Career Development Series 2023

Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health
Session 3

UNIVERSITY of WASHINGTON

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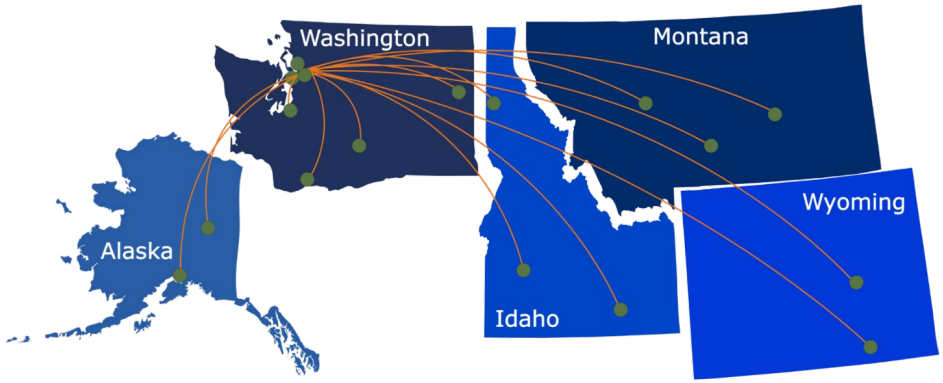

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1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

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

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- Strategic Direction
- Resources and Networking

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

Upcoming Career Development Series 2023

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Career Development Series 2023

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

Session 3

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Disclosures

Today's speaker has no financial relationships with an ineligible company relevant to this presentation to disclose.

None of the planners have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients

All relevant financial relationships have been mitigated

UW Medicine
UW SCHOOL OF MEDICINE

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.

SCENARIO: DEVICE-RELATED DIGITAL HEALTH

A large primary care clinic is looking to streamline its management of and to improve clinical outcomes for its patients with cardiovascular disease, with a focus on heart failure. It is developing a computerized platform to do the following:

1. Provide a dedicated space in its patient portal for heart failure/hypertension/a-fib patients to upload or enter data as applicable from the following:
    a. Wearables re step count and exercise
    b. Home BP readings
    c. Home O2 saturation readings
    d. Weight

SCENARIO: DEVICE-RELATED DIGITAL HEALTH

2. Use algorithms to analyze the patient data against recommended heart failure management/clinical target guidelines that are integrated into the system, and generate the following:

a. Graphic representation of patient's data over time, including comparison to target goals, with provider flags for concerning values
b. Patient reminders to make follow-up appointment based on patient status and guidelines—automatically sent to patient
c. Suggested medication adjustments, including a proposed order, flagged for ordering provider

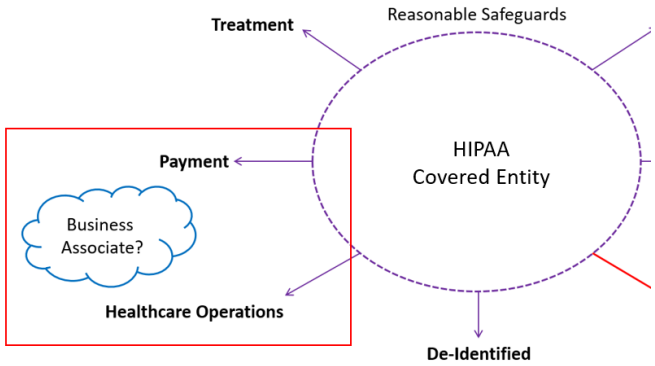
QUESTIONS FOR DISCUSSION

1) Is this platform a "medical device" under the Food, Drug & Cosmetic Act"? Why or why not?
2) What are the FDA requirements, if any, for the platform?
3) What are the privacy and security issues involved with use of the platform?
4) Can the clinic recover reimbursement for use of the platform? If so, how/when?
5) Are there other business, design, or compliance factors the clinic needs to consider?

HIPAA Privacy Issues: To BA or not to BA

Does HIPAA govern the computerized platform developer?

