Career Development Series 2023

Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health
Session 1

UNIVERSITY of WASHINGTON

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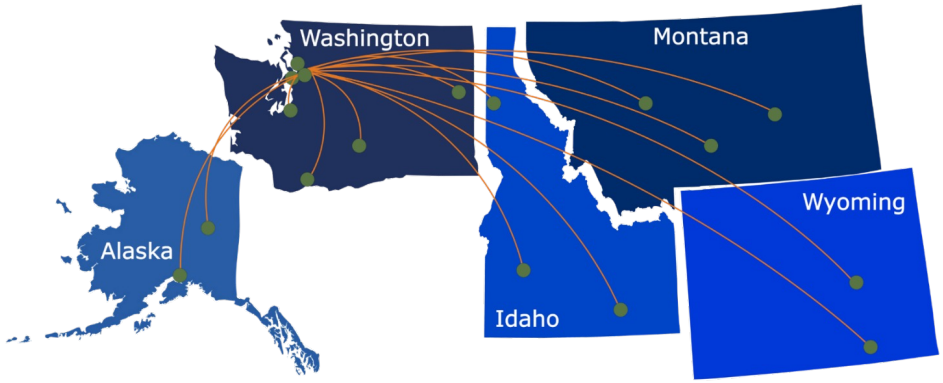

What We Offer:

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. 8 -- How to Be an Effective Principal Investigator with Ann Melvin

Sept. 12 -- Clinical, Regulatory, and Business Considerations in Telemedicine and Device-Related Digital Health: **Session 2**

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

ITHS | Institute of Translational Health Sciences
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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 1

Presented by:

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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:

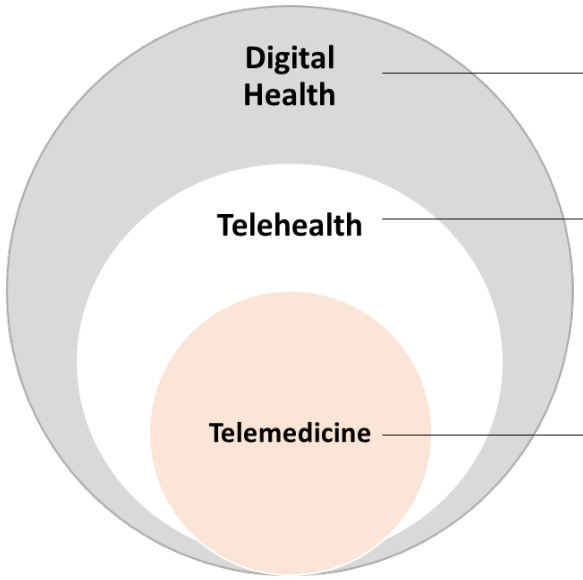
1. Identify and describe basic overall clinical, regulatory, and business concepts underlying telehealth/telemedicine and device-related digital health, including how the two areas are generally related to or different from each other.

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.

Definitions: Digital Health, Telehealth and Telemedicine

The terms **telemedicine** and **telehealth** are often used interchangeably, however there are differences.

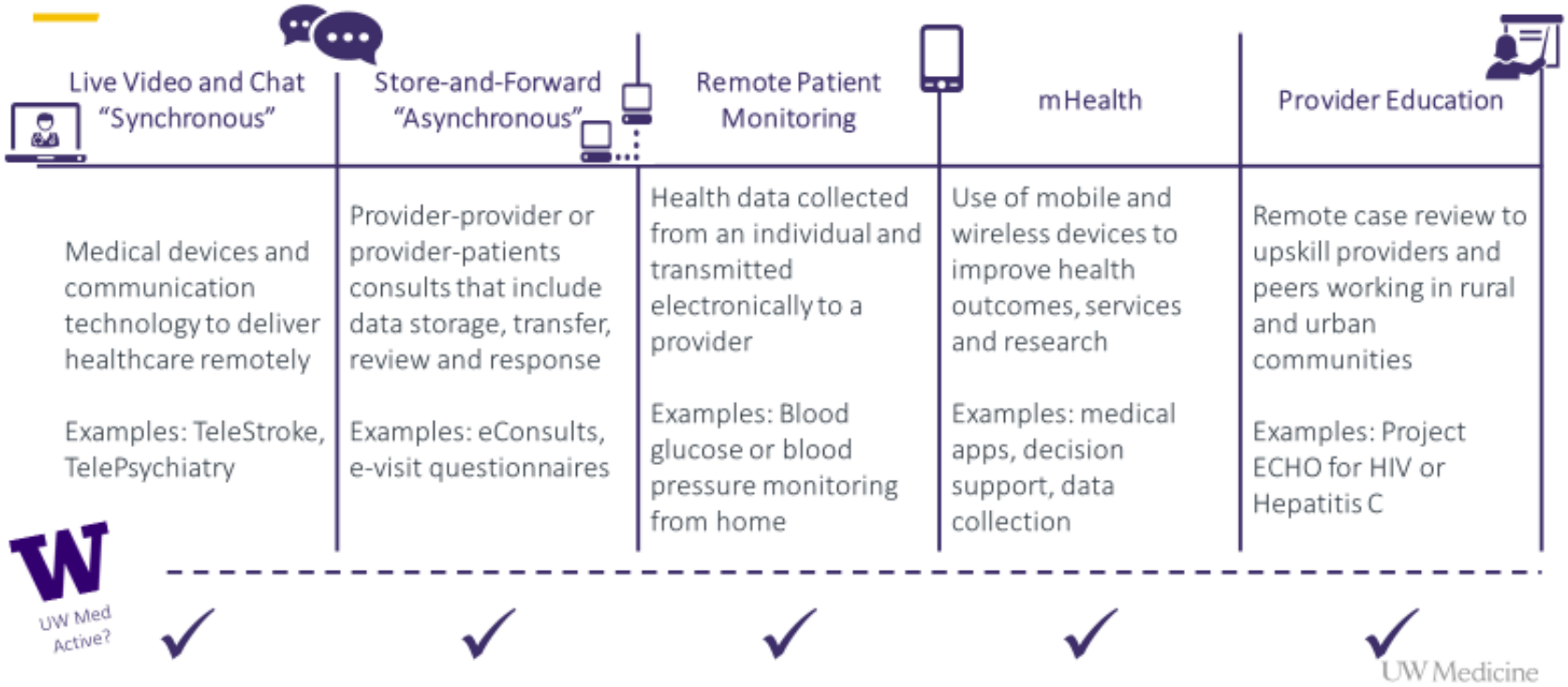


Digital Health is an umbrella term for all health-related activity involving technology including all digital interactions with patients and telehealth services *such as patient portals, online scheduling, mHealth, and all telehealth services.*

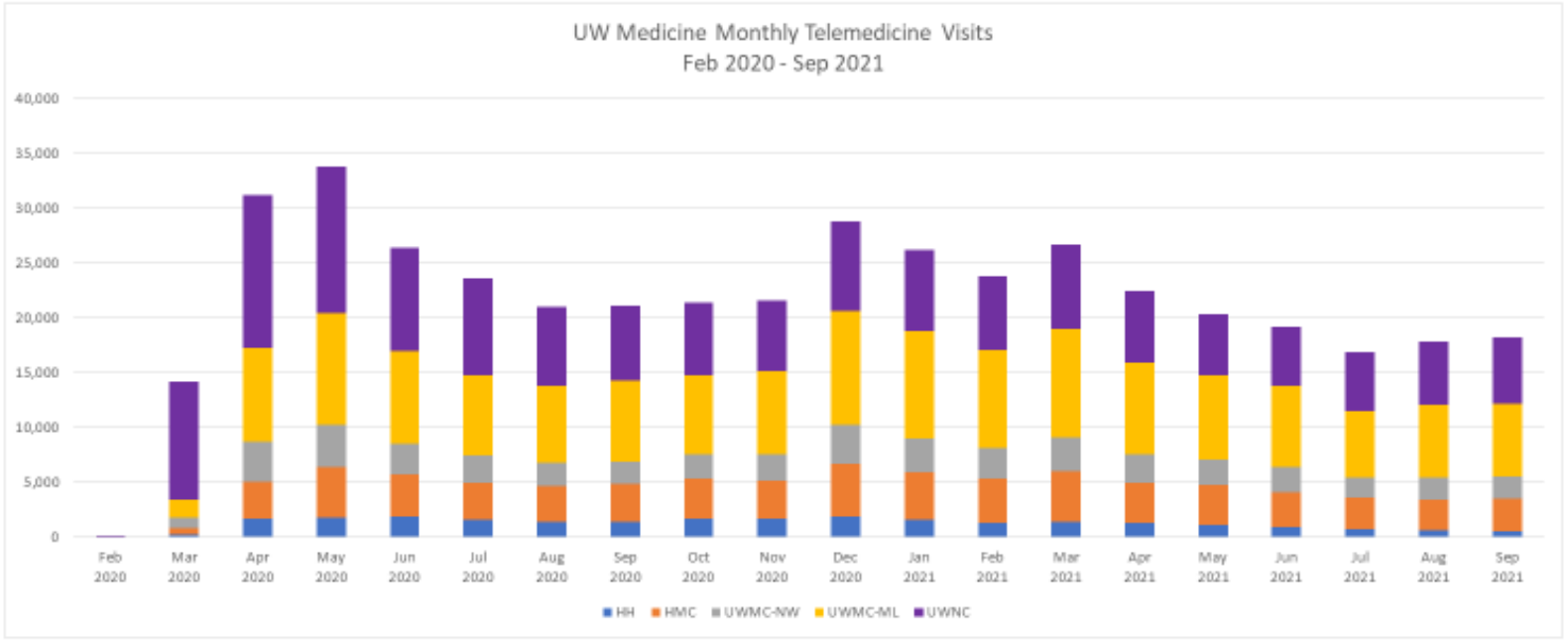
Telehealth refers to the delivery and facilitation of healthcare services via telecommunications and digital communication technologies including *telemedicine, remote patient monitoring, eConsult, and provider education programs such as the Project for Extension for Community Healthcare Outcomes (ECHO).*

