Career Development Series 2023

Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health
Session 2

UNIVERSITY of WASHINGTON

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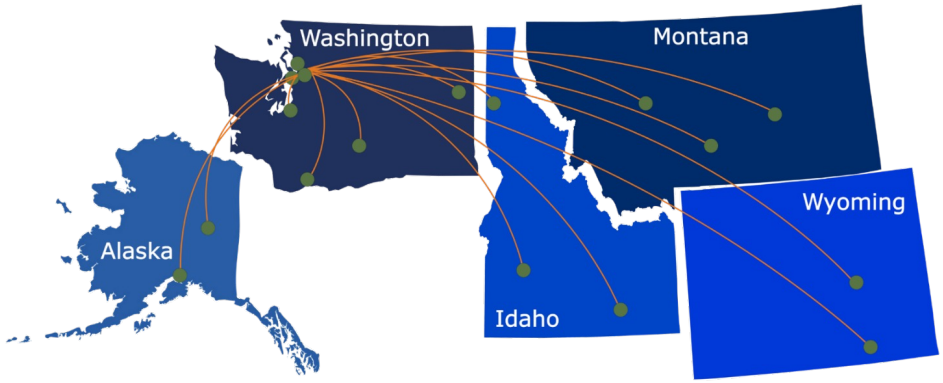

What We Offer:

1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2. **Community Engagement:** Members can connect with regional and community based practice networks

3. **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4. **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact ITHS

Director of Research Development

- Project Consultation
- Strategic Direction
- Resources and Networking

Melissa D. Vaught, Ph.D.
ithsnav@uw.edu
206.616.3875

Scientific Success Committee

- Clinical Trials Consulting
- Guidance on Study Design, Approach and Implementation
- Feedback on Design and Feasibility

https://www.iths.org/investigators/services/clinical-trials-consulting/

Upcoming Career Development Series 2023

Sept. 14 -- How We Discover, Nurture, and Sustain Successful Academic-Community Collaborations with Emily Tomayko

Sept. 19 -- Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health: **Session 3 (***1:00-3:00pm PT***)**

Oct. 4 -- How to Prepare for your Biostats Consult: Tips, Tricks and What to Expect with Anna Faino; Greta Linse; and Susanne May

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Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2023

Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health

Session 2

Presented by:

Cindy Jacobs, RN, JD

John Scott, MD, MSc, FIDSA

Joseph "Augie" D'Agostino, MEd, CISO

Teddy Johnson, PE, MBA

Lenny Sanchez, JD, CHC

Terri Butler, PhD

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Learning Objectives

At the end of the session, participants will be able to:

1. Identify and describe basic overall clinical, regulatory, and business concepts underlying telehealth/telemedicine and device-related digital health, including how the two areas are generally related to or different from each other.

2. Identify and describe examples of key clinical, regulatory, and business considerations separately related to a) telehealth/telemedicine practice and b) development/use of device-related digital health.

3. Identify and describe key clinical, regulatory, and business considerations specifically related to data privacy and security in both the telehealth/telemedicine and device-related digital health arenas.

Case Scenario

- A large health system (located in WA state) is being approached by a hospital in Idaho to provide telehealth services.
- The Idaho hospital is quite small so has limited staff and therefore is interested in a "super camera" with technology to assist in emergent consultations for stroke and for preventing falls.

Case Scenario

- The technology has AI built in such that if an at-risk patient starts to get up (and potentially fall), an alert would be sent to the large hospital, which would be monitoring this room and several others. The large hospital team would have ability to verbally interact with the patient and also call the small hospital's on-site nurses to resettle the patient.
- The technology also can detect the early physical signs of stroke, like facial droop and slurred speech, and automatically call the stroke team at the large hospital.

Clinical and Operational View

Question: What kind of telemedicine does the Idaho hospital wish to perform?