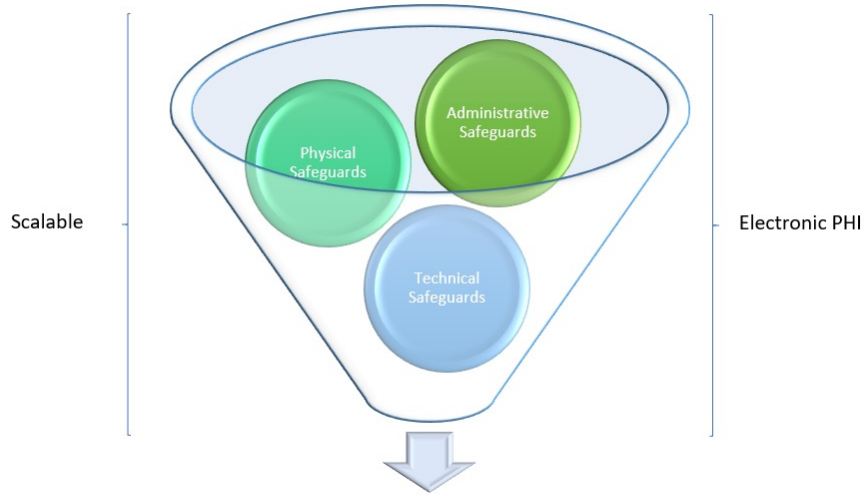
- If developed by a HIPAA covered entity: Yes
- If developed <u>on behalf of</u> the covered entity: Yes, if developer will have access to PHI (business associate)
- If developed for general consumer use: No



Recommended source:
https://www.hhs.gov/sites/default/files/ocr-health-app-developer-scenarios-2-2016.pdf

HIPAA Privacy Issues: Benefits of Being a BA

1) Market your product to healthcare providers
2) Tailor your information security program to locations where you store ePHI or subcontract to sub-BA
3) HIPAA covered entities/BAs (or PHI) often excluded from state laws regulating personal data
4) Good understanding of HIPAA is an opportunity to stand out
5) BUT: Limited to HIPAA/BAA rules governing use of PHI



"HIPAA Compliant"

HIPAA Privacy Risks – Vendor Engagement

1) How much does the clinic trust the vendor and their claims?
2) Will platform truly limit their use of primary care clinic's patient data to the terms of the BAA?
3) Does the platform seek to "de-identify" the clinic's PHI to carry out contract or use for its own purposes?
   - May need to demonstrate de-identification methodology
   - Some organizations do not believe you can truly de-identify data
4) Will platform agree to pay costs of breach it causes?
5) Has platform engaged the use of AI in a "compliant" fashion?
   - Using AI algorithm in closed environment or with a sub-BAA with AI vendor

What is the HIPAA Security Rule?

The Security Rule

The HIPAA Security Rule establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.

View the combined regulation text of all HIPAA Administrative Simplification Regulations found at 45 CFR 160, 162, and 164.

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

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.

HIPAA Security Questions?

1) When should a risk review of the vendor take place?
2) What are the access controls?
3) Is Multi-Factor Authentication in place?
4) How will data be protected in motion?
5) How will data be protected at rest?
6) How and when will data be removed or destroyed?
7) Does the contract ensure breach notification?
8) Who will own the technical relationship with the vendor for long-term communication and upkeep?

Business Perspective on System Value

Value is created by improving quality of care, reducing costs, and monetizing improvements.

Beneficiaries:

- Patients
- Clinicians
- Hospitals
- Product Developers

Poll Question: Business Perspective

Which of the following would be most valuable to the patient?
(choose one)

A. Dashboard of patient data
B. Selection of biomarkers for monitoring disease risk & progression
C. Early identification of heart failure risk
D. Optimization of treatment through clinical study
E. Selection of most efficacious drugs through clinical study

Poll Question: Business Perspective

Which of the following would be most valuable to the company developing the product/system? (choose one)

A. Dashboard of patient data

B. Selection of biomarkers for monitoring disease risk & progression

C. Early identification of heart failure risk

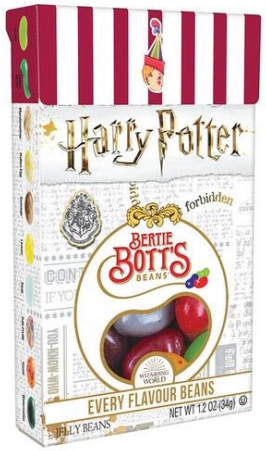
D. Optimization of treatment through clinical study