Telemedicine refers specifically to the subset of telehealth provided via live, real-time video interactions between patient & provider.

Types of Telehealth

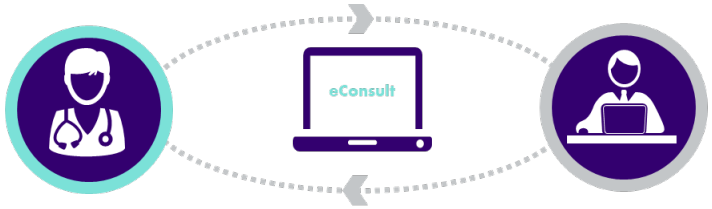


UW Medicine COVID-19 Telehealth Response



eConsults Program

eConsults are a cost-effective solution to improve access to specialty care



Referring Provider

"I have a clear clinical question for a specialist to help me manage my patient's care plan."

- Timely access to specialty input
- Improved continuity of care for patients

Specialist

"I reply with recommendations and next steps for the patient so the referring provider can continue managing the patient's care."

- Improved access for higher acuity patients and new patients
- More efficient referrals

eConsults

- Secure written exchange between providers
- Condition-specific templates
- Include relevant labs, tests, images
- 3 business day turnaround

Impact

- Over 25,000 eConsults completed since 2016

Live Specialties at UW Medicine

- Allergy, Cardiology, Dermatology
- Endocrinology, Gyn, Heme
- Infectious Dis, Renal, Neuro
- Psychiatry, Pulmonary, Rheum
- Urology, Wt loss, Palliative Care

eConsults

- Improved access by 30% for first 4 specialties
- Helps PCPs to work at top of their license
- Support collaborative care model
- Reimburse both requesting provider and responding specialist 0.7 rVU
  - -CMS, WA Medicaid and most commercial insurance companies reimburse
- Leverages electronic medical record
- Currently only available within UW Medicine system

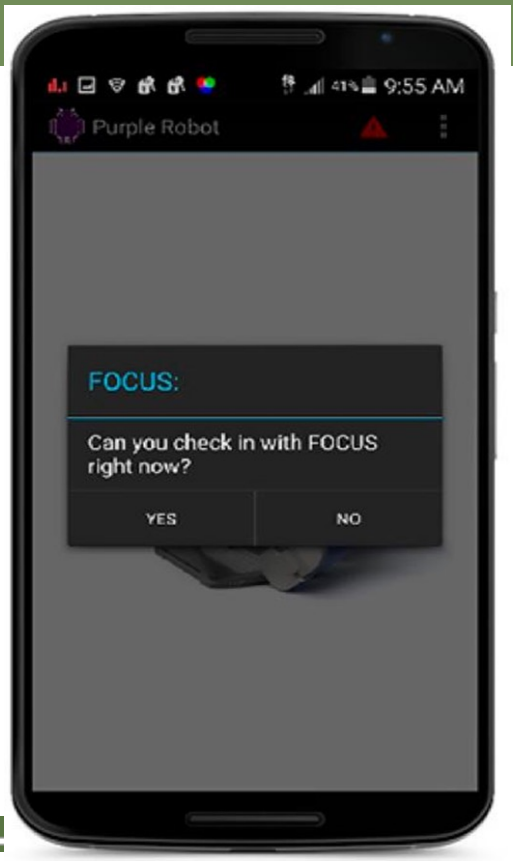
Source: Gaye M, Mehrotra A, Byrnes-Enoch H, et al. Association of eConsult Implementation With Access to Specialist Care in a Large Urban Safety-Net System. JAMA Health Forum 2021, 2(5):e210456.doi: 10.1001/jamahealthforum.2021.0456

mHealth

- mHealth = mobile health
- Use of medical apps to track health
- Privacy and security are a big concern
- Integration into EMR not standard
- FDA rules and regulations may apply!

FOCUS: a UW developed app for patients with serious MH issues

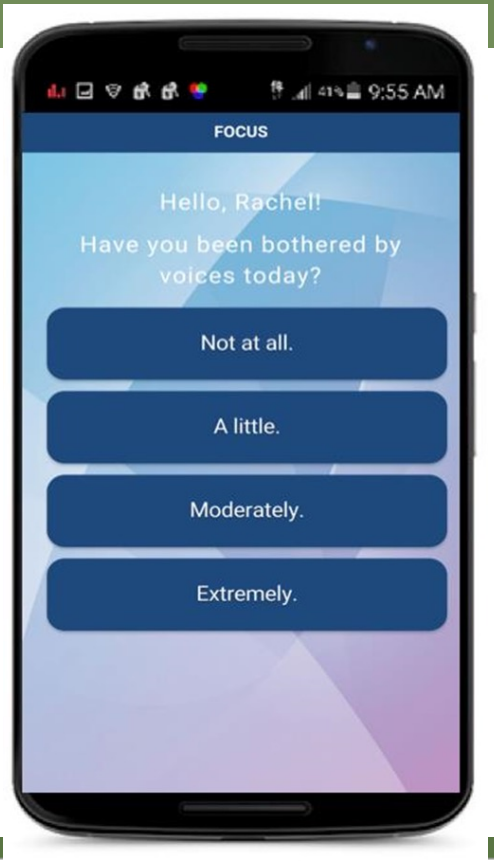
- 3 daily prompts
- 'on-demand' resources
- 5 targets: sleep, voices, social, meds and mood



Slide courtesy Dr. Dror Ben-Zeev

FOCUS Process

- 6th grade reading level
- Simple interface
- Low working memory required
- Intuitive