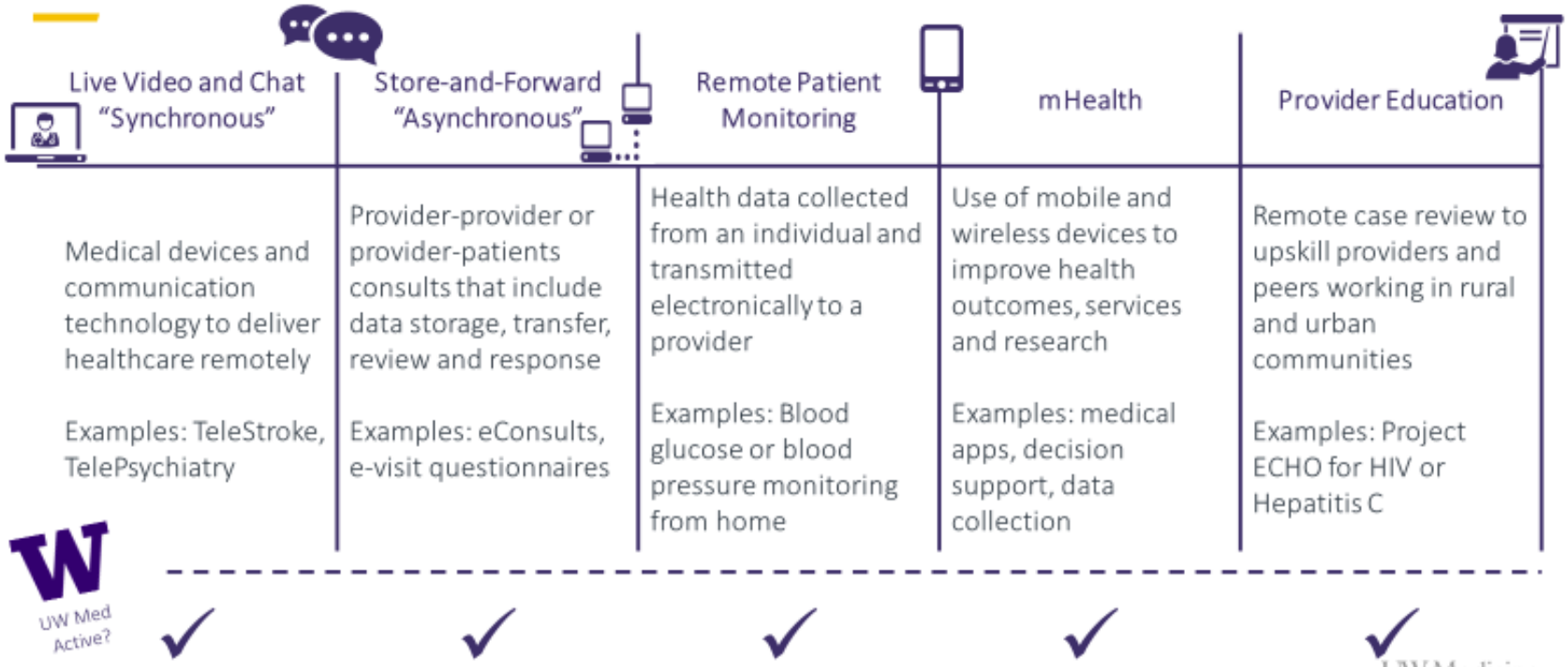
A) live video telemedicine

B) asynchronous store and forward

C) remote patient monitoring

D) A and C

Types of Telehealth



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Clinical and Operational View