E. Selection of most efficacious drugs through clinical study

Knowledge is Valuable AND Risky

Clinicians want to improve quality of care without the liability of unused information

Companies want to optimize devices and formulations without narrowing indications



LEGAL/REGULATORY ISSUES

- 21st Century Cures Act (December 2016), Section 3060: Modified the definition of "device" to **remove** certain categories of software from FDA's jurisdiction, including software for:
  - displaying, analyzing, or printing medical information about a patient or other medical information;
  - supporting or providing recommendations to a healthcare professional about prevention, diagnosis or treatment of a disease or condition, AND
  - enabling the health professional to independently review the basis for such recommendations rather than primarily rely on it when making diagnostic and treatment decisions.

Is this system “Non-Device CDS”?

- Most recent CDSS (Clinical Decision Support Software/System) guidance--September 28, 2022
  - Analyzes the “4 criteria” for Non-Device CDS in detail
  - Non-Device CDS software functions do not
    - acquire, process, or analyze images, signals from an in vitro diagnostic device (IVD), or patterns or signals from a signal acquisition system **(Criterion 1)**.
    - No real definitions for "pattern" OR "signal acquisition system," but examples include "A blood pressure result (e.g., “120/80 mmHg”) from a legally marketed device."

Is this system “Non-Device CDS”?

- Non-Device CDS software functions display, analyze, or print medical information (Criterion 2)
  - in order to provide recommendations about a patient’s care to a healthcare professional user (provided Criterion 3 is met).

Is this system “Non-Device CDS”?

- Criterion 3
  - Non-Device CDS software functions provide sufficient information about the basis for the recommendations to the HCP user, so that the user does not rely primarily on any of the recommendations to make a clinical decision about an individual patient.

Is this system “Non-Device CDS”?

- Criterion 3, cont'd
  - Software functions that provide the following outputs may also be considered “supporting or providing recommendations to an HCP” and would meet Criterion 3, as long as they were not intended to support time-critical decision-making and/or replace or direct the HCP’s judgment:
    - List of preventive, diagnostic or treatment options;
    - Prioritized list of preventive, diagnostic or treatment options; or
    - List of follow-up or next-step options for consideration (e.g., after a physician office visit, hospitalization, procedure)

Is this system "Non-Device CDS"?

- Criterion 4
  - CDS (as defined above) is not a device when the HCP can independently review the basis for the recommendation.
- The revised guidance has been petitioned for repeal by an industry group of CDSS developers
  - Petitioners allege that the guidance is overly restrictive, and that FDA should stay with the more flexible IMDRF framework articulated in the previous guidance.

FDA Device Cybersecurity Requirements

- FDA had issued 2 guidances setting forth its rationale for authority to require cybersecurity compliance (device safety)
  - 2018 guidance set up "tier 1" and "tier 2" device cybersecurity requirements
    - Tier-1: (i) the device is capable of connecting to another medical or non-medical product network or the internet; and (ii) a cybersecurity incident affecting the device could directly result in harm to patients.

FDA Device Cybersecurity Requirements

- April 2022 draft guidance:
  - Flagged as "not for implementation"
  - Eliminated tiers
    - All devices must be designed securely, enabling emerging cybersecurity risks to be mitigated throughout the Total Product Life Cycle, and to outline the FDA's recommendations more clearly for premarket submission content to address cybersecurity concerns.
- Digital Health Center of Excellence also has a separate cybersecurity page with detailed resources (e.g., a cybersecurity "playbook")

FDA Device Cybersecurity Requirements

- **FDA's guidance approach was reinforced and broadened by statutory law in December 2022**
  - Consolidated Appropriations Act of 2023, Section 3305, "Ensuring Cybersecurity of Medical Devices," amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 524B to the Act regarding requirements for "cyber devices."

FDA Device Cybersecurity Requirements

- **Definition**
  - In this section, the term "cyber device" means a device that
  1) includes software validated, installed, or authorized by the sponsor as a device or in a device;
  2) has the ability to connect to the internet; and
  3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.

FDA Device Cybersecurity Requirements

The sponsor of an application or submission described in subsection (a)* shall—

(1) submit to the Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures;

(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address

(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;

*Application or submission under section 360(k), 360c, 360e(c), 360e(f), or 360j(m) of this title [basically, all registered/listed devices] for a device that meets the definition of a cyber device under this section.