Slide courtesy Dr. Dror Ben-Zeev

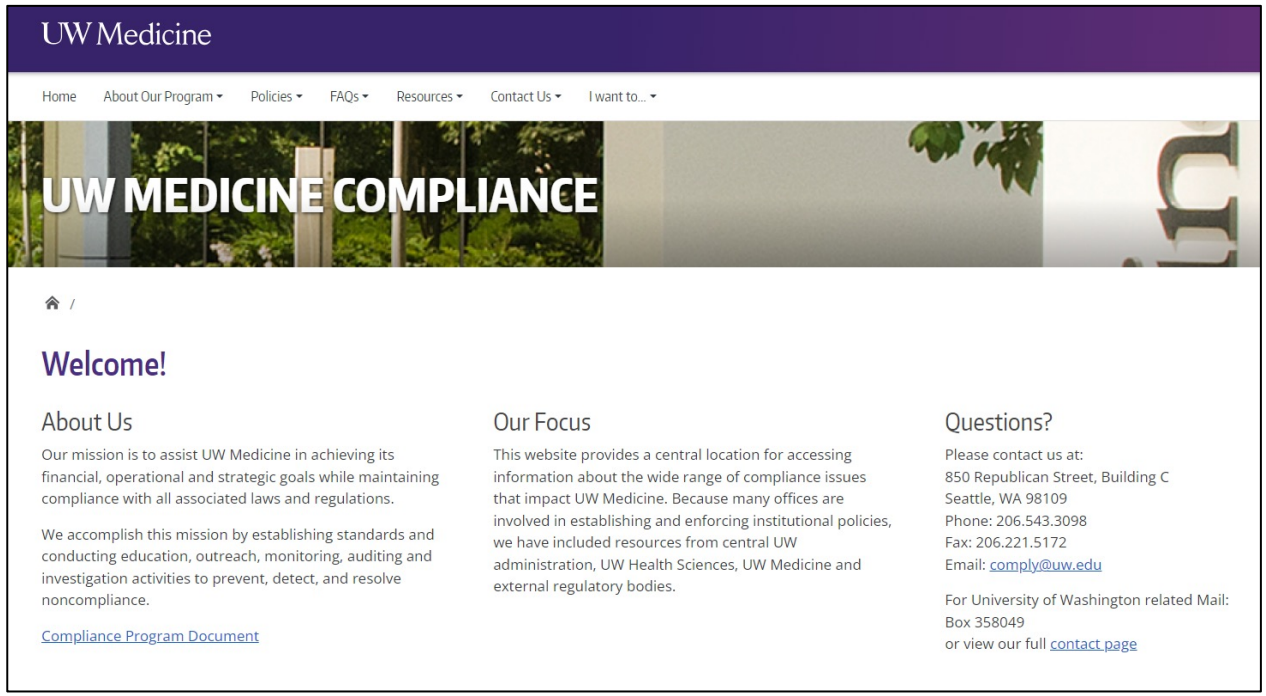
Dashboard


Summary
9AM - 1PM
Social
1PM - 5PM
Social
5PM - 9PM
Social
PAST WEEK
PAST MONTH
Copy to clipboard
Social
Improved
Poor to Good
GREAT
POOR
SCORE
Mon Tue Wed Thu Fri Sat Sun
0 0 1 2 1 0 1
OF RESPONSES
Score Average 2.00
Responses 5
Voices
Improved
Poor to Great
0 0 1 2 1 0 1
Score Average 2.50
Responses 5
Sleep
Improved
Poor to Great
0 0 1 3 1 0 1
Score Average 2.67
Responses 6
Mood
Improved
Poor to Great
0 0 1 3 1 0 1
Score Average 2.67
Responses 6

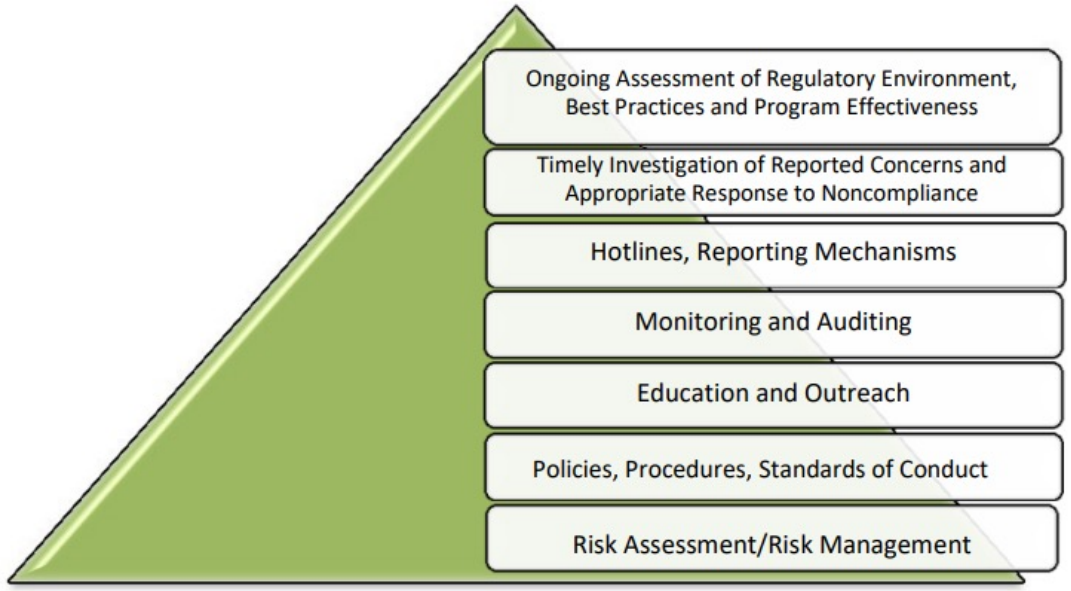
Current Challenges

- Rollback of PHE and many policies are changing
- Privacy and security for mHealth
- Ryan Haight Act regulations for prescribing controlled substances
- Integration of patient-reported information into EMR
- Who owns data?
- Payment system and misalignment of incentives

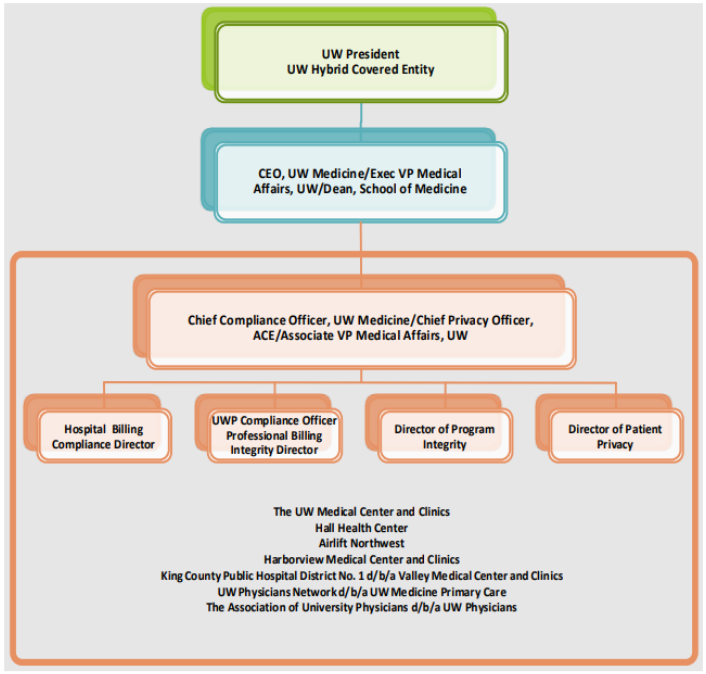
HIPAA Compliance Overview



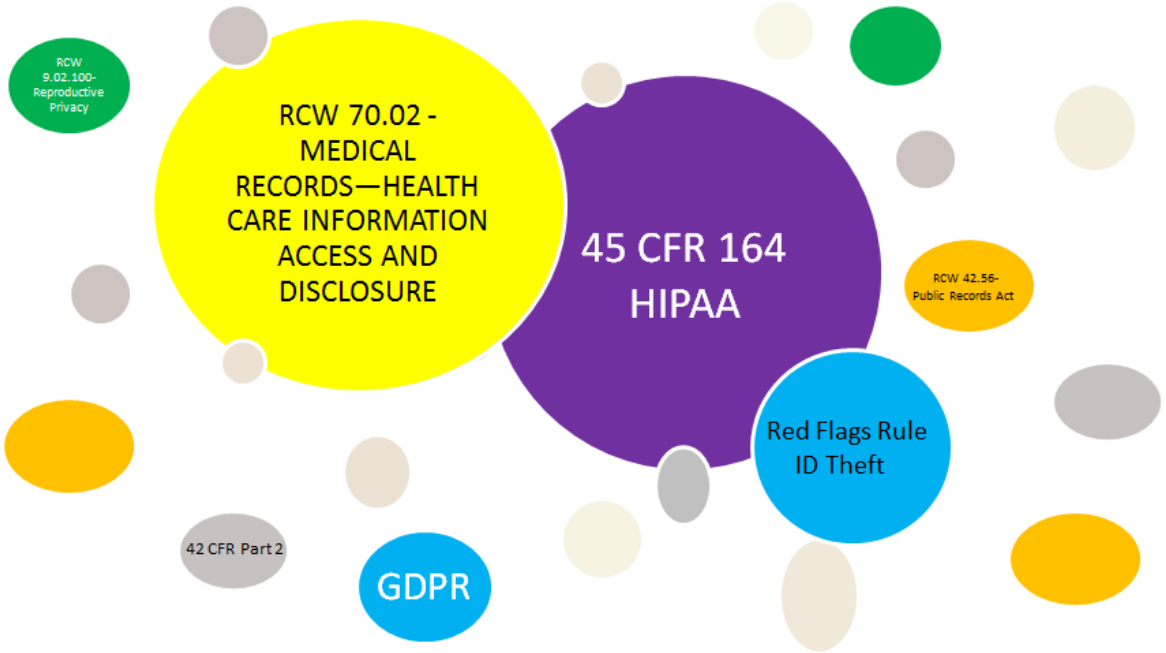
What Does “Compliance” Mean?