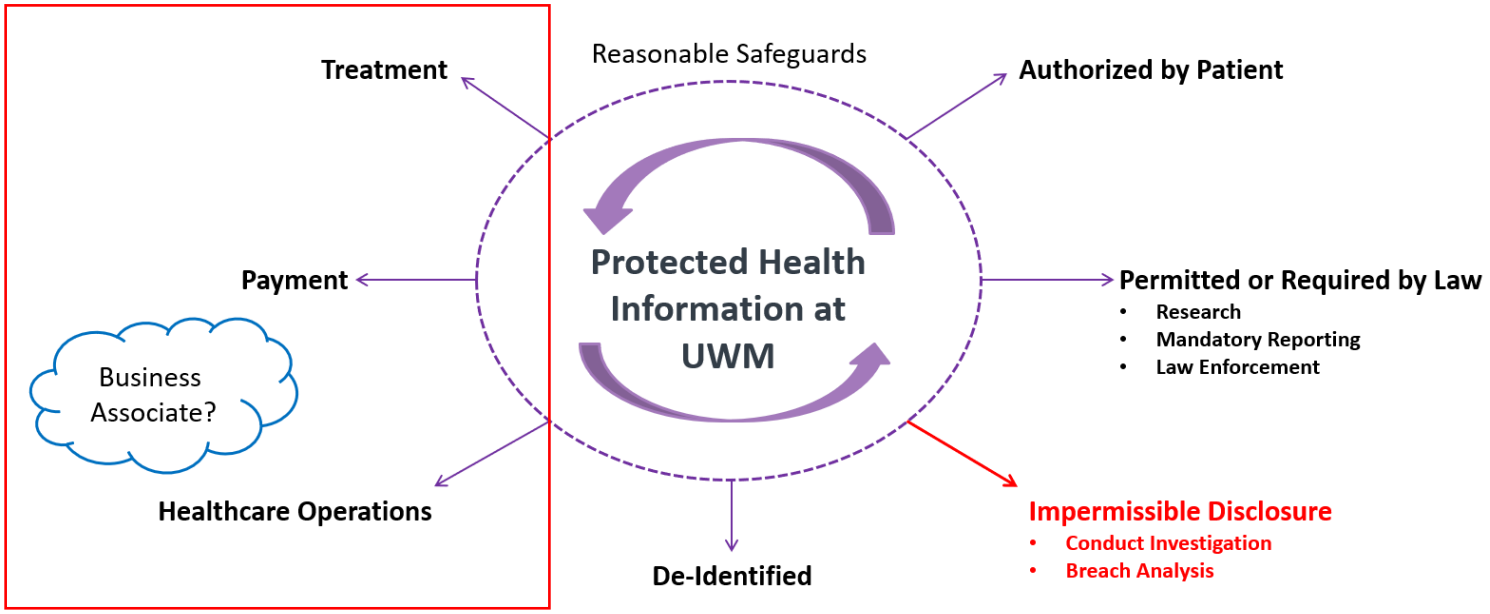
- Do you have clinical capacity to take this on?
- Who is in charge? How do you handle the communication?
- How does this fit into traditional workflow?
- How much time of a clinician do you need?
- How much should you charge?

HIPAA Poll Question #1

Is the activity described in the case scenario allowed by HIPAA?

1. Yes, the purpose of the arrangement meets a treatment, payment or healthcare operations purpose
2. Yes, but only if the patient signs a HIPAA authorization allowing the remote monitoring to occur
3. No, the arrangement involves AI technology which is too risky under HIPAA
4. Unsure

General HIPAA Privacy Framework



HIPAA Poll Question #2

What kind of data privacy contract might be needed to permit the arrangement to move forward?

1. Business Associate Agreement
2. Data Use Agreement for a Limited Data Set
3. UW Data Processing Agreement
4. Need more facts/context to determine this

What is a Business Associate?

1. An entity that is not a part of the HIPAA covered entity;
2. That performs a service or activity for or on behalf of the covered entity; and
3. That involves the use or disclosure of PHI.

What is NOT a Business Associate?

1. A health care provider concerning the treatment of a patient
2. “Conduits”: Transmission-only services where any access to PHI is *transient* in nature