FDA Device Cybersecurity Requirements

(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components; and

(4) comply with such other requirements as the Secretary may require through regulation to demonstrate reasonable assurance that the device and related systems are cybersecure.

FDA Device Cybersecurity Requirements

- 3/29/2023 Guidance: "Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices Under Section 524B of the FD&C Act"
  - The FDA generally intends not to issue "refuse to accept" (RTA) decisions for premarket submissions for cyber devices that are submitted before October 1, 2023, based solely on information required by section 524B of the FD&C Act. Instead, the FDA will work collaboratively with sponsors of such premarket submissions as part of the interactive and/or deficiency review process.

Device-related Reimbursement

- Remote Patient [physiologic] Monitoring (RPM)/Remote Therapeutic Monitoring (RTM)
    - Remote Patient Monitoring involves the use of digital technologies to capture and monitor information regarding the physical or behavioral functioning of an individual. An example of RPM is the monitoring of blood pressure, weight or oxygen saturation using automated digital technology.
    - Remote Therapeutic Monitoring refers to the management of an individual's non-physiologic information by a healthcare provider. An example of RTM is the monitoring of patient adherence to a treatment plan.
- Could both be billed for patient visits related to a CDSS?

RPM – Set up, Monitoring and Service CPTs

CPT	Who Can Perform	RVU – Non-Facility	Natl Avg Reimb	Description
99453	MD, NP, PA, MA, staff	0.57	19.32	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment **Notes**: Do not report more than once per episode of care or for less than 16 days of monitoring
99454	MD, NP, PA, MA, staff	1.48	50.15	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days **Notes:** ((Do not report 99454 for monitoring of less than 16 days) (Do not report 99453, 99454 in conjunction with codes for more specific physiologic parameters [eg, 93296, 94760]) (For self-measured blood pressure monitoring, see 99473, 99474)
99457	MD, NP	1.44	48.8	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes **Notes:** (Report 99457 once each 30 days, regardless of the number of parameters monitored) (Do not report 99457 for services of less than 20 minutes) (Do not report 99457 in conjunction with 93264, 99091, nor in same month as 99473, 99474)
99458	MD, NP	1.17	39.65	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure) **Notes:** (Use 99458 in conjunction with 99457) (Do not report 99458 for services of less than an additional increment of 20 minutes)

Source: Arizona Telemedicine Program and the Southwest Telehealth Resource Center

Facility Considerations: OPPS Reimb

CPT	Who Can Perform	APC	OPPS Reimb	Description
98975	OT, PT, SLP. Includes staff.	5012	$120.86	Initial set-up and patient education on use of equipment
98976	OT, PT, SLP	5741	$35.00	Device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) **transmission to monitor respiratory system**, each 30 days)
98977	OT, PT, SLP	5741	$35.00	Device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) **transmission to monitor musculoskeletal system**, each 30 days
98978	LCSW	5741	$35.00	Device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) **transmission to monitor cognitive behavioral therapy**, each 30 days
99453	Staff member.	5012	$120.86	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
99454	RNs	5741	$35.00	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days

APC - Ambulatory Payment Classification

Source: Arizona Telemedicine Program and the Southwest Telehealth Resource Center

RTM – Set up and Monitoring CPTs

CPT	Who Can Perform	RVU – Non-Facility	Natl Avg Reimb	Description
98975	MD, NP, PA, CNS, OT, PT, SLP and possibly psychologists & other providers may bill these codes. Includes staff.	0.57	$18.84	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	MD, NP, PA, CNS, OT, PT, SLP and possibly psychologists & other providers may bill these codes.	1.48	$48.93	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) **transmission to monitor respiratory system**, each 30 days)
98977	MD, NP, PA, CNS, OT, PT, SLP and possibly psychologists & other providers may bill these codes.	1.48	$48.93	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) **transmission to monitor musculoskeletal system**, each 30 days
98978	MD, NP, PA, CNS, OT, PT, SLP and possibly psychologists & other providers may bill these codes.	Not priced yet	$0.00	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) **transmission to monitor cognitive behavioral therapy**, each 30 days

Source: Arizona Telemedicine Program and the Southwest Telehealth Resource Center