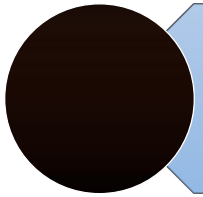
UW Medicine Compliance



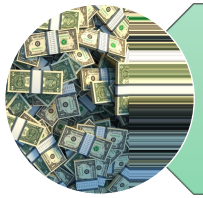
HIPAA Basics



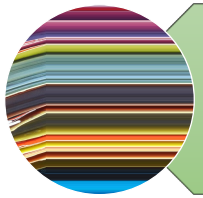
What triggers HIPAA Jurisdiction?



Health care providers who transmit health information electronically related to covered transactions

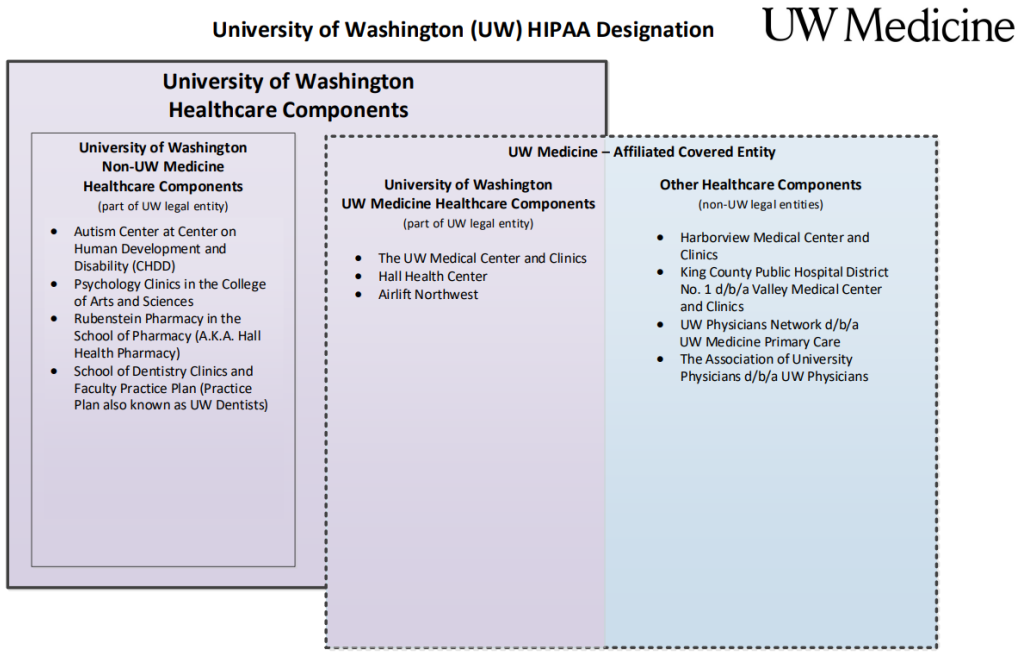


Health Plans

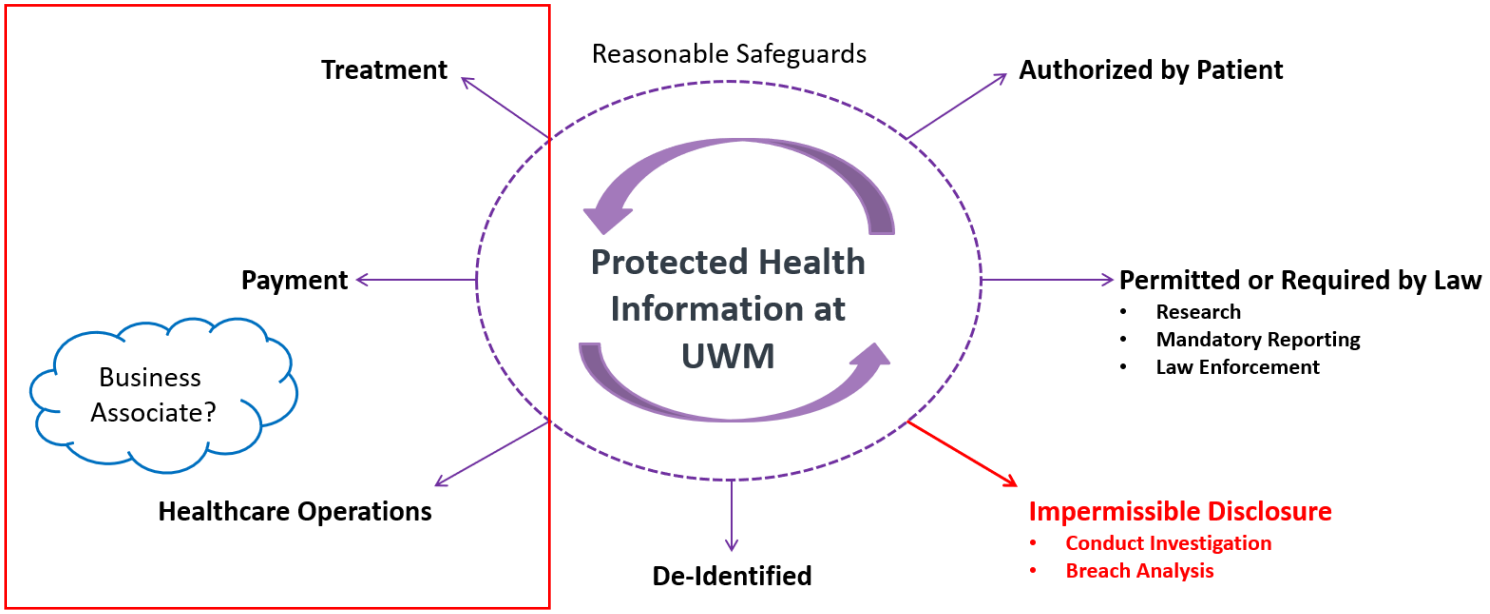


Healthcare Clearinghouses

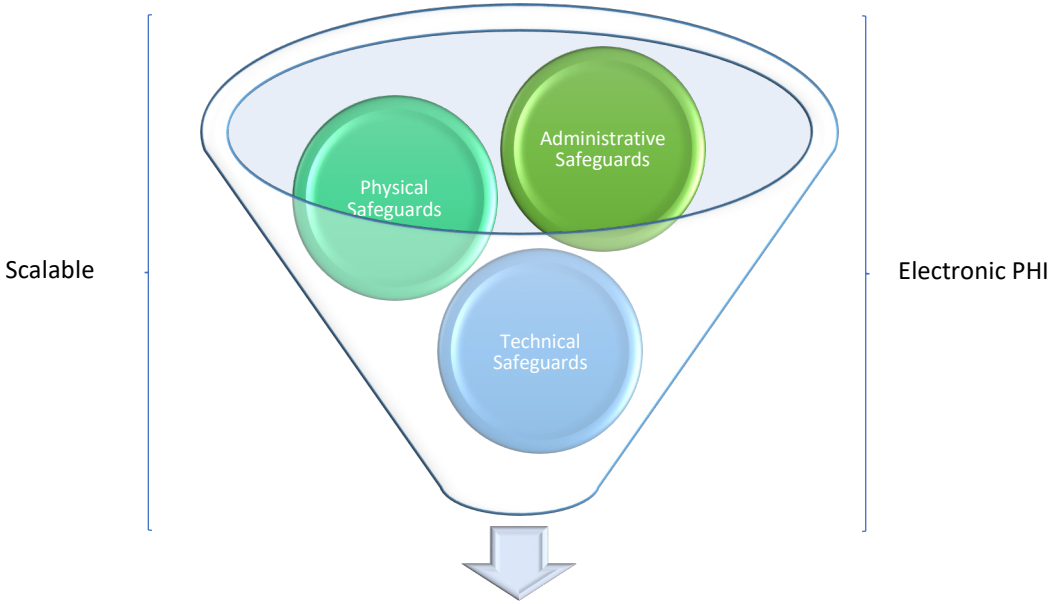
UW/UW Medicine Hybrid Covered Entity



General HIPAA Privacy Framework



General HIPAA Security Framework



"HIPAA Compliant"

