5706]; IDAPA 22.01.15.013)
- "[S]ome situations and patient presentations are appropriate for the utilization of telemedicine technologies ... while others are not."

(Idaho BoM, Guidelines for Appropriate Regulation of Telemedicine (12/14)



**Evaluation and Treatment.** 

- Prior to treatment, including a prescription, a provider shall obtain and document a patient's relevant clinical history and current symptoms to establish the diagnosis and identify underlying conditions and contraindications to the treatment recommended.
- If a patient's presenting symptoms and conditions require a physical examination, lab work or imaging studies in order to make a diagnosis, the provider shall not provide diagnosis or treatment through telehealth services unless or until such information is obtained.
- Treatment based solely on an online questionnaire does not constitute an acceptable standard of care.

(IC 54-5606 [54-5706]; IDAPA 22.01.15.013)



**Prescriptions.** A provider with an established provider-patient relationship may issue prescription drug orders using telehealth services within the scope of the provider's license and according to any applicable laws, rules and regulations.

- Must comply with community standard of care;
- Cannot prescribe controlled substance unless prescribed in compliance with 21 USC 802(54)(A).

(IC 54-5607 [54-5707])





Home > Government > Law & Regulation



RELATED CONTENT

Ohio GOP wants to add 20-week abortion ban to heartbeat bill

Lawsuits challenge abortion restrictions in 3 states

## Judge overturns Idaho laws banning telemedicine abortions

By Maria Castellucci | January 24, 2017

A federal judge overturned two Idaho laws that banned women from receiving a medication-induced abortion via telemedicine.

The ruling Monday from U.S. District Judge B. Lynn Winmill stemmed from a lawsuit filed in 2015 by Planned Parenthood of the Great Northwest and





**Medical Records.** 

- Must generate and maintain medical records for each patient using such telehealth services in compliance with any applicable state and federal laws, rules and regulations, including HIPAA and HITECH.
- Medical record should include copies of all patient related electronic communications, including patient-physician communications, prescriptions, lab and test results, evaluations and consultations, relevant info of past care, and instructions obtained or produced in connection with the utilization of telehealth technologies.
- Records must be accessible to other providers and to the patient in accordance with applicable laws, rules and regulations.
   (IC 54-5611 [54-5711]; IDAPA 22.01.15.012)



**Continuity of Care.** Provider must be available for follow-up care or to provide info to patients who make use of such services.

**Referral to Other Services.** Must be familiar with and have access to available medical resources, including emergency resources near the patient's location, in order to make appropriate patient referrals when medically indicated.

(IC 54-5608 to -5610 [54-5708 to -5710])



**Enforcement and Discipline.** 

- A provider is prohibited from offering telehealth services in his or her practice if the provider is not in full compliance with applicable laws, rules and regulations, including this act and the Idaho community standard of care.
- A provider who fails to comply with applicable laws, rules and regulations is subject to discipline by his or her licensing board.

(IC 54-5612 [54-5712])

• Unlicensed provider may be liable for practicing without a license...



#### Licensure





#### Licensure

- State laws generally require that providers be licensed in state where patient resides.
- States differ re telehealth licensure.
  - Some allow for limited license.
  - Most require full license.
- Consequences of practicing without a license:
  - Criminal and administrative sanctions for engaging in the unauthorized practice of law.
  - Possible loss of liability insurance.
  - No reimbursement for services.
    - Medicare and Medicaid require licensure



#### **Idaho Licensure**

- "Practice medicine" =
  - To investigate, diagnose, treat or prescribe for any disease, ailment, injury, or other condition by any means.
  - To apply principles or techniques of medical science in the prevention of any such conditions.
  - To offer, undertake, attempt or hold oneself out as able to do any of the foregoing.

(IC 54-1803(1))

- Unauthorized practice of medicine = felony
  - Up to \$10,000 fine
  - 5 years in prison
  - Adverse action against license



#### **Idaho Licensure**

- "Consultation" exception:
  - A person residing and licensed in another state or country may practice medicine in Idaho if:
    - He consults with a physician licensed in Idaho, and
    - He or she does not open an office or appoint a place to meet patients or receive calls in Idaho.

(IC 54-1804(b))

- Test: direct care v. consultation
  - Frequency?
  - Other physician involved?
- If telehealth provider contracts to provide services for hospital, practitioner must be licensed in Idaho.



#### Licensure

- Practitioners in military, VA, Public Health Service
  - May practice within their organization across states.
- Nurse Licensure Compact
  - Allows multistate licensure for nurses.
- Interstate Medical Licensure Compact
  - Developed by Federation of State Medical Boards ("FSMB").
  - Allows expedited licensure for physicians licensed in another state that is a member of the compact.
  - Several states (including Idaho), have passed laws to participate, but still a year or two away from implementing. (*See* IC 54-1842 et seq.)