RTM – Provider Service CPTs

CPT	Who Can Perform	RVU – Non-Facility	Natl Avg Reimb	Description
98978	MD, NP, PA, CNS, OT, PT, SLP and possibly psychologists & other providers may bill these codes.	Not priced yet	$0.00	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) **transmission to monitor cognitive behavioral therapy**, each 30 days
98980	MD, NP, OT, PT, SLP, OTA, PTA	1.46	$48.27	Remote therapeutic monitoring treatment management services, physician/ other qualified health care professional time in a calendar month **requiring at least one interactive communication** with the patient/caregiver during the calendar month; first 20 minutes
98981	MD, NP, OT, PT, SLP, OTA, PTA	1.17	$38.68	Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; **each additional 20 minutes** (List separately in addition to code for primary procedure)

Source: Arizona Telemedicine Program and the Southwest Telehealth Resource Center

RPM/RTM Billing

- Only one provider may bill codes 99453, 99454, 98976, 98977, 98980, and 98981 in a 30-day period w/16 days of device data
  - Must have 16 days of data
- RPM may be billed only for an established patient
- PTs and OTs can bill RTM for PTAs and OTAs under General Supervision

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A large primary care clinic is looking to streamline its management of and to improve clinical outcomes for its patients with cardiovascular disease, with a focus on heart failure. It is developing a computerized platform to do the following:

1. Provide a dedicated space in its patient portal for heart failure/hypertension/a-fib patients to upload or enter data as applicable from the following:
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    b. Home BP readings
    c. Home O2 saturation readings
    d. Weight

SCENARIO: DEVICE-RELATED DIGITAL HEALTH

2. Use algorithms to analyze the patient data against recommended heart failure management/clinical target guidelines that are integrated into the system, and generate the following:

a. Graphic representation of patient's data over time, including comparison to target goals, with provider flags for concerning values
b. Patient reminders to make follow-up appointment based on patient status and guidelines—automatically sent to patient
c. Suggested medication adjustments, including a proposed order, flagged for ordering provider

PANEL DISCUSSION

1) Is this platform a "medical device" under the Food, Drug & Cosmetic Act"? Why or why not?
2) What are the FDA requirements, if any, for the platform?
3) What are the privacy and security issues involved with use of the platform?
4) Can the clinic recover reimbursement for use of the platform? If so, how/when?
5) Are there other business, design, or compliance factors the clinic needs to consider?

POLLING QUESTION

Is this platform a "medical device" under the Food, Drug & Cosmetic Act"? Why or why not?

1. Yes, it's a medical device because it uses an algorithm that the healthcare professional can't see in detail.
2. Yes, it's a medical device because it can create an order based on the algorithm alone.
3. No, it's not a medical device because it satisfies all criteria to be considered "Non-Device CDS."
4. It could go either way; more detailed information is needed.

POLLING QUESTION—VARIATION #1

Is this platform a "medical device" under the Food, Drug & Cosmetic Act under the following variation?

- The platform uses algorithms to present findings, propose a recommendation, and place a draft order on the scratchpad.
  - Like this: “This patient’s blood pressure has consistently been high. Consider increasing the metoprolol succinate from 20mg daily to 30mg daily.” [Order to change dose from 20mg daily to 30mg daily on scratchpad awaiting signature or cancel order.]
- **Yes, it's a medical device**
- **No, it's not a medical device**

POLLING QUESTION—VARIATION #2

Is this platform a "medical device" under the Food, Drug & Cosmetic Act under the following variation?

- The platform uses AI to propose orders. Clinicians can request a list of variables that were used by the machine learning algorithm to affect its decision.
  - Like this: "This patient's bedtime Glargine should be increased from 10 units to 15 units" (*note: this would likely involve diabetic patients uploading blood glucose data in addition to the other listed data*). Clinician clicks info button or "why?" icon to learn more and sees a list like this:
    [pt_lab_crpos] [pt_hx_chfpos] [pt_demo_age] [pt_lab_bgtestfreq] [pt_demo_bmi] [pt_lab_amgluc]
- **Yes, it's a medical device**
- **No, it's not a medical device**

ADDITIONAL QUESTIONS?

- Attendee questions related to this session or either of the two previous sessions
  - Session 1: Overview of telemedicine and device-related digital health
  - Session 2: Telemedicine case scenario—panel discussion
- Other questions about telemedicine or device-related digital health

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.