HIPAA and Telemedicine/Digital Health: Common Issues

- Does the technology serve a treatment, payment or healthcare operation purpose?
- Does vendor understand the HIPAA regulatory regime and that they may be a business associate?
- Does business associate agreement meet HIPAA requirements?
- Will vendor accept financial responsibility in the event of a breach that they cause?
- Does vendor understand what it means to be “HIPAA compliant” or “HIPAA secure”?
- Does vendor want to de-identify UW Medicine data and use for other purposes?
- Could another law govern the data (e.g., EU GDPR, My Health My Data)

HIPAA Security Overview

Email Guidance

Options:

- Email Encryption
- Phishing & Spam Email Guidance
- Approved Email Domains

Teleworking

Options:

- Video Conferencing
- Secure Teleworking
- Working Outside the Office
- Mobile Security

Services

Options:

- Threat Management
- Vulnerability Management
- Risk Management
- Security Governance
- Security Education, Training, and Awareness

Contact Us

Options:

Information Security Team
uwmed-security@uw.edu

IT Service Desk
mcsos@uw.edu
(206) 543-7012

Report a Cyber Security Incident

Our Mission

The Information Security Team exists to ensure the confidentiality, integrity, and availability of UW Medicine's data, information assets, and clinical systems as part of UW Medicine's commitment to excellence in patient care, medical education, and research.

About Us

The Information Security Team provides enterprise-level cyber security services to UW Medicine through its Vulnerability Management, Threat Management, Risk Management, and Security Awareness programs. Our Cyber Security Analysts and Engineers help the UW Medicine workforce deliver world-class patient care securely and confidently. In addition to our enterprise services, the team provides security governance, guidance, and best practices so the workforce has the information and tools required to prevent cyber security incidents. In the event that a cyber security incident occurs, our team leads response efforts and navigates the workforce through the process to ensure rapid recovery and minimize adverse impacts to UW Medicine.

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?

NIST Functional Mapping

Identify	Protect	Detect	Respond	Recover
Asset Management	Access Control	Anomalies and Events	Analysis	Communications
Business Environment	Data Security	Detection Processes	Communications	Improvements
Governance	Information Protection Processes and Procedures	Security Continuous Monitoring	Improvements	Recovery Planning
Risk Assessment	Maintenance		Mitigation	
Supply Chain Risk Management	Protective Technology		Response Planning	
	Training and Awareness			

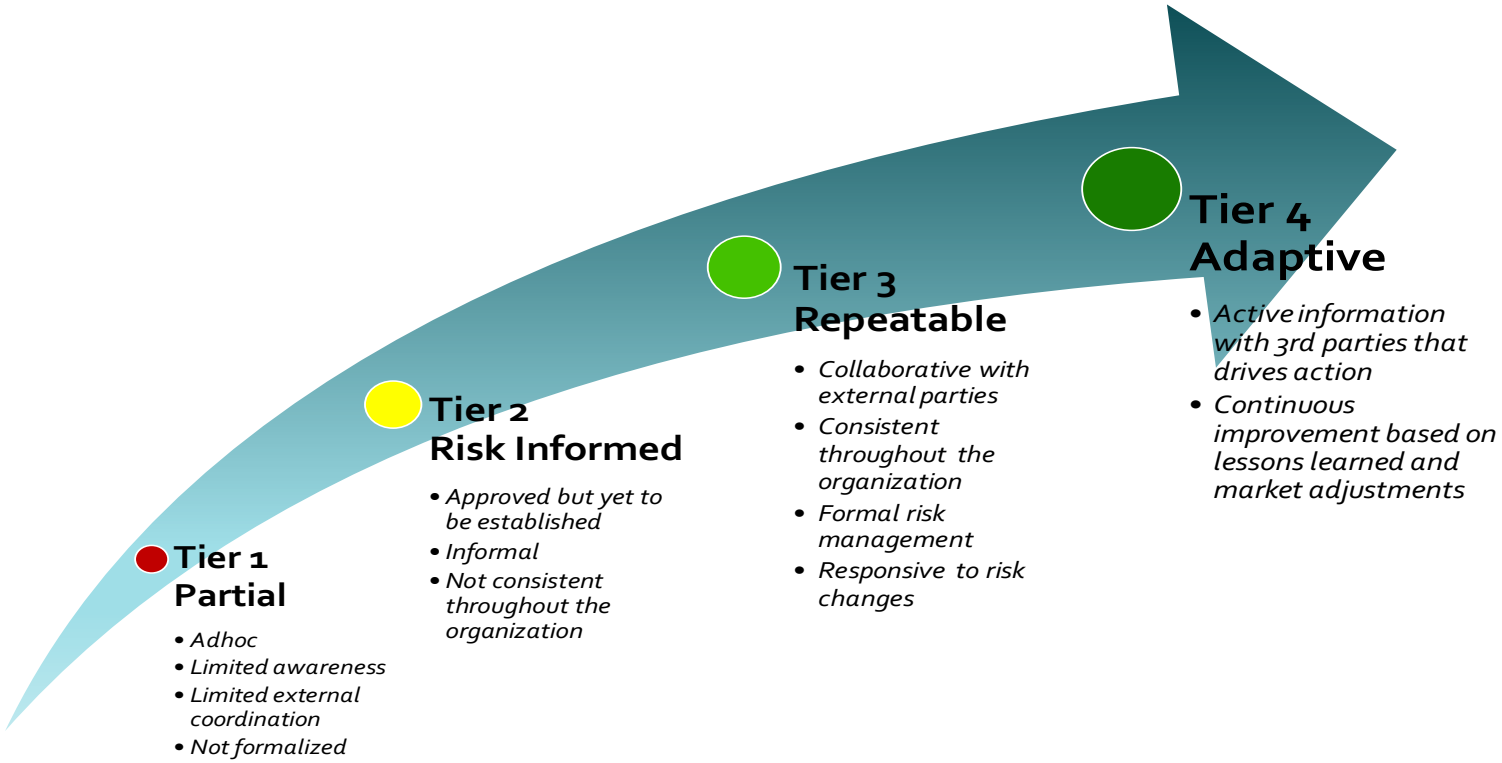
The NIST Cybersecurity Framework

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

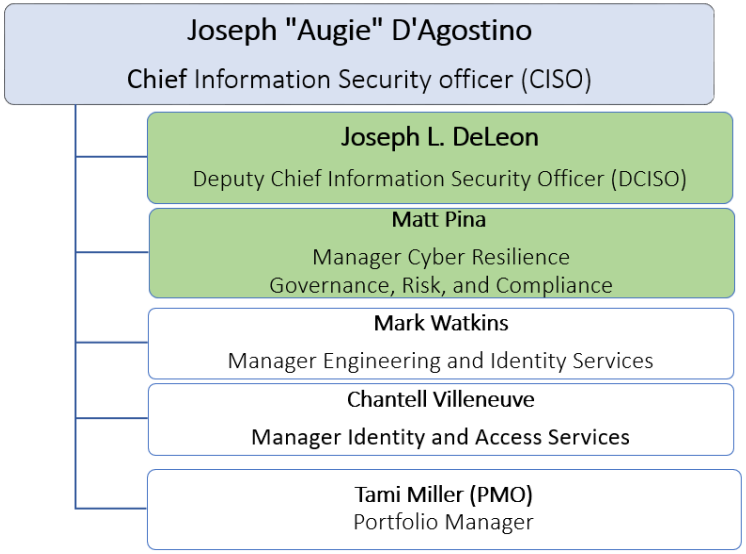
Maturity Tiers



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.

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

Business Perspective

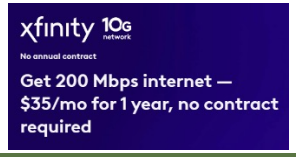
Companies choose to develop products and services that they can sell for enough money to make the development effort worthwhile given the following considerations:

- Talent and resource limitations
- Opportunity cost of one choice over another
- Future market demand
- Future profit potential

Comparing Business Models and Challenges

xfinity

- Buy the hardware
- Pay periodically for service
- Does “service” include repairs and support?
- Could you charge more for support?