HIPAA Poll Question #3

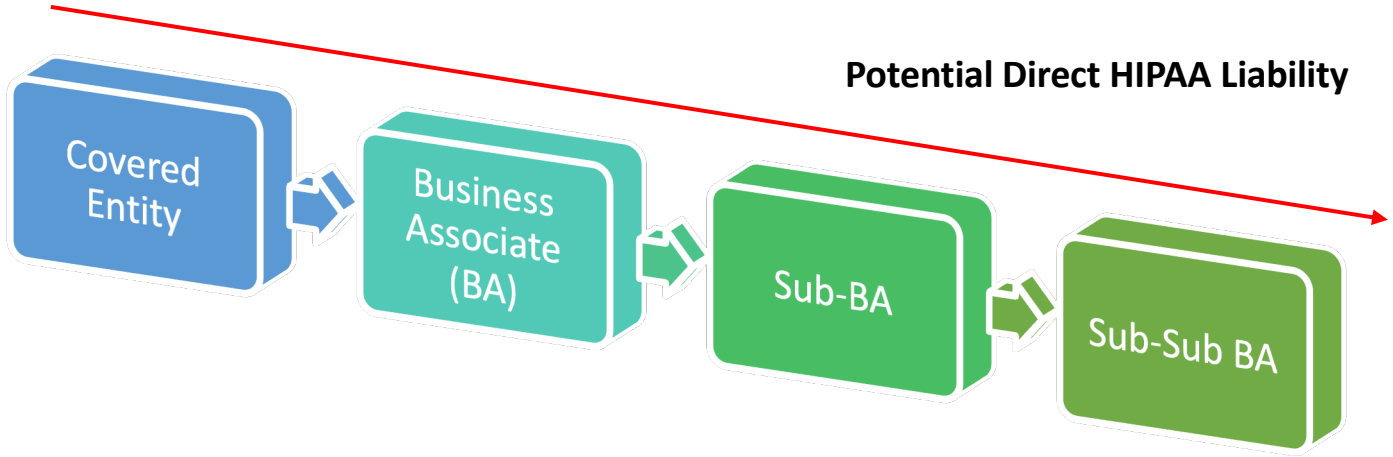
Which party is a Business Associate?

1. The hospital in Idaho
2. The large health system in Washington state
3. The developer of the super camera technology
4. The cloud storage platform hosting the data captured by the super camera

Why Do BA/BAAs Matter?

- Create contractual obligation to abide by HIPAA Rules (PHI is protected downstream)
- Refine how PHI should be protected according to covered entity's privacy values
- Obligate business associate to notify covered entity of breaches affecting their PHI
- Provide a method to end contractual relationship in the event of a breach that isn't cured
- Require return/destruction of PHI when terms end

Why Do BA/BAAs Matter Cont...



HIPAA Poll Question #4

Which of the following controls need to be in place to support the HIPAA Security Rule?

(select the answer(s) that are appropriate)

1. Inventory Controls (Applications and Hardware)
2. Data Protection
3. Secure Configuration
4. Account Access and Management
5. All of the above

UW Medicine Information Security Framework

The NIST Cybersecurity Framework

National Institute of Standards and Technology Cyber Security Functions
IDENTIFY *Do we know our critical assets, threats,* and risks? What do we need to secure?
PROTECT Are controls in place to guard against known and emerging threats?
DETECT Can we detect malicious or unauthorized activity, including a privacy breach?
RESPOND Can we react appropriately and timely?
RECOVER Can we recover quickly to minimize impact?

Critical Security Controls (CIS-18)

- CIS Controls are easy for technical people to understand
- They are prioritized and build on each other
- As you inform and educate executive leaders and business partners they resonate
- They map well to frame works
- NIST and CIS are the “love language” of external auditors and regulatory entities

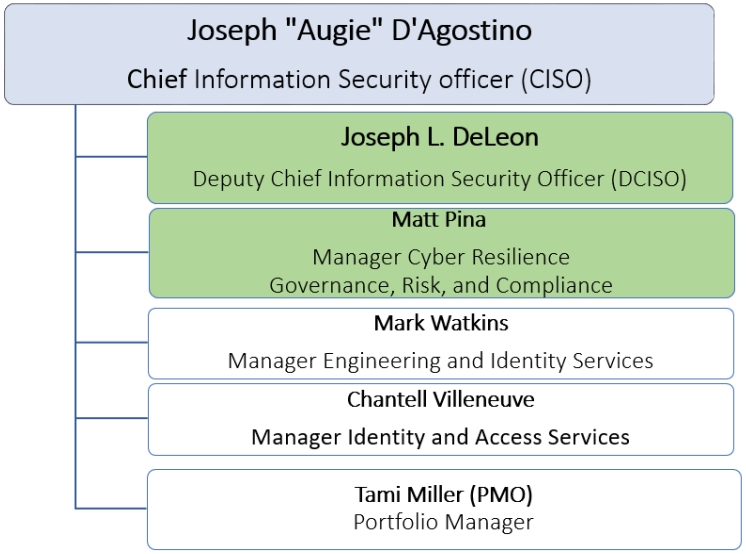
CIS Controls Version 8	
01	Inventory and Control of Enterprise Assets
02	Inventory and Control of Software Assets
03	Data Protection
04	Secure Configuration of Enterprise Assets and
05	Account Management
06	Access Control Management
07	Continuous Vulnerability Management
08	Audit Log Management
09	Email and Web Browser Protections
10	Malware Defenses
11	Data Recovery
12	Network Infrastructure Management
13	Network Monitoring and Defense
14	Security Awareness and Skills Training
15	Service Provider Management
16	Application Software Security
17	Incident Response Management
18	Penetration Testing