#### **Privacy and Security**





#### HIPAA

Health Insurance Portability and Accountability Act of 1996

- Privacy Rules, 42 CFR 164.500
  - Must protect confidentiality of patient info
  - Gives patients certain rights concerning their protected health info ("PHI")
- Security Rules, 42 CFR 164.300
  - Must implement specified administrative, technical and physical safeguards to protect e-PHI.
  - Designed to protect
    - Confidentiality
    - Integrity
    - Availability



### **HIPAA Security**

- Must implement specified physical, technical, and administrative safeguards for e-PHI, including:
  - *Transmission security.* Implement technical security measures to guard against unauthorized access to [e-PHI] that is being transmitted over an electronic communications network.
  - *Integrity controls* (Addressable). Implement security measures to ensure that electronically transmitted [e-PHI] is not improperly modified....
  - *Encryption* (Addressable). Implement a mechanism to encrypt [e-PHI] info whenever deemed appropriate.

(45 CFR 164.312)



#### **HIPAA Business Associates**

- Other treatment providers are not business associates while providing treatment. (45 CFR 160.103)
- May need business associate agreement with vendors or other outsiders who assist with telemedicine, including:
  - Entity that transmits PHI and has regular access to PHI, not "conduit".
  - Entity that stores PHI.
- Exceptions:
  - Members of workforce.
    - You have control over person while onsite.
  - Members of organized health care arrangement ("OHCA")
    - Integrated delivery of patient care.



#### **Additional Regulations**

- FDA regulates medical devices, which may include telemedicine equipment and software if used in the diagnosis or treatment of a disease or condition.
- On 9/23/13, FDA issued guidance on mobile medical apps. See

http://www.fda.gov/medicaldevices/productsandmed icalprocedures/connectedhealth/mobilemedicalapplic ations/default.htm.

• Ryan Haight Online Pharmacy Consumer Protection Act places limits on internet pharmacies



#### **Liability Issues**



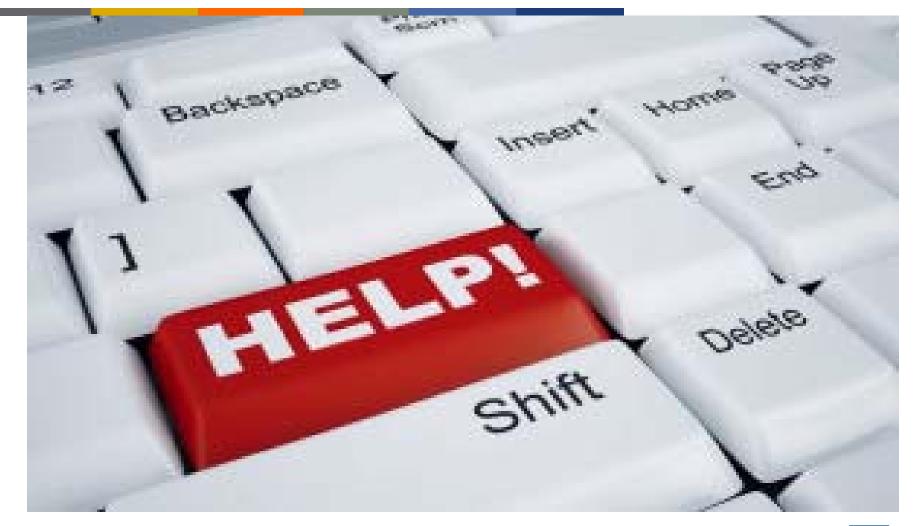


#### **Liability Issues**

- Different laws and procedure if cross state boundaries.
- Provider-patient relationship may be established even if not intended.
- May be held to community standard of care for in-person treatment instead of some telehealth standard.
- Informed consent should address risks of telehealth.
- Beware abandoning patient after telehealth session.
- Malpractice liability insurance may not provide coverage, e.g., practice without license, practice in another state, administrative or criminal actions.
- Ensure claims are properly documented and submitted consistent with applicable laws and regulations.



#### **Additional Resources**





#### **Additional Resources?**

- Federation of State Medical Boards, http://www.fsmb.org/grpol\_telemedicine.html.
  - Summaries of state laws governing telemedicine.
  - Legislative update.
- Center for Telehealth & e-Health Law ("CTel"), http://www.fsmb.org/grpol\_telemedicine.html.
  - Publications and guides.
  - News and information.
- American Telemedicine Ass'n, http://www.americantelemed.org/
  - Practice standards and guides.
  - News and information.



#### **Questions?**

Kim C. Stanger office 208-383-3913 cell 208-409-7907 <u>kcstanger@hollandhart.com</u>

Rob Low office 208-383-3914 <u>rblow@hollandhart.com</u>