NETFLIX

- Use your existing network
- Pay periodically per (shared) account
- Is it possible to track actual number of users?
- Could you charge per user?

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

Digital Health vs. Telemedicine

Remote Patient Monitoring

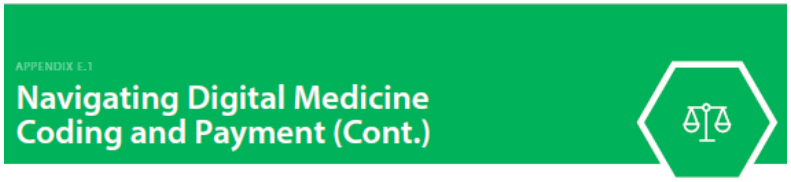
- Company needs to:
  - understand the use case and users
  - engineer the medical device
  - design, code, and validate the system software
  - optimize remote connectivity
  - manage support team for compatibility, up-time, security, bug-fixes, updates, etc.
  - manage training team
- Regulatory approval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

Remote Patient Monitoring Reimbursement Guide excerpted from AMA Remote Patient Monitoring Playbook

@ https://www.ama-assn.org/system/files/ama-remote-patient-monitoring-playbook.pdf



APPENDIX E.1

Navigating Digital Medicine Coding and Payment (Cont.)

REMOTE PATIENT MONITORING

Effective January 1, 2018, Medicare began coverage and payment for the collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional (CPT® Code 99091). Effective January 1, 2019, coverage and payment were made available for remote physiologic monitoring codes, and on January 1, 2022, coverage and payment were made available for remote therapeutic monitoring codes.

CODE	DESCRIPTION
CPT® Code 98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
CPT® Code 98976	Device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
CPT® Code 98977	Device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
CPT® Code 98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
CPT® Code 98981	Each additional 20 minutes (List separately in addition to code for primary procedure)
CPT® Code 99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up and patient education on use of equipment. (Initial set-up and patient education of monitoring equipment)
CPT® Code 99454	Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days. (Initial collection, transmission, and report/summary services to the clinician managing the patient)
CPT® Code 99457	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
CPT® Code 99458	Each additional 20 minutes (List separately in addition to code for primary procedure)

APPENDIX E.1

Navigating Digital Medicine Coding and Payment (Cont.)

APPENDIX E.1

Navigating Digital Medicine Coding and Payment (Cont.)

TELEHEALTH VISITS

Synchronous audio/visual visit between a patient and clinician for evaluation and management (E&M).

CODE*	DESCRIPTION
CPT® Code 99202-99205 POS 02 for Telehealth (Medicare) Modifier 95 (Commercial Payers)	Office or other outpatient visit for the evaluation and management of a new patient
CPT® Code 99211-99215 POS 02 for Telehealth (Medicare) Modifier 95 (Commercial Payers)	Office or other outpatient visit for the evaluation and management of an established patient

*A list of all available codes for telehealth services can be found here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

Medicare pays for telehealth on a limited basis: when the beneficiary receiving the service is in a designated rural area and when they leave their home and go to a clinic, hospital, or certain other types of medical facilities for the service.

Check with your payer to determine the appropriate Place of Service (POS) code for your telehealth visits. The AMA is aware that some commercial payers are requiring the use of POS 02 – Telehealth (the location where health services and health-related services are provided or received through a telecommunication system).

ONLINE DIGITAL VISITS

These services are the kind of brief check-in services furnished using communication technology that are employed to evaluate whether or not an office visit or other service is warranted. When the check-in services are furnished prior to an office visit, then the Medicare program considers them to be bundled into the payment for the resulting visit, such as through an evaluation and management (E/M) visit code. However, in cases where the check-in service does not lead to an office visit, then there is no office visit with which the check-in service can be bundled. Therefore, Medicare will cover and pay for such services to the extent these are medically necessary and reasonable.

ONLINE DIGITAL VISITS (CONT.)

CODE	DESCRIPTION
CPT® Code 99421	Online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the seven days: 5–10 minutes
CPT® Code 99422	11–20 minutes
CPT® Code 99423	21 or more minutes
CPT® Code 98970	Qualified non-physician health care professional online digital assessment and management, for an established patient, for up to seven days, cumulative time during the seven days: 5–10 minutes
CPT® Code 98971	11–20 minutes
CPT® Code 98972	21 or more minutes
HCPCS Code G2012	Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment: 5–10 minutes of medical discussion

Additional coverage requirements for use of HCPCS Code G2012 include:

- Advance patient content: Practitioners must obtain advance consent for the service and document in the patient's record.
- This service is only covered for established patients.
- The technology that can be used by the patient includes real-time, audio-only telephone interactions and synchronous, two-way audio interactions that are enhanced with the video or other kinds of data transmission.
- Telephone calls that involve only clinical staff cannot be billed using this code.

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Remote Patient Monitoring Reimbursement Guide excerpted from AMA Remote Patient Monitoring Playbook
@ https://www.ama-assn.org/system/files/ama-remote-patient-monitoring-playbook.pdf

Telemedicine & Device-Related Digital Health Regulatory Overview

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Telemedicine & Device-Related Digital Health Regulatory Overview

- First, a placeholder for an additional privacy/security issue: Specific device-related cybersecurity
  - The FDA (separate from overall HHS HIPAA regulation) requires certain security standards in medical devices that generate/store PHI
  - To be discussed in more detail in session 3 of this workshop series

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Licensing
    - Governed by state law for the state where the patient is "located"
    - If silent, presume that a full license is needed
    - Other scenarios
      - "Consultation exemptions"
      - Special registration
      - COVID relaxation
    - Interstate Medical Licensure Compact (37 participating states)