HIPAA Poll Question #5

What team(s) of the security organization should you contact first in your process?

1. Governance
2. Risk
3. Compliance
4. Cyber Resilience
5. Engineering
6. Identity Services

Information Security Services



Governance

Framework
Controls
Program
Policies/Standard
Regulations
Laws
Guidelines
Interpretation

Risk

HIPAA Risk Analysis
Risk Register
Risk Exceptions
Risk Mitigation
Reporting
Interpretation
Consulting

Compliance

Monitoring
Enforcement
Escalation
Education
Interpretation
Consulting

Cyber Resilience

Monitoring
Investigation
Incident Response
Reporting
Phishing
Vulnerabilities
Consulting

Engineering

Platform Support
Configuration
Development
Change Management
Vendor Relations
Automation
Epic
Consulting

Identity Services

Access
Attestation
Roles
Terminations
Training Validation
Automation
Epic
Consulting

HIPAA Poll Question #6

How do cloud solutions or the use of AI impact the Information Technology guiding principles and Information Security controls needed?

1. It has zero impact to the principles and controls
2. It does on a case by case basis
3. It depends on if it is internal resources or a third party
4. It can be managed for you if you use a vendor
5. The technology is too new for us to know yet

UW Medicine Information Technology (IT) Guiding Principles

1	**Integration** Integrated, vendor supported applications from our core vendors take precedence over single-use, one-off, best of breed, or internally developed solutions.	5	**Best Practices** Identify and incorporate industry best practices and broadly accepted standards across our hardware, software, and data. Benefits and risks are balanced through best practices.
2	**Security** Adequate controls must be in place for all systems and services to ensure minimum requirements are met. The level of controls required reflect best practices, regulatory requirements, and the sensitivity of the data being utilized.	6	**Value** Solutions must provide value to the organization and as applicable, requests must include cost, risk, ROI calculations, impact to patient care and safety, and alignment with organizational strategies and objectives.
3	**Privacy & Compliance** Information systems, applications and practices must comply with all applicable laws and data privacy policies.	7	**Enterprise** An enterprise approach supported by enterprise technology governance will be followed with standardized solutions deployed across all UW Medicine entities.
4	**Ownership** Systems will have operational owners, operations will oversee technology governance, and projects will be operationally led.	8	**Innovation** Technology will be used in new ways, or new technology will be used, when existing solutions do not meet the operational or strategic needs of the organization.

Business Perspective: Digital Health vs. Telemedicine

Remote Patient Monitoring

- Company needs to:
  - understand the use case and users
  - engineer the medical device
  - design, code, and validate the system software
  - optimize remote connectivity
  - manage support team for compatibility, up-time, security, bug-fixes, updates, etc.
  - manage training team
- Regulatory approval as required

Telehealth Visit Platform

- Company needs to:
  - understand the use case and users
  - design, code, and validate the system software
  - manage support team for compatibility, up-time, security, bug-fixes, updates, etc.

Poll Question: Business Perspective

How would you expect the system manufacturer to make money with the system? (mark all that apply)

A. Sell the equipment
B. Loan the equipment
C. Charge the hospital a monthly/yearly use fee
D. Charge the hospital for interface customization
E. Charge the hospital for a technical support contract
F. Offer discounts for multiple installations
G. Sell de-identified data to third parties
H. Promote fall prevention technologies

What is a reasonable price?

Remote Patient Monitoring

- Charge per device + service or all-inclusive price per patient?
- Discount for data access?
- *Reimbursement relates to set-up, alert frequency, recordings, clinician time, etc.
- What are the overall costs of treatments enhanced by physiologic or therapeutic monitoring? What % is reasonable to apply to the price?