Telemedicine & Device-Related Digital Health Regulatory Overview

August 2023 Update

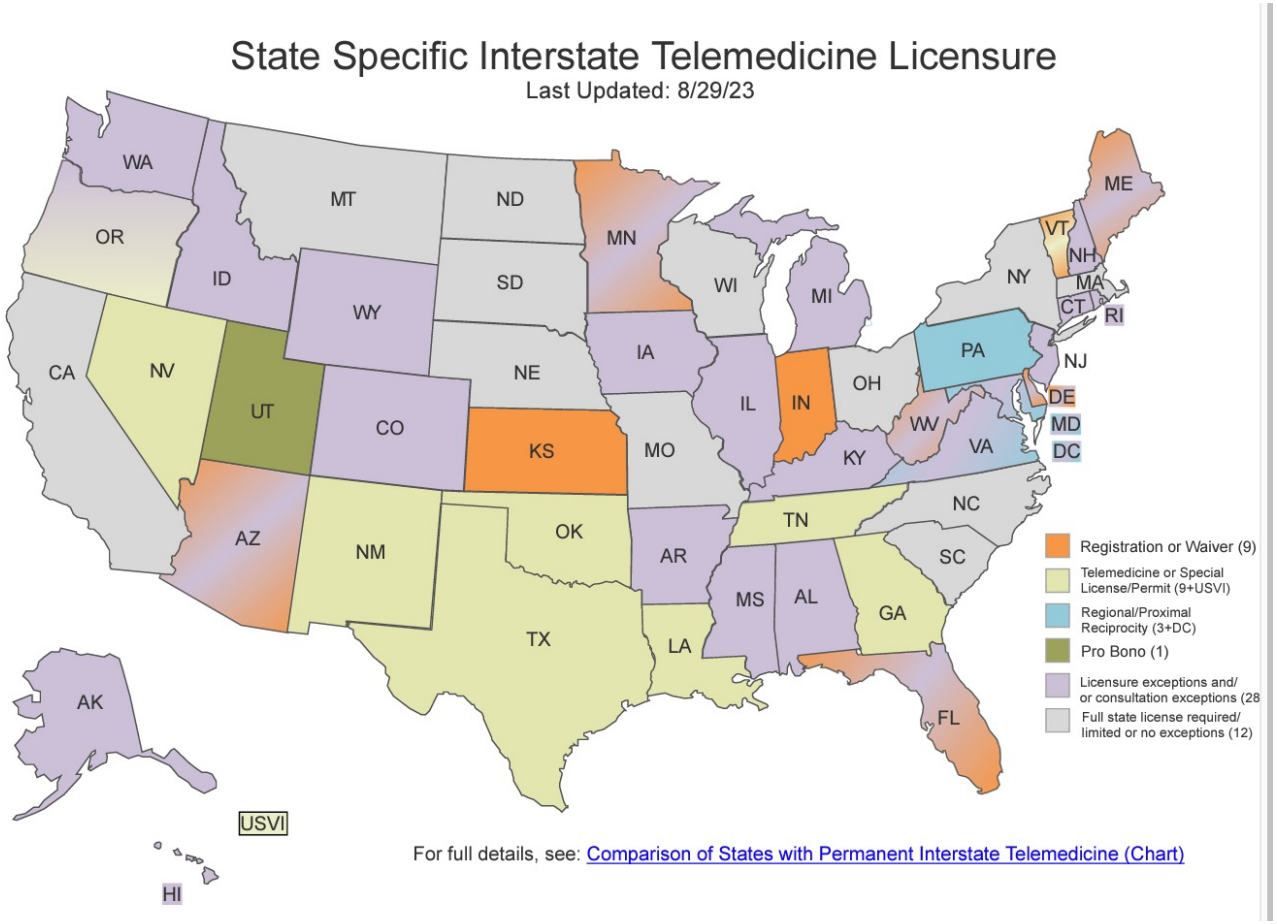
FEDERATION OF STATE MEDICAL BOARDS

Comparison of States with Permanent Interstate Telemedicine

States with Permanent Interstate Telemedicine	**21 + DC + USVI***
Mechanism	*TOTAL*
Telemedicine or Special License or Permit	**9 + USVI**
Registration or Waiver	**9**
Regional/Proximal Reciprocity	**3 + DC**
Pro Bono Interstate Telemedicine	**1**
States with licensure exceptions and/or consultation exceptions‡	**29**

**Note: Some states utilize multiple mechanisms, total may not add up.*
‡Note: Licensure exceptions are classified separate from permanent interstate telemedicine mechanisms

Telemedicine & Device-Related Digital Health Regulatory Overview



Telemedicine & Device-Related Digital Health Regulatory Overview

"WWAMI-O" states (minus Montana, which has no exemptions to full licensure)

Washington	Licensure exception/ Consultation exception	The legislature created a specific exemption to the licensure requirement for telemedicine practitioner-to-practitioner consultations. The consultation exemption permits a practitioner licensed in another state in which the practitioner resides to use telemedicine or other means to consult with a Washington licensed practitioner who remains responsible for diagnosing and treating the patient in Washington. The law does not require real time communication between practitioners. Additionally, the WMC does not require a license when a patient seeks a second opinion or a consultation with a specialist out of state, such as a cancer center, and sends medical records to the specialist to review and provide input on treatment. In this case, the specialist in the distant state does not need a license to practice medicine in Washington to review the records and provide an opinion, but not treatment, regarding the patient's care. Another common situation that is not specifically addressed by a statutory exemption is when a patient with an established relationship with a practitioner licensed in another state crosses the border into Washington and requires medical care. In some cases, permitting the physician in the patient's home state to provide temporary continuous care is in the patient's best interest. So long as the out-of-state practitioner provides temporary continuity of care to the patient, the practitioner would not require a Washington license.		WA Medical Commission Updated Telemedicine Policy (July 2022)

Telemedicine & Device-Related Digital Health Regulatory Overview

Wyoming	Licensure exception/ Consultation exception	Wyoming licensure requirements do not apply to: • An out-of-state physician who consults by telephone, electronic or any other means with an attending physician licensed by the state… for a total of not more than twelve (12) days in any fifty-two (52) week period; • An out-of-state physician who is specifically exempt from licensure pursuant to Wyo. Stat. § 33-26-103; o Rendering care at the scene of an emergency o Medical students serving as residents or interns o Medical officers in the United States armed services, public health service, Dept. of Veterans Affairs discharging their official duties (and licensed in at least one jurisdiction) o Consultations with Wyoming-licensed physicians (including foreign medical professionals)		WY Rules and Regulations, Agency 83, Ch. 3, § 4

Telemedicine & Device-Related Digital Health Regulatory Overview

Alaska	Licensure exception/ Limited referral system	HB 265 (2022) includes a provision that allows Alaskans with suspected or diagnosed life-threatening conditions, such as cancer, to be treated by an out-of-state physician as long as they: • Have a referral from their Alaska-licensed physician. • Have an existing patient-physician relationship with the out-of-state physician. • And the out-of-state physician has previously conducted an in-person visit with the patient.		AK HB 265 (2022)

Telemedicine & Device-Related Digital Health Regulatory Overview

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 & Device-Related Digital Health Regulatory Overview

Oregon	Telemedicine License	Upon application, the Oregon Medical Board may issue to an out-of-state physician a license for the practice of medicine across state lines if the physician holds a full, unrestricted license to practice medicine in any other state of the United States, has not been the recipient of a professional sanction by any other state of the United States and otherwise meets the standards for Oregon licensure . In the event that an out-of-state physician has been the recipient of a professional sanction by any other state of the United States, the board may issue a license for the practice of medicine across state lines if the board finds that the sanction does not indicate that the physician is a potential threat to the public interest, health, welfare and safety.	$253 (Source)	ORS 677.139 Oregon.gov - Telemedicine Telemedicine License Request

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Credentialing
  - "Telemedicine privileges": allow an institution's medical staff to provide telemedicine services to the institution's own patients

    vs.
  - "Distant site provider privileges": allow providers from another institution 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 clinical and telemedicine privileges 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 & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Scope of practice—basically includes the scope of practice articulated in licensing laws (given feasibility in a telemedicine setting)
  - Standards of care
    - Telemedicine standards may be articulated by state licensing boards, although SOC is not usually included in state licensing statutes/regulations

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Standards of care
    - E.g., Washington Medical Commission Policy Statement (revised 2021)
      - Recites specific generally understood/accepted standards of clinical care, such as need to provide informed consent, establish a physician-patient relationship, perform an appropriate assessment, etc.
      - Also now calls out specific device-related obligations for physicians practicing in a telemedicine setting:
        - Expected to confirm whether devices used in telemedicine practice are/need to be FDA cleared/approved
        - If using AI/ML technology, expected to understand its bias and related aspects, and should complete a CME course regarding AI/ML

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Prescribing
    - Federal restrictions still exist re DEA controlled substance drugs (in-person visit required)
      - The DEA still has not developed the special registration process for providers to be able to prescribe controlled substances without an in-person exam
        - First mandated in 2008 as part of the original Ryan Haight Act and again 10 years later in the SUPPORT for Patients and Communities Act of 2018.

- **Telemedicine regulation**
  - Prescribing
    - DEA COVID waivers for controlled substance telemedicine prescribing are extended through November 11, 2023 for new patients, and through November 11, 2024 for patients established during the waiver period.
    - Per CCHP, "most states consider using only an internet/online questionnaire to establish a patient-provider relationship (needed to write a prescription in most states) as inadequate. States may also require that a physical exam be administered prior to a prescription being written, but not all states require an in-person examination, and some specifically allow the use of telehealth to conduct the exam."

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Telemedicine reimbursement
    - CMS—some COVID waivers r/t Medicare restrictions for telemedicine reimbursement (e.g., originating site) have been made permanent (mostly r/t behavioral health), and others will expire at the end of 2024 absent Congressional action
      - July 2023 updated chart by Center for Connected Health Policy (CCHP) re PHE reimbursement discontinuation dates
    - Medicaid—per CCHP, all 50 states and Washington DC provide reimbursement for some form of live video in Medicaid fee-for-service. However, what and how it is reimbursed varies widely with some Medicaid programs limiting the types of reimbursable services and placing additional requirements and restrictions such as provider type and originating site stipulations.