Telehealth Visits

- Charge per visit, per patient, per clinician user, or per year?
- Discount for data access?
- *Reimbursement payments to clinician and clinic are affected by setting, visit length, provider, etc.
- If the new way generates a savings, what % is reasonable to apply to the product price?
- How does new way compare to the old way ($/hour)?

* From AMA Remote Patient Monitoring Playbook @ https://www.ama-assn.org/system/files/ama-remote-patient-monitoring-playbook.pdf

Telemedicine Regulatory Issues

- Licensing
  - Governed by state law for the state where the patient is "located"
  - Idaho and Washington are both Interstate Medical Licensure Compact states

Idaho	Licensure exception/ Consultation exception	Licensure exceptions include: • Established patient-provider relationships with a patient who is in Idaho temporarily for business, work, education, vacation, or other reasons; • Established patient-provider relationships with a patient and provides temporary or short-term follow-up health care services to ensure continuity of care; • If the provider is employed by or contracted with an Idaho facility or hospital to provide care services for which the provider has been privileged and credentialed; • Care rendered in a time of disaster and follow-up care rendered after to ensure continuity of care; • Providing health care services in preparation for a scheduled in-person care visit; or • Consultation with, or patient referral to an Idaho licensed provider.		Idaho Code Ann. § 54-5713

Telemedicine Regulatory Issues

- Credentialing
  - "Distant site provider privileges" are needed for the large system's providers in order to provide telemedicine services to the originating site's patients
    - Privileges may be awarded "by proxy"/reliance on information from the distant site (**would include both clinical and "telemedicine privileges" held by those providers at the distant site**)
    - Clinical privileges by proxy are limited to the same practice area/specialty for which the distant site has granted clinical privileges
    - Privileges by proxy are allowed by TJC and DNV as well as CMS; also allowed by WA DOH

Telemedicine Regulatory Issues

- Standards of care
  - Distant site providers (Washington) would be expected to confirm whether the super camera as a device used in telemedicine practice is/needs to be FDA cleared/approved

FDA Regulatory Issues—Device Requirements

- 21st Century Cures Act (December 2016) modified the definition of "device" to remove certain categories of software from FDA's jurisdiction
  - Software functions that are solely intended to transfer, store, convert formats, or display medical device data or medical imaging data, **unless the software function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings**, are not devices and are not subject to FDA laws and regulations applicable to devices.

FDA Regulatory Issues

- September 2022 FDA Guidance: "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices"
  - Software functions intended to generate alarms or alerts or prioritize patient-related information on multi-patient displays, which are typically used for active patient monitoring, are considered device software functions because these functions involve analysis or interpretation of laboratory test or other device data and results.

FDA Regulatory Issues

- Software functions that are device functions intended for active patient monitoring to enable immediate awareness for potential clinical intervention include the following characteristics:
  - The clinical context requires a timely response (e.g., in-hospital patient monitoring).
  - The clinical condition (disease or diagnosis) requires a timely response (e.g., a monitor that is intended to detect life-threatening arrhythmias, such as ventricular fibrillation, or a device used to actively monitor diabetes for time-sensitive intervention).

Regulatory Poll Question

May the large healthcare system provide the camera to the smaller system free of charge? Select one of the answers below.

1. No free camera allowed: That would violate the Anti-Kickback Statute (AKS) because it would constitute knowing and willful payment of "remuneration" to induce or reward patient referrals to the large system.
2. Free camera is okay: There would be no AKS violation in this set of circumstances.
3. It could go either way depending on the contract language.

Case Scenario

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- The technology also can detect the early physical signs of stroke, like facial droop and slurred speech, and automatically call the stroke team at the large hospital.

Case Scenario Open Discussion Questions

- How do the two systems need to contract?
- What state licensure issues, if any, are there?
- Should the super camera be an FDA-regulated device?
- May the WA hospital provide the camera to the Idaho hospital?
- How do you manage personal and legal privacy concerns when there is a continuously monitored video stream?
- What issues does AI raise?

Thank You!

Open for Questions

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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.