Telemedicine & Device-Related Digital Health Regulatory Overview

- **Telemedicine regulation**
  - Telemedicine reimbursement
    - State parity laws—private payers
      - All states required private payers to cover telemedicine during the pandemic, but many have reverted to pre-pandemic status (no parity law)
      - Washington has had a payment parity law for several years, which requires not only reimbursement, but also payment **amount** parity. It also applies to audio-only telemedicine, as long as there is a pre-existing patient-provider relationship.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - Effects of 21st Century Cures Act
  - Medical device definitions
    - Non-device software
    - SaMD (vs. SiMD)
    - DRS/MMAs
    - CDSS
  - FDA resources—Digital Health Center of Excellence, clinician learning modules, etc.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - Mobile Medical Apps—history of regulation before Cures Act
    - September 2013 "Final" Guidance: How the FDA intends to regulate software applications intended for use on mobile platforms.
    - Broad categories
      - Unregulated apps considered outside of FDA's jurisdiction
      - Apps considered within FDA jurisdiction but where FDA will exercise enforcement discretion and refrain from regulation on the basis of low patient risk
      - Regulated apps

Telemedicine/Device-Related Digital Health Regulatory Overview

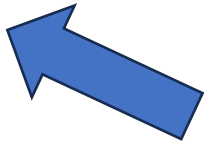
- **Device-related digital health regulation**
  - 21st Century Cures Act (December 2016)
  - Section 3060. Modified the definition of "device" to remove certain categories of software from FDA's jurisdiction.
    - Software that provides administrative support of a healthcare facility.
    - Software for maintaining or encouraging a healthy lifestyle, and not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
    - Software that serves as electronic patient records, provided that such function is not intended to interpret or analyze patient data or images for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
    - Software for transferring, storing, converting formats, or displaying data/results and associated findings by a healthcare professional (e.g., MDDS), unless intended to interpret or analyze the data, results or findings**.**

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - Mobile Medical Apps—history of regulation before Cures Act
  - February 2015 “Final Final” Guidance--Superseded September 25, 2013 Final Guidance
    - Updated to be consistent with the February 2015 MDDS guidance document (which had down-classed MDDS).
    - “Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers.”
    - FDA "regulates by function, not by platform”

Telemedicine/Device-Related Digital Health Regulatory Overview

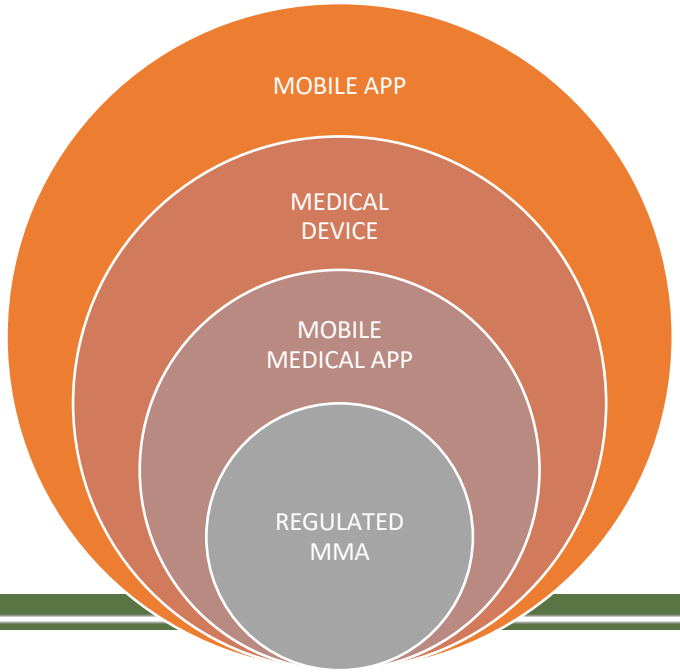
- **Device-related digital health regulation**
  - Software for:
    - displaying, analyzing, or printing medical information about a patient or other medical information;
    - supporting or providing recommendations to a healthcare professional (i.e., clinical decision support) about prevention, diagnosis 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.



CDSS?

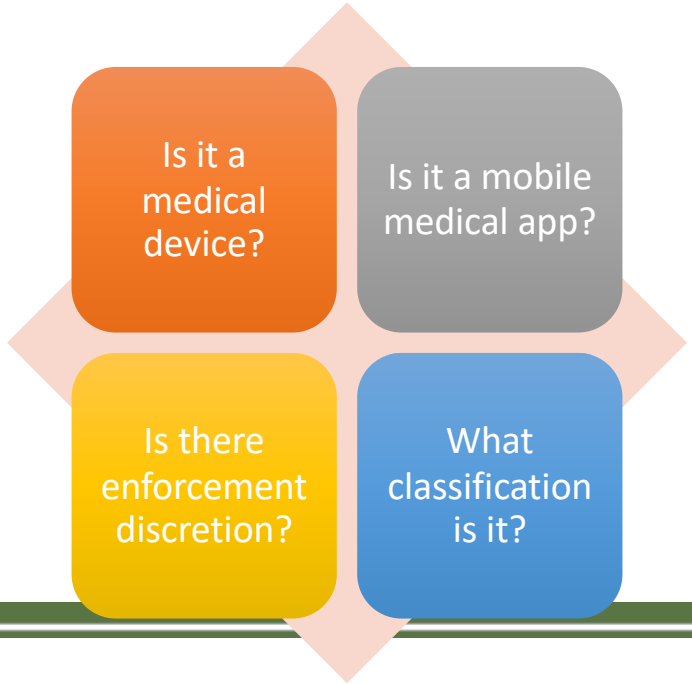
Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - **Mobile Medical Apps—or is it Device-Related Software?**



Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - **Mobile Medical Apps—or is it Device-Related Software?**



Telemedicine/Device-Related Digital Health Regulatory Overview

- Device-related digital health regulation
  - Most recent DRS guidance: "Policy for Device Software Functions and Mobile Medical Applications"
    - September 28, 2022
    - “Document originally issued on September 25, 2013”
    - “This document supersedes ‘Policy for Device Software Functions and Mobile Medical Apps’ issued September 27, 2019.”
    - Previous “final” version: February 9, 2015

Telemedicine/Device-Related Digital Health Regulatory Overview

- Most recent DRS guidance: Policy for Device Software Functions and Mobile Medical Applications
  - FDA refers to software functions that are device functions as "device software functions." Device software functions may include "Software as a Medical Device (SaMD)" and "Software in a Medical Device (SiMD)." Software functions that meet the definition of a device may be deployed on mobile platforms, other general-purpose computing platforms, or in the function or control of a hardware device.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - AI/ML: FDA Definitions
    - Artificial Intelligence: A device or product that can imitate intelligent behavior or mimics human learning and reasoning. Artificial intelligence includes machine learning, neural networks, and natural language processing. Some terms used to describe artificial intelligence include computer-aided detection/diagnosis, statistical learning, deep learning, or smart algorithms.
    - Machine learning is used to design an algorithm or model without explicit programming but through the use of automated training with data (e.g., a regression function or deep learning network). Devices that include Adaptive Algorithms, i.e., algorithms that continue to learn and evolve in time, are also another area of Artificial Intelligence.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements
    - On December 29, 2022, the Consolidated Appropriations Act, 2023 was signed into law. Section 3305 of the bill-- "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."
    - Digital Health Center of Excellence has a separate cybersecurity page with detailed resources (e.g., a cybersecurity "playbook")
    - New guidances—dramatic changes from former device cybersecurity guidance, e.g., no more "tier 1" and "tier 2" devices.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements
    - 03/29/2023 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.
    - 04/07/2022 Draft Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions This draft guidance (flagged as "not for implementation") replaces the 2018 draft version and is intended to further emphasize the importance of ensuring that devices are 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.

Basically, see section 524B of the FD&C Act (found at 21 USC §360n–2)

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements
- §360n–2. Ensuring cybersecurity of devices

  (a) In general

  A person who submits an application or submission under section 360(k), 360c, 360e(c), 360e(f), or 360j(m) of this title for a device that meets the definition of a cyber device under this section shall include such information as the Secretary may require to ensure that such cyber device meets the cybersecurity requirements under subsection (b).

  (b) 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;

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements

    (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;

    (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.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements

    (c) 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.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - FDA device cybersecurity requirements

    (d) Exemption

    The Secretary may identify devices, or categories or types of devices, that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices, or categories or types of devices, so identified by the Secretary.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - Reimbursement r/t devices (vs. reimbursement focused on the telemedicine visit itself)
    - 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.

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - CPT reimbursement codes for RPM

  (Source: Arizona Telemedicine Program and the Southwest Telehealth Resource Center)

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)

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

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - CPT reimbursement codes for RTM [note: RTM initial "set-up" code requires a device that meets the FDA's definition of a medical device]

  (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

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)

Telemedicine/Device-Related Digital Health Regulatory Overview

- **Device-related digital health regulation**
  - 2024 proposed CMS rule vs. 2023 rule
    - No major changes re RPM/RTM, but some clarifications, e.g.,
      - Only one provider may bill codes 99453, 99454, 98976, 98977, 98980, and 98981 in a 30-day period w/16 days of device data
      - RPM may be billed only for an established patient
      - PTs and OTs can bill RTM for PTAs and OTAs under General Supervision

